

International Collaboration for Research methods Development in Oncology

6th CReDO workshop

5th to 10th March 2023

Lonavala, India





About the workshop

The Tata Memorial Centre, Mumbai and the National Cancer Grid of India conducted a six-day residential workshop on oncology research protocol development at Lonavla, near Mumbai between 5th and 10th March 2023. This workshop was the sixth in a series of workshops.

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 was a combination of protocol development group sessions, didactic talks, small-group breakaway sessions, office-hours (one-to-one direct consultation with experts) and "homework". We also had a series of pre-workshop webinars, starting 2 months prior to the workshop. The faculty consisted of international and national experts with extensive experience in oncology research and training in research methodology workshops.

The Tata Memorial Centre

The Tata Memorial Centre (TMC), comprising the Tata Memorial Hospital (TMH), Mumbai, and the Advanced Centre for Training, Research and Education in Cancer (ACTREC), Navi Mumbai, the Centre for Cancer Epidemiology (CCE), Mumbai, the Homi Bhabha Cancer Hospital and Research Centre, Visakhapatnam, the Homi Bhabha Cancer Hospital, Sangrur, the B Barooah Cancer Institute, Guwahati, the Homi Bhabha Cancer Hospital, Varanasi, the Mahamana Pandit Madan Mohan Malaviya Cancer centre, Varanasi, and the Homi Bhabha Cancer Hospital and Research Centre, Muzaffarpur, is the oldest and largest cancer centre in the country. Between them, the TMC centres have an annual registration of over 46000 125000 new patients with cancer and caters to patients from all over the country. Based on a "Disease Management Group" concept, evidence-based treatment is provided to all patients regardless of their socioeconomic status. Over the years, TMC has been responsible for training many cancer specialists and creating quality human resource for comprehensive cancer management in India. TMC also has a long tradition of high-quality research in basic, translational and clinical research in cancer. Currently, several large practice-changing randomized trials have been completed or are ongoing in breast, oral, esophageal, soft tissue and cervical cancers, addressing important questions in the management of these cancers. TMC is committed to advancing the cause of clinical research in general and cancer research in particular.

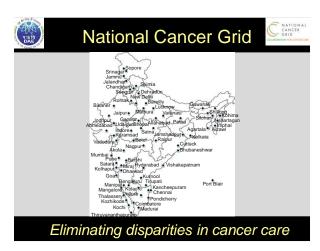




The National Cancer Grid of India

The National Cancer Grid (NCG) of India is a collaboration of close to 300 major cancer centres, research institutes, charitable trusts and patient groups, virtually 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 and to create a ready network of centres for collaborative research in cancer. The NCG is poised to transform the overall spectrum of cancer care, education and research in India and serve as a model for other specialties to emulate. 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, radiation oncology quality assurance amongst others.

Some of the research proposals developed at the CReDO workshop are being considered for funding by the National Cancer Grid, as multi-centric trials.



Workshop Advisory Board

Rajendra Badwe Tata Memorial Centre, Mumbai

Marc Buyse International Drug Development Institute, Belgium and California

Mahesh Parmar MRC-CTU at University College London

Arnie Purushotham King's College, London

Ian Tannock 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

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Shivakumar Thiagarajan	Tata Memorial Centre, Mumbai
Elisabete Weiderpass	International Agency for Research on Cancer, Lyon
Denis Xavier	St John's Medical College and Research Institute, Bengaluru, India

Workshop participants and observers

National			
1.	Akash Pradhan	Karkinos Healthcare, India	
2.	Ameya Bindu	Tata Memorial Centre, India	
3.	Amiti Varma	Centre for Mental Health law and Policy, Pune, India	
4.	Anhad Mehra	Medica Cancer Centre, Kolkata	
5.	Anil Tibdewal	Tata Memorial Centre, India	

6.	Anuj Kumar	Tata Memorial Centre, India
7.	Dharma Ram Poonia	AIIMS, Jodhpur, India
8.	Gargi Das	Cancer Institute, Adayar, India
9.	Hemavathi Baskarane	AIIMS, IRCH, New Delhi
10.	Indhuja M.V	Cancer Institute, Adayar, India
11.	Indraja Devidas Dev	Tata Memorial Centre, India
12.	Jyotiman Nath	BBCI, Guwahati, India
13.	Kantamani Teja	Tata Memorial Centre, India
14.	Laboni Sarkar	Tata Memorial Centre, India
15.	Latika Kansal	Tata Memorial Centre, India
16.	Laxma Reddy Mekala	Tata Memorial Centre, India
17.	Manisha Nandkumar Pawar	Tata Memorial Centre, India
18.	Maqbul Alam	Tata Memorial Centre, India
19.	Maya Prasad	Tata Memorial Centre, India
20.	Nalla Anuraag Reddy	Kasturba Medical College, Mangalore, India
21.	Parmod Kumar	AIIMS Rishikesh, India
22.	Partha Pratim Medhi	AIIMS Guwahati, India
23.	Prakash S	AIIMS Rishikesh, India
24.	Prakruthi S. Kaushik	Kidwai Memorial Institute of Oncology, India
25.	Prasanna Vani Vanamail	Cancer Institute, Adayar, India
26.	Rakesh L John	Amala Institute, Kerala, India
27.	Rakesh Mishra	Benares Hindu University, India
28.	Reshma A	JIPMER, Puduchery, India
29.	Sankalp Singh	Army R and R Hospital, New Delhi, India
30.	Sharath Kumar HJ	Tata Memorial Centre, India
31.	Shruti Kakkar	DMC Ludhiana, India
32.	Siva Sree Kesana	Cancer Institute, Adayar, India

33.	. Srinivas Kodaganur Gopinath Tata Memorial Centre, India	
34.	Sunaina Wadhwa	CNCI, Kolkata, India
35.	Sushil Selvarajan	CMC Vellore, India
36.	Venkatesh Kapu	Tata Memorial Centre, India
37.	Vignesh Subramani	Tata Memorial Centre, India
38.	Vikas Gupta	MGM Mumbai, India
39.	Vineet Kumar	Tata Memorial Centre, India
40.	Vinod Ramani	HCG Bengaluru, India
41.	Vinotha Thomas	CMC Vellore, India
	International	
1.	Adriana Morais	Hospital Universitário Oswaldo Cruz, Brazil
2.	Aleksandre Iovashvili	Caucasus Medical Centre, Georgia
3.	Anip Joshi Bir Hospital, National Academy of Medical Sciences (NAMS),	
4.	. Anna Zelwianska Institute of Mother and Child, Poland	
5.	Astrid Riveros	Hospital del Niño, Bolivia
6.	Eliana Lopez Baron	Hospital Pablo Tobon Uribe, Colombia
7.	Emile Munyambaraga University of Rwanda, Rwanda	
8.	Erika Elena Villanueva Hoyos Solca-Quito Hospital, Ecuador	
9.	Erika Montalvo	Solca-Quito Hospital, Ecuador
10.	Evelinda Nava	Venezuelan Institute of Social Security, Venezuela
11.	Glaucia Regina Costa Murra	Barretos Children's Cancer Hospital, Brazil
12.	. Hasan Hashem King Hussein Cancer Center, Jordan	
13.	Hugo Antonio Romo Rubio Hospital Civil de Guadalajara, Mexico	
14.	Nur Melani Sari Universitas Padjadjaran-Dr. Hasan Sadikin Hospital, Indonesia	
15.	Pablo Miguel Gonzalez-Montalvo	Servicios De Salud De Yucatan, Mexico
16.	Prabani Madumarachchi	National Cancer Institute, Sri Lanka
17.	7. Pradeep Siriwardena National Cancer Institute, Sri Lanka	

18.	Rasheed Ofosu-Poku	Komfo Anokye Teaching Hospital, Ghana
19.	Richard Nyeko	Uganda Cancer Institute, Uganda
20.	Sabrina Q. Florendo (Villanueva)	Baguio General Hospital and Medical Center, Phillipines
21.	Shushan Hovsepyan	Pediatric Cancer and Blood Disorders Center of Armenia
22.	Sol Irupé Aponte Bonzi	Hospital de Clínicas, Paraguay
23.	Suman Khanal	BP Koirala Memorial Cancer Hospital, Nepal
24.	. Urvashi Jain King's College London	
	Observers	
1.	Kiran Rajole	SMBT Hospital, Nashik, India
2.	2. Lovin Wilson SMBT Hospital, Nashik, India	
3.	Akash Pawar (Statistician)	Tata Memorial Centre, India
4.	Mohit Pandey (Statistician) International Institute for Population Sciences, Mumbai, India	
5.	Omkar Salvi (Statistician) Tata Memorial Centre, India	
6.	Anil Patil (Statistician) Tata Memorial Centre, India	
7.	Jagathnath Krishna (Statistician) Regional Cancer Centre, Thiruvananthapuram, India	
8.	Vishal Deo (Statistician) Indian Council of Medical Research, New Delhi, India	

CReDO 2023 faculty and participants





CReDO Workshop 2023 LDA, Lonavla March 5 - 10, 2023





CReDO Workshop 2023 LDA, Lonavla March 5 - 10, 2023

Workshop application process

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 fluent in written and spoken English and have good 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. Proposed trial description
- 3. Applicant's statement of purpose
- 4. Supervisor's statement of support

Selection of participants:

The workshop committee selected 65 participants (41 national and 24 international) to attend the workshop. In addition, 8 individuals were given direct entry (as observers) based on the felt need to augment national capacity in biomedical research, biostatistics and public health amongst the NCG centres and government research institutions like the ICMR.

Preference was given to early or mid-career level researchers from academic institutions who demonstrated commitment to continuing research in oncology.

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

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

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 course of the workshop.

Workshop venue

The workshop was held at the Leadership Development Academy of Larsen and Toubro, which is located at Lonavla, 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 sessions

Pre-workshop webinars

Starting January 2023, participants attended a series of webinars on the following topics:

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

The webinars were interactive, and participants were encouraged to submit their questions and problems for discussion during the webinar.

During the workshop

The workshop sessions were carefully formulated to meet the objectives while stimulating interactive discussions and avoiding monotony. Learning sessions were in the following four 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 according to the stage of the protocol they were likely to develop on that day.

B. Protocol Development Groups (PDGs)

The PDGs formed the core activity of the workshop and enabled participants to convert their one-page research idea into a full-fledged research protocol ready for IRB / Ethics submission. Workshops participants were divided into groups of eight/nine each, with each of these groups being mentored by 4 to 5 experts on clinical trials / research protocols. Each of the PDG sessions gave participants constructive critiques of their respective projects by the mentors, while applying the knowledge gained from the other sessions.

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 could also be used for 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 sessions but were important parts of certain research protocols; these also dealt with essential elements to the success of research projects, as well as stimulated 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.

Topics for focused group discussions

Methodological aspects of randomized trials		
Novel trial designs		
Ethics and Informed Consent		
Screening studies		
Patient-reported outcomes and Quality of Life research		
Implementation research		
Statistics for observational studies		
Health Economics		
Random doubts in Statistics		

Special session: selection of the best protocols at the workshop

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 (eight in all) were presented to all faculty and participants, during a one-hour session on 9th March 2023.

Workshop Evaluation

Evaluation of participants

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 30 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. Almost all participants showed an improvement in overall scores after the workshop.

Feedback from participants

We conducted a post-workshop online survey to obtain feedback from the participants related to various aspects of the workshop - more than 90% of participants rated the workshop sessions and arrangements (venue, amenities, travel, food, and overall arrangements) as excellent. We received some useful suggestions regarding the workshop:

What faculty and participants had to say

"This was an absolute cracker of a week in every way possible" - Sankalp Singh

"Thank you, CReDO for giving such wonderful moments" - Jagath Nath Krishna

"This was a great opportunity for learning, networking and enjoying" - Eliana Lopez Baron

"Thank you to the CReDO team. Today I take with me a lifetime of friendships and an enlightened mind. What else can beat that in life?" – Anhad Mehra

"An enriching and lifetime experience" - Sunaina Wadhwa

"Stimulating conversations, cross-learning and so many new connections" - Amiti Verma

"Thank you for this amazing experience" – Erika Montalvo

"The whole workshop was a great learning experience for me. It was so meticulously organized. I had a fabulous time, academically and socially." – Denis Xavier

Research ideas developed at the workshop

1.	Adriana Morais	Thymus and activation-regulated chemokine (TARC) as diagnosis and treatment response marker for paediatric Hodgkin lymphoma: A multi-institutional study on the north east coast	
2.	Akash Pradhan	Training a cadre of Informal Healthcare Providers at the block-level in West Bengal for early identification of common cancers and reduction in delayed diagnosis: A Randomised Controlled Trial.	
3.	Aleksandre Iovashvili	Collaborative Care model for patient well-being	
4.	Ameya Bindu	Study of long-term clinical outcomes and quality of life in patients with Orbitomaxillary defect (Brown Type III) reconstruction using free tissue transfer	
5.	Amiti Varma	Exploring associations between drivers and risk factors of suicide among cancer patients	
6.	Anhad Mehra	Resection in locally advanced oral cancers post NACT – based on pre NACT versus post NACT extent: a Randomised Controlled Trial	
7.	Anil Tibdewal	PROton based Dose Escalation to Gross Disease versus Photon based Standard Dose in Locally Advanced Non-Small Cell Lung Cancer – A Phase II/III Randomized Controlled Trial (PRODEL)	
8.	Anip Joshi	To find out the outcome of breast cancer patients in Bir Hospital, National Academy of Medical Sciences	
9.	Anna Zelwianska	Cabozantinib in newly diagnosed patients with high risk soft tissue sarcoma.	
10.	Anuj Kumar	Optimal Chemoradiation for Unresectable Head and Neck Cancers	
11.	Astrid Riveros	Determination of serum asparaginase levels in pediatric patients being treated for ALL and LY with the POLA guide, in the Hospital Del Niño Dr. Ovidio Aliaga, from 2023 to 2028.	
12.	Dharma Ram Poonia	Upfront Surgery vs Induction Chemotherapy followed by surgery in Oral Cancers with advanced nodal disease (SurVIc Trial): A Randomised Controlled Trial	
13.	Eliana Lopez Baron	Vitamin D levels in children with cancer admitted to a pediatric intensive care in a middle income country and its relation to outcomes	
14.	Emile Munyambaraga	Evaluation of a cancer patient navigation program in Rwanda: a mixed method.	
15.	Erika Elena Villanueva Hoyos	Identify opportunities for improvement in the diagnosis and treatment of patients with CNS tumors	
16.	Erika Montalvo	Improved outcomes after successful implementation of a pediatric early warning system (PEWS) in an emergency area in a resource-limited pediatric oncology hospital	
17.	Evelinda Nava Prada	Nimotuzumab in the treatment of pediatric patients with malignant brain tumors, Two (2) years' experience in the Republic Bolivarian from Venezuela February 2016 –February 2018.	
18.	Gargi Das	Nasogastric tube feeding versus oral feeding for treatment of moderate to severe acute undernutrition in children with cancer: a randomized, open-label, parallel-group, phase III trial.	

19.	Glaucia Regina Costa Murra	Acute Leukemias - Amarte Alliance epidemiologic study
20.	Hasan Hashem	Using Machine Learning Algorithms to Delineate Intestinal Microbiome Diversity for the prediction of Acute Graft-versus-Host-Disease (GvHD) in Allogeneic Hematopoietic Cell Transplantation (HCT).
21.	Hemavathi Baskarane	Liquid biopsy-based risk stratification and intensification of treatment in EGFR mutant advanced NSCLC
22.	Hugo Antonio Romo Rubio	Minimal residual disease-based guided therapy for pediatric acute lymphoblastic leukemia in México through prospective evaluation and precision risk classification
23.	Indhuja M.V	A multicenter phase 3 open label randomised control non inferiority trial comparing low dose Dasatinib and standard of Care in newly diagnosed chronic phase chronic myeloid leukemia patients
24.	Indraja Devidas Dev	Phase I/II trial of 177 Lu-DOTA-RGD radioligand therapy in progressive/ recurrent high-grade gliomas.
25.	Jyotiman Nath	Temozolomide added to preoperative chemoradiotherapy in MGMT hypermethylated locally advanced rectal cancer patients: Hospital based prospective study.
26.	Kantamani Teja	Impact of early palliative care in operable locally advanced oral cavity SCC - a RCT
27.	Laboni Sarkar	Outcomes of telemedicine in comparison with outpatient visits in patients with hematological malignancies: A randomized controlled study
28.	Latika Kansal	Utilizing Sentinel Lymph Node Biopsy to Identify the Lymphatic Drainage Pattern in Clinically Node Negative Recurrent Oral Cavity Squamous Cell Carcinoma.
29.	Laxma Reddy Mekala	A phase II study to determine the efficacy of Posaconazole as antifungal prophylaxis in adolescent and adults with acute lymphoblastic leukemia.
30.	Manisha Nandkumar Pawar	Effect of virtual reality headset device on pain, fear and anxiety in Pediatric Cancer Patients during Lumbar Punctures (LP) at tertiary care center in Mumbai.
31.	Maqbul Alam	Primary (immediate) versus secondary (delayed) dental implants in the prosthetic rehabilitation of head and neck cancer (HNC) patients undergoing free-fibula flap - A prospective randomized controlled study
32.	Maya Prasad	The impact of micronutrient supplementation in children with cancer: A randomized open-labelled controlled study
33.	Nalla Anuraag Reddy	Back to School project: Factors affecting school re-integration of Indian children with Acute Lymphoblastic Leukaemia (ALL) on maintenance chemotherapy.
34.	Nur Melani Sari	Evaluation of Rituximab Efficacy and Safety in High Risks B-NL and B-AL in Modified LMB Protocol in Low-Middle-Income Country
35.	Pablo Miguel Gonzalez- Montalvo	MAS-ALL-23, a Minimal Residual Disease based, Risk-Adapted treatment for Acute Lymphoblastic Leukemia in Mexico
36.	Parmod Kumar	Gemcitabine and Carboplatin Versus Gemcitabine and Paclitaxel Chemotherapy in Cisplatin

	1	Inclinible Advanced Stage Urethelial Concers A Prospective Pendemized Central Study
37.	Partha Pratim Medhi	Ineligible Advanced Stage Urothelial Cancers- A Prospective Randomized Control Study.
37.	Partna Pratim Medni	Intensity modulated radiotherapy to reduced target volume after neoadjuvant chemotherapy in
		locoregionally advanced nasopharyngeal carcinoma and its impact on survival, toxicities and quality
20	Deshaui	of life: A prospective randomized clinical trial.
38.	Prabani	Identifying the best indicator of nutritional status at baseline that can predict outcomes of childhood
00	Madumarachchi	Acute Lymphoblastic Leukaemia (ALL) in Sri Lanka
39.	Pradeep	Developing a risk prediction model to guide treatment in low resource setting for treating adults with
10	Siriwardena	Acute Myeloblastic Leukaemia(AML)
40.	Prakash S	Factors causing delay in diagnosis of lung cancer assessed at a tertiary care centre in North India
41.	Prakruthi S. Kaushik	Graded prednisolone therapy in Pediatric Acute lymphoblastic Leukemia/Lymphoma – An open label randomised control trial
42.	Prasanna Vani	A multicentric, randomized controlled trial to determine the effect of Surgical Plethysmographic Index
	Vanamail	guided anaesthesia management in reducing the post-operative complication in major oral surgeries
		for cancer.
43.	Rakesh L John	A comparative study between Buprenorphine sublingual and Tramadol oral tablets in the
		management of moderate pain in cancer patients.
44.	Rakesh Mishra	Radiomics in adult and pediatric neurooncology: Correlation study with extent or resection, survival
		and Prognosis
45.	Rasheed Ofosu-	Development and Trial of an Integrated Model for Oncology and Palliative care for Management of
	Poku	Breast and Cervical Cancer in the Kumasi City (IMOP-Trial)
46.	Reshma A	A Multi-Stage Mixed-Method Study to understand factors associated with abandonment of treatment
		among adult patients with cancer and to develop a tool for its prediction.
47.	Richard Nyeko	Reduced-intensity induction regimen and maintenance therapy for acute myeloid leukemia in a
		resource-limited context: a randomized clinical trial
48.	Sabrina Q. Florendo	Effect of Web-Based Short Message Service (SMS) Reminders on Scheduled Appointments of
	(Villanueva)	Pediatric Cancer patients in a Tertiary Hospital: A Randomized Controlled Trial
49.	Sankalp Singh	A study of the benefit of combination of palliative radiotherapy with immunotherapy in the treatment of
		metastatic lung cancer
50.	Sharath Kumar Hj	A two-stage basket study to evaluate the prophylactic efficacy of Sodium Copper Chlorophyllin for the
		prevention of acute radiation injury at various anatomical sites in cancer patients
51.	Shruti Kakkar	Prognostic implication of measurable residual disease in children with acute myeloid leukemia.
52.	Shushan Hovsepyan	A randomized, placebo-controlled study investigating the neuroprotective effect of oral vitamin B
		complex in combination with glutamine and separately in children, adolescents, and young adults
		with cancer receiving vincristine
53.	Siva Sree Kesana	Role of mirtazapine in cancer-associated anorexia cachexia and quality of life in patients with
		advanced lung cancer - A randomized, double-blind, placebo-controlled phase II trial.

54.	Sol Irupé Aponte Bonzi	Development of a follow-up plan for the cancer survivor patient. Clinical and paraclinical aspects.	
55.	Srinivas Kodaganur Gopinath	High Intensity Interval Training (HIIT) for pre-habilitation in patients undergoing major lung resections: A Randomised controlled trial.	
56.	Suman Khanal	Billroth-II with Braun anastomosis vs Roux en Y gastrojejunostomy in D2 distal gastrectomy for operable gastric cancer	
57.	Sunaina Wadhwa	Title: Lymphadenectomy in Early-stage epithelial Ovarian Cancer, Is it needed? A Prospective Randomized Trial for the assessment of benefits of role of lymphadenectomy and its effect on survival outcomes.	
58.	Sushil Selvarajan	Safety and feasibility of cellular therapy with CD45RA depletion for the prophylaxis of viral infections in Haplo-identical stem cell transplantation	
59.	Urvashi Jain	A non-inferiority based randomised controlled trial comparing immediate pre-pectoral implant-based breast reconstruction (IBBR) with and without biological Extra-Cellular Matrix (ECM)	
60.	Venkatesh Kapu	A phase III Randomized study to compare two different dosing strategies of Rasburicase in adult acute leukemia and high-grade lymphomas with established tumor lysis syndrome.	
61.	Vignesh Subramani	Efficacy of baseline rectal swab culture-directed antimicrobial therapy for management of febrile neutropenia in children with hematological malignancies – A randomised phase III study.	
62.	Vikas Gupta	Cancer screening study, to screen for breast, cervix and head/neck cancers at the community level	
63.	Vineet Kumar	Comparison of clinical, cosmetic and quality of life outcomes of oncoplastic breast surgery excised and reconstructed by same surgeons versus different surgeons	
64.	Vinod Ramani	Associated risk factors and the interaction of obesity, alcohol consumption and physical inactivity among colorectal cancer cases: a case control study from a South Indian cancer hospital.	
65.	Vinotha Thomas	An evaluation of the diagnostic role of cell free HPV DNA during surveillance following treatment of cervical cancer in detection of recurrence: an observational study.	

Summary of workshop outcomes and impact

The objectives of this workshop were:

- a) To train researchers in oncology in various aspects of clinical trial design and
- b) To help them to develop a research idea into a structured protocol.
- c) To develop research capacity by training biostatisticians from across the country

To assess these outcomes

- 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 65 participants who had submitted a one-page research concept sheet at the time of workshop application, converted their ideas into full-fledged protocols.
- c) Six biostatisticians and 2 other observers from various academic institutes in India attended the workshop and participated in the training and discussions.

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 will be 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: Six biostatisticians from different academic centers in India were trained at the workshop. Their attendance at the workshop will help with capacity building at each of these institutions.

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World Health Organization South-East Asia Region (WHO SEAR)
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King's College, London
Tata Memorial Centre, Mumbai

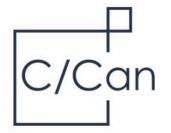
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