



**International
Collaboration for
Research methods
Development
in Oncology**

5th CReDO workshop

1st to 7th March 2020

Lonavala, India



Organised by



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American Society of Clinical Oncology

Making a world of difference in cancer care

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The future of cancer therapy

Collaborating partner



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 1st and 7th March 2020. This workshop was the fifth in a series of workshops and was modeled on similar workshops held in the United States (the AACR/ASCO Workshop on Methods in Clinical Cancer Research, Vail), Europe (AACR-EORTC-ESMO Workshop on Methods in Clinical Cancer Research) and Australia (the ACORD Protocol Development Workshop).

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

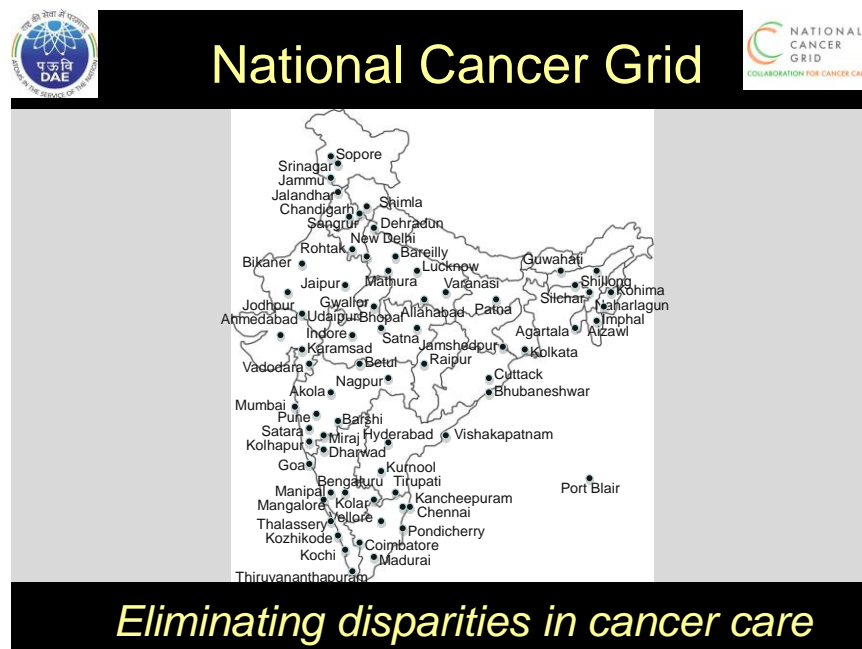
The Tata Memorial Centre (TMC), comprising the Tata Memorial Hospital (TMH) and the Advanced Centre for Training, Research and Education in Cancer (ACTREC) is the oldest and largest cancer centre in the country. TMC has an annual registration of over 46000 new patients with cancer and caters to patients 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 a large number of 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 193 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.

The best 7 research proposals developed at the workshop are being considered for funding by the National Cancer Grid, as multi-centric trials.



Workshop Advisory Board

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|-------------------|--|
| 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

| | |
|------------------------|------------------------------|
| Girish Chinnaswamy | Tata Memorial Centre, Mumbai |
| Durga Gadgil | Tata Memorial Centre, Mumbai |
| C S Pramesh | Tata Memorial Centre, Mumbai |
| Priya Ranganathan | Tata Memorial Centre, Mumbai |
| Manju Sengar | Tata Memorial Centre, Mumbai |
| Shivakumar Thiagarajan | Tata Memorial Centre, Mumbai |

Workshop faculty

| | |
|-----------------------|---|
| Ajay Aggarwal | Clinical Oncologist and Senior Visiting Research Fellow at The Institute of Cancer Policy, King's College, London |
| Christopher Booth | Medical Oncologist and Health Services Researcher at Queen's University, Kingston, Canada |
| Marc Buyse | Founder, International Drug Development Institute and CluePoints, Belgium and USA |
| Carlo Caduff | Reader in Global Health and Social Medicine at King's College London, Director of Postgraduate Research Studies and Chair of the Culture, Medicine and Power research group |
| Girish Chinnaswamy | Professor in Paediatric Oncology, Tata Memorial Centre, Mumbai |
| David Collingridge | Editor-in-Chief, Lancet Oncology |
| Chris Frampton | Professor of Biostatistics, University of Otago, New Zealand |
| Durga Gadgil | Consultant, Tata Memorial Research Administrative Council |
| Allan Hackshaw | Professor of Epidemiology & Medical Statistics at University College London, and Deputy Director of the Cancer Research UK & UCL Cancer Trials Centre |
| Sally Hunsberger | Mathematical Statistician, Biostatistics Research Group, National Institute of Allergy and Infectious Disease, USA |
| Amit Khot | Consultant Hematologist, Peter MacCallum Cancer Centre, Melbourne |
| Mark Krailo | Professor of Research, University of Southern California and a Senior Statistician with the Children's Oncology Group. |
| Ruth Langley | Medical Oncologist, Medical Research Council – Clinical Trials Unit at University College London |
| Marie-Cecile Le Deley | Associate Professor of Biostatistics at University Paris-Sud / Paris-Saclay and Head of the Biostatistics and Methodology Unit of Oscar Lambret Cancer Centre |
| Indranil Mallick | Senior Consultant, Department of Radiation Oncology, Tata Medical Center, Kolkata |

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| Sreekumaran Nair | Professor & Head, Department of Biostatistics, JIPMER |
| Xavier Paoletti | Professor of Biostatistics at the University of Versailles St Quentin and at the Institut Curie, Paris |
| Mahesh Parmar | Professor of Medical Statistics and Epidemiology and Director of the MRC Clinical Trials Unit at UCL and the Institute of Clinical Trials and Methodology at University College London. |
| Prachi Patil | Professor, Department of Digestive Diseases and Clinical Nutrition, Tata Memorial Centre, Mumbai |
| C S Pramesh | Professor, Thoracic Surgery, Tata Memorial Centre and Coordinator, National Cancer Grid of India |
| Arnie Purushotham | Professor of Breast Cancer at King's College London and Director of King's Health Partners Comprehensive Cancer Centre |
| Priya Ranganathan | Professor of Anaesthesiology, Tata Memorial Centre, Mumbai |
| Manju Sengar | Professor, Adult hematolymphoid disease management group, Medical Oncology, Tata Memorial Centre |
| James Spicer | Professor of Experimental Cancer Medicine, King's College London, and Consultant in Medical Oncology, Guy's and St. Thomas' Hospitals London, UK |
| Martin Stockler | Professor of Oncology and Clinical Epidemiology, University of Sydney and Oncology Co-Director at the NHMRC Clinical Trials Centre |
| Richard Sullivan | Professor of Cancer and Global Health at Kings College London and Director of the Institute of Cancer Policy |
| Ian Tannock | Emeritus Professor of Medicine and Medical Biophysics at Princess Margaret Cancer Centre and University of Toronto |
| Shivakumar Thiagarajan | Associate Professor, Head and Neck surgical oncology, Tata Memorial Centre |
| Camilla Zimmermann | Professor of Medicine and Director of the Division of Palliative Medicine at the University of Toronto |

Workshop participants

| PARTICIPANTS | |
|---------------------------|---|
| Adam Fundytus | Alberta Health Services, Canada |
| Adhara Chakraborty | Tata Memorial Centre, Mumbai |
| Akhil Rajendra | Tata Memorial Centre, Mumbai |
| Amrut Kadam S | Bangalore Medical College & Research Institute, Bangalore |
| Anand Narayan Chinnachamy | GKNM Hospital, Coimbatore |
| Anjum Joad | Bhagwan Mahaveer Cancer Hospital, Jaipur |
| Anupama Borker | Goa Medical College |
| Archi Agrawal | Tata Memorial Centre, Mumbai |
| Arjun Mandade | M.S. Ramaiah Medical college, Bangalore |
| Arpitha Anantharajju | JIPMER, Puduchery |
| Ashok Kumar Das | Dr B. Borooah Cancer Institute, Guwahati |
| Baphiralyne Wankhar | NEIGRIHMS, Shillong |
| Bhavika Kothari | Tata Memorial Centre, Mumbai |
| Bishesh Sharma Poudyal | Civil Service Hospital, Nepal |
| Chetan Anil Dhamne | Tata Memorial Centre, Mumbai |
| Deepa Joseph | AIIMS, Rishikesh |
| Divya Pillai | Clinical Development Services Agency, New Delhi |
| Dorothy Lombe | Government Republic of Zambia |
| Fidel Rubagumya | Ministry of Health, Rwanda |
| Florida Sharin | Tata Memorial Centre, Mumbai |
| Fouzia Aboobacker | Christian Medical College, Vellore, Tamil Nadu |
| Gangothri Selvarajan | Cancer Institute, Adayar, Chennai |
| Hemantkumar Onkar Nemade | Basavatarakam Indo American Cancer Hospital and Research Institute, Hyderabad |
| Jyothsna Kuriakose | Tata Memorial Centre, Mumbai |
| Kanika Batra Modi | Max Hospital, Saket, New Delhi |
| Karthik Rengaraj | Tata Memorial Centre, Mumbai |
| Krishnakumar Thankappan | Amrita Institute of Medical Sciences, Kochi |
| Mahendra Pal | Tata Memorial Centre, Mumbai |

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| Mayur Raman Mantri | Tata Memorial Centre, Mumbai |
| Mingma Sherpa | Sikkim Manipal Institute of Medical Sciences, Gangtok, Sikkim |
| Nagarajan Murugaiyan | GKNM Hospital, Coimbatore |
| Nandini Menon | Tata Memorial Centre, Mumbai |
| Naveen Mummudi | Tata Memorial Centre, Mumbai |
| Neha Sharma | Tata Memorial Centre, Mumbai |
| Niharendu Ghara | Tata Medical Center, Kolkata |
| Nikesh Hanumanthappa | Guys and St Thomas's NHS Hospital, London |
| Nithyanand C | Tata Memorial Centre, Mumbai |
| Nivedhyaa Srinivasaraghavan | Cancer Institute, Adayar, Chennai |
| Nuthan Kumar Mk | Kidwai Memorial Institute Of Oncology, Bangalore |
| Nuworza Kugbey | University of Health and Allied Sciences, Ghana |
| Pooja Ramakant | King Georges' Medical University, Lucknow |
| Preethi S Shetty | Tata Memorial Centre, Mumbai |
| Priyanka Augustine | Kasturba Medical College, Manipal |
| Priya Eshpuniyani | Asian Cancer Institute, Mumbai |
| Punitha Chockalingam | Cancer Institute, Adayar, Chennai |
| Rasmi Palassery | M.S. Ramaiah Medical College, Bangalore |
| Revathi Rajagopal | CyteCare Hospitals, Bangalore |
| Rutula Sonawane | Tata Memorial Centre, Mumbai |
| Sachit Ganapathy | JIPMER, Puduchery |
| Sandip Kumar Barik | Acharya Harihar Regional Cancer Centre, Cuttack |
| Shyam S | Tata Memorial Centre, Mumbai |
| Sravan Kumar | Basavatarakam Indo-American Cancer Hospital, Hyderabad |
| Sreedevi Warriar | Manipal Academy of Higher Education, Manipal |
| Sucharita Tuladhar | Tata Medical Center, Kolkata |
| Suja Johnson | ACTREC, Tata Memorial Centre, Mumbai |
| Tanma Mahanta | Assam Cancer Care Foundation, Guwahati, Assam |
| Tejshri Telkhade | Tata Memorial Centre, Mumbai |
| Umesh Velu | Kasturba Medical College, Manipal |
| Vadaparty Annapurna | Sri Shankara Cancer Hospital & Research Centre, Bangalore |

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|------------------------------|--|
| Vandhana Rajgopal | All India Institute of Medical Sciences, New Delhi |
| Vasu Babu Goli | Tata Memorial Centre, Mumbai |
| Venkata Rama Mohan Gollamudi | Tata Memorial Centre, Mumbai |
| Vijay G | Cancer Institute, Adayar, Chennai |
| Vijay Kumar Srinivasalu | Narayana Hrudayalaya, Mazumdar Shaw Medical Center, Bangalore |
| | |
| OBSERVERS | |
| Akshay Patil | Tata Memorial Centre, Mumbai |
| Ajit Venniyoor | Ministry of Oman |
| Binu V S | NIMHANS, Bangalore |
| Maya Padmanabhan | Malabar Cancer Centre, Thalassery |
| Shivam Pandey | All India Institute of Medical Sciences, New Delhi |
| Vineeta Deshmukh | Integrated Cancer Treatment and Research Center, Wagholi, Pune |

CReDO 2020 faculty and participants



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 64 participants from a total of 166 applicants. In addition, 6 participants were given direct entry (as observers) based on the felt need to augment national capacity in biostatistics and public health amongst the NCG centres. 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 fees

Participants from India:

Academic institutions: Indian Rupees Ten thousand only

Industry participants: Indian Rupees One lakh fifty thousand only

Participants from outside India:

World Bank Low, lower-middle and upper-middle income economies: Two hundred US dollars only

World Bank High income economies: One thousand US dollars only

The registration fees offset a very small fraction of the actual workshop costs per participant and included the following:

- Shuttle-bus service from a pre-specified pickup point in Mumbai to the workshop venue on 1st March 2020
- Shuttle-bus service from the workshop venue to a pre-specified drop-off point in Mumbai or Mumbai airport on 7th March 2020
- Accommodation (twin sharing) in the workshop venue from 1st to 7th March 2020
- Food and beverages throughout the duration of the workshop
- Wi-fi access throughout the duration of the workshop
- Access to all workshop material

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 for swimming, volleyball, basketball, tennis, golf, carrom, chess, table tennis and snooker along with a gymnasium, spa, jacuzzi and sauna



Workshop sessions

Pre-workshop webinars

Starting December 2019, 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. Research ethics and Informed consent
5. Biostatistics (two sessions)
6. Qualitative Research

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

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 enable 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 3 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

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| Methodological aspects of randomized trials |
| Novel trial designs |
| Ethics and Informed Consent |
| Screening studies |
| Patient-reported outcomes and Quality of Life research |
| Implementation research |
| Observational studies |
| Personalized medicine and biomarker-based research |
| 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 (seven in all) were presented to all faculty and participants, during a one-hour session on 6th March 2020.

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. Participants showed a 7% improvement in overall scores (from 53% to 60%) during 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 - 92% of participants rated the various teaching sessions as good to excellent. More than 90% of participants rated the workshop arrangements (venue, amenities, travel, food and overall arrangements) as excellent.

What faculty and participants had to say:

"I have thoroughly enjoyed myself over the past 1 week. My sincere thanks to my entire team of mentors of the PDG and the entire faculty. The hard work put in by the mentors and the faculty is really commendable. I hope all of us do justice to this hard work" – Prriya Eshpuniyani, Asian Cancer Institute, Mumbai

"It was a great learning experience for me. All the mentors were very approachable and helpful. The knowledge acquired in these days will be useful for me not only for this protocol but all my future research projects" – Mayur Mantri, Tata Memorial Centre, Mumbai

"Thank you very much for such a lovely and enriching experience" Dorothy Lombe, Zambia

"Thanks to the organizers of CReDO for such a wonderful 7 days. It changed my perspective of conducting a clinical trial. So much gained and these 7 days will help me gain even more" – Sandip Barik, Cuttack

"Thank you so much for mentoring us with so much of patience and passion. It was a wonderful opportunity to be mentored by you all" - Arpitha Anantharaju, Chennai

“It was a memorable experience at CReDO for me- learnt a lot. A big shout out to the whole CReDO team and the faculty!!! – Annapurna Vadaparthi, Bangalore

“Thank you very much for a week full of learning and fun. I hope to make you all proud by getting my study done and publishing it! – Rasmi Palassery, Bangalore

“Thanks again for organizing such a wonderfully productive, fulfilling, and uplifting week”! – Martin Stockler, Australia

“It was a fascinating, albeit intense, experience! I certainly learned a lot from it, and seeing how the attendees developed from last Sunday through to their presentations on Friday was remarkable and gratifying in equal measure. You have really created something incredibly important and transformative.” - David Collingridge, UK

Research ideas developed at the workshop

1. A Prospective Comparative Analysis Financial Toxicity Within the Public and Private healthcare Systems of India compared with Canada.
2. Development Of A Novel Voice Prosthesis Using Indigenous Design For Post Laryngectomy Voice Rehabilitation
3. A phase II study to evaluate the feasibility of a switch TKI strategy in adolescents and adults with De-Novo Philadelphia positive Acute Lymphoblastic Leukemia (Ph+ ALL).
4. Comparison of MRI based versus CT based brachytherapy for gynaecological cancers
5. Prospective assessment of Bone Mineral Density Changes after Pelvic Radiotherapy in women with Cervical or endometrial Cancer.
6. ERAS in head and neck commando surgery (with a microvascular free flap) : will an evidence based perioperative protocol impact perioperative outcome
7. Self-esteem and quality of life of breast cancer patients following mastectomy and the impact of external breast prosthesis.
8. Radionuclide therapy with ¹⁷⁷Lu-PSMA as second line treatment in hormone sensitive prostate cancer versus docetaxel chemotherapy - A prospective, phase 2, randomized controlled trial.
9. Role of Extensive education about the disease, chemotherapy, benefits of completion of therapy and effective management of side effects to avoid abandonment of treatment.
10. Postoperative intra-peritoneal chemotherapy after primary cytoreduction- a randomised phase three trial
11. Assessment of High-Risk HPV and p16 expression in Oropharyngeal Cancer for prognostication in North-East India
12. Development and validation of an automated tool to evaluate radiological response to treatment for lung carcinoma
13. A prospective study to evaluate the role of imaging to predict shrinkage patterns post neoadjuvant chemotherapy and its correlation with histopathological factors.
14. A mixed-methods study of well-being of cancer caregivers in Nepal
15. Pre-exposure prophylaxis (PrEP) in a pediatric oncology unit with year-round exposure to varicella. Aim: To study the efficacy of pre-exposure acyclovir-prophylaxis in pediatric oncology patients at risk of varicella.
16. Randomised Trial of Neoadjuvant Chemoradiation followed by Surgery and Chemotherapy vs Perioperative Chemotherapy in Esophageal Adenocarcinoma
17. Designing Community - based Models for Breast Cancer Risk Stratification for the Indian Population - an initiative to address the extremities of low resource settings
18. Validation of ultrasound-based imaging for 3-D brachytherapy planning in the treatment of locally advanced cervical cancer in Zambia
19. Molecular characterization of human papilloma virus (HPV) associated head and neck squamous cell carcinomas in Rwanda

20. A prospective study to evaluate the impact of Narrow Band Imaging(NBI) versus white light directed marginal assessment in achieving local control for operable oral cavity cancers.
21. Comparing the effect of hypomethylating agents versus standard 7/3 protocol as initial induction chemotherapy for young acute myeloid leukemia patients.
22. A randomised study of methotrexate versus paclitaxel followed by methotrexate and celecoxib with or without cyclophosphamide as metronomic in recurrent non-nasopharyngeal squamous cell carcinomas.
23. Ultrasound Elastography as a predictor of post-operative complications in patients undergoing total thyroidectomy in tertiary care cancer hospitals: A multicentric, prospective, observational study.
24. Effect of early integration of specialist palliative care for adult patients with hematolymphoid cancers versus usual care : a randomized controlled trial.
25. Clinical outcomes and cost analysis of ERAS pathway for ovarian cancer surgery: a randomised control trial
26. A phase II study to evaluate the activity of 177-Lu-DOTA rituximab in adult patients with relapsed low-grade b-cell lymphomas.
27. Free Fibula Flap versus PMMC flap for the reconstruction of the lateral mandibular defects: A Prospective two-armed comparative study to evaluate the Qol outcomes and Cost utility Analysis
28. Intravesical BCG: Is Urinary Bladder Ready To Receive It?
29. To study the relationship between flap ischemia time and flap related complications in free flap reconstruction for Head and Neck cancers.
30. Spectrum of molecular biomarkers in intra-ductal proliferative lesions of breast. Role of Immunohistochemistry in risk stratification of the various precancerous lesions of breast.
31. A prospective Randomized trial of IMRT versus Adaptive Radiotherapy in locally advanced Head and Neck Cancers
32. Oral metronomic therapy in metastatic castrate resistant prostate cancer in second and subsequent lines of therapy
33. Adjuvant Radiation therapy to Tumour bed alone In oral Cavity cancer (ARTIC study)
34. A study in elderly patients with Non Hodgkin lymphoma to evaluate the applicability of clinical trial results to the general population: a prospective cohort study.
35. The Indian Paediatric Oncology Group collaborative multicentre treatment protocol for children and adolescents with relapsed acute lymphoblastic leukaemia (InPOG ALL R1)
36. Toxicity and safety of single dose radiotherapy (SDRT) to prostate with 14Gy using stereotactic body radiotherapy (SBRT) technique with rectal spacers in oligometastatic (1-5 metastases) prostate cancer (Pca) patients
37. A prospective study analysing surgeries for differentiated thyroid cancers- is less really more?

38. Intraoperative ventilatory strategies and its association with postoperative pulmonary complications(PPC) in patients undergoing one lung ventilation (OLV) for thoracic surgeries: A randomized controlled trial.
39. Metronomic therapy in children with recurrent or refractory High Risk Neuroblastoma - A phase 2 study
40. Information needs and preferences among cancer patients in Ghana: implications for patient-centred care in a low resource setting
41. Efficacy and safety of pre-operative concurrent chemoradiation in patients with locally advanced breast cancer.
42. Does addition of proactive intra-peritoneal chemotherapy improve recurrence rates in signet rectal adenocarcinoma ? A RCT.
43. An Open Label, Randomized Controlled Phase II Trial comparing Preoperative Chemotherapy followed by Chemo-irradiation vs Chemo-irradiation alone in Resectable Oesophageal Cancers
44. Perioperative Serum albumin levels and its effect of postoperative outcomes in operated patients of Carcinoma lung and Carcinoma Esophagus
45. Prospective randomized control Trial to see the association of anesthetic agents and cancer recurrence in primary cancer surgeries by measuring the Biomarkers released by Natural killer cells.
46. A prospective observational study of cancer in adolescent and young adult (AYA) patients to understand the disease pattern, treatment outcomes and the voids in treatment adherence and post-treatment rehabilitation.
47. Efficacy of a Psycho-oncology care model to alleviate psychological distress among patients with head and neck cancer: A non-randomized clinical trial from a tertiary cancer hospital
48. Is Cognitive Behavioral Therapy along with routine counselling more effective for Body Image Dysfunction in Patients with Advanced Head and Neck Cancers.
49. Bayesian Network modeling for the prognosis of Head and Neck cancer
50. Observation versus Adjuvant Radiotherapy in Post-operative Early Stage Head and Neck Squamous cell Cancer (HNSCC) of Oral Cavity
51. Granulocyte transfusion for severe sepsis in pediatric oncology
52. Relevance of Post-treatment surveillance in Oral Cancer: A prospective observational study
53. Facilitators and barriers in screening for cancers in HIV patients in a community setting in India- A qualitative study
54. Evaluating the safety and feasibility of outpatient management of children with fever and neutropenia during anti-cancer therapy
55. A phase 1/ 2 open-label, dose-escalation, safety and efficacy study of mTORC1 inhibitor, rapamycin, combined with cisplatin-pemetrexed in KRAS mutant lung cancer.
56. How cultural & social issues impact patients' health related behavior in accessing health care services, treatment adherence & symptom management.
57. Optimizing follow up cystoscopy use after bladder preservation in muscle invasive bladder cancer(MIBC)

58. Phase II trial comparing the reduction of radiation dose to the intermediate and low risk region versus conventional radiotherapy doses in p16 positive head and neck cancer patients
59. Prevalence of HPV infection in rural India from urine sample in the community
60. A randomized control study evaluating the use of oral metronomic chemotherapy versus conventional systemic chemotherapy in LABC; to further conduct an RCT trial on patients amenable, to breast conservation surgery versus mastectomy after chemotherapy.
61. A Phase II randomised study to evaluate the role and efficacy of Post remission therapy in Acute Myeloid Leukaemia(AML)
62. Levofloxacin prophylaxis in children with Acute Lymphoblastic Leukemia (ALL) -An open label randomised phase III study.
63. Phase III, randomized controlled trial of intraperitoneal chemotherapy versus intravenous chemotherapy after neoadjuvant chemotherapy and optimal cytoreduction in stage III epithelial carcinoma of ovary/ fallopian tube/ primary peritoneal cancer
64. Study of immune contexture of gastroesophageal tumours

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. There was a 7% improvement in the overall percentage of correct answers to the test questions (from 53% to 60%).
- b) All 64 participants who had submitted a one-page research concept sheet at the time of workshop application, converted their ideas into full-fledged protocols.
- c) Five biostatisticians 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: Five biostatisticians from different academic centers in India were trained at the workshop. Their attendance at the workshop will help in capacity building at each of these institutions.

Acknowledgements

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Funding agencies

Tata Trusts, Mumbai

Tata Memorial Centre, Mumbai

King's College, London

American Society of Clinical Oncology

Cancer Research UK

Indian Council of Medical Research

US National Cancer Institute through the CRDF grant

Collaborating partner

The Medical Oncology Group of Australia (MOGA) Incorporated through the Australia and Asia Pacific Clinical Oncology Research Development (ACORD) Initiative

Endorsing agency

Medical Research Council - Clinical Trials Unit at University College London

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