CReDO
Shaping research ideas

International Collaboration for Research methods Development in Oncology

CReDO workshop

5th to 10th February 2017

Lonavala, India

TATA MEMORIAL CENTRE
टाटा स्मारक केंद्र
SERVICE RESEARCH EDUCATION

NATIONAL CANCER GRID
COLLABORATION FOR CANCER CARE

Organised by

TATA MEMORIAL CENTRE
टाटा स्मारक केंद्र
SERVICE RESEARCH EDUCATION

NATIONAL CANCER GRID
COLLABORATION FOR CANCER CARE

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UCL

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This workshop was organised under the auspices of

EORTC
The future of cancer therapy

Collaborating partner

acord
Australia & Asia Pacific
Clinical Oncology Research
Development Workshop

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 February 2017. This workshop was the second 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 (ECCO-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". The faculty consisted of international and national experts with extensive experience in oncology research and training in research methodology workshops.

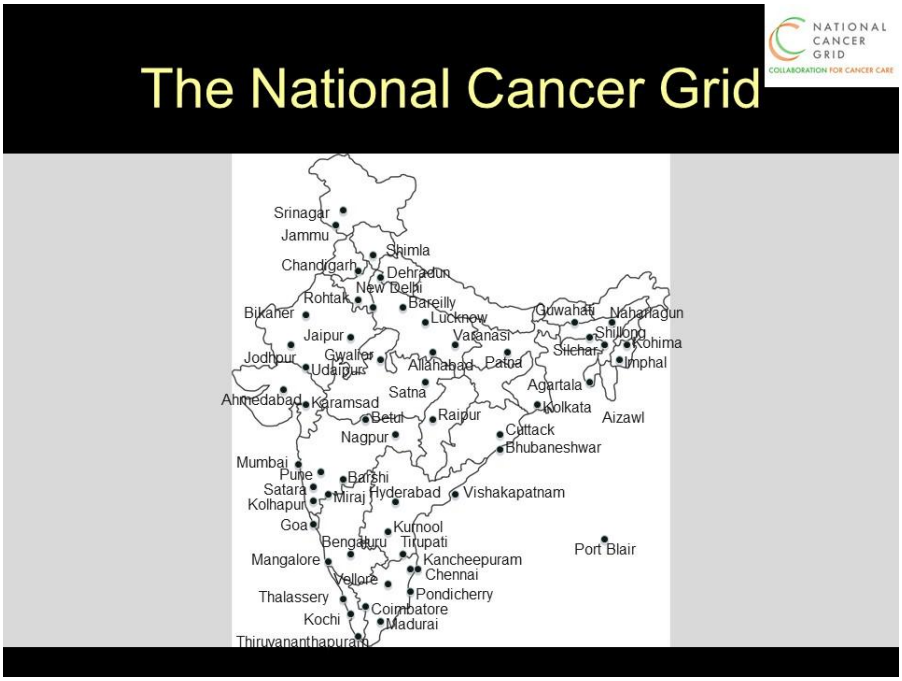
The Tata Memorial Centre

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 37000 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 104 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 submitted for the 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
Bogda Koczwara	Flinders University, Australia
Mahesh Parmar	MRC-CTU at University College London
Arnie Purushotham	King's College, London
Ian Tannock	Princess Margaret Cancer Centre, Toronto
Sabine Tejpar	EORTC, Belgium
Jack Welch	National Cancer Institute, USA

Workshop Organising Committee

Girish Chinnaswamy	Tata Memorial Centre, Mumbai
Durga Gadgil	Tata Memorial Centre, Mumbai
Hari Menon	Cytecare Hospitals, Bangalore
C S Pramesh	Tata Memorial Centre, Mumbai
Priya Ranganathan	Tata Memorial Centre, Mumbai
Manju Sengar	Tata Memorial Centre, Mumbai

Workshop faculty

Rajendra Badwe	Tata Memorial Centre, Mumbai
Christopher Booth	Queen's University, Kingston, Canada
Marc Buyse	International Drug Development Institute, Belgium and USA
Girish Chinnaswamy	Tata Memorial Centre, Mumbai
Gary Clark	Colorado, USA
Chris Frampton	University of Otago, New Zealand
Durga Gadgil	Tata Memorial Centre, Mumbai
Sarbani Ghosh Laskar	Tata Memorial Centre, Mumbai
Allan Hackshaw	Cancer Research UK
Sally Hunsberger	National Institute of Allergy and Infectious Disease, NIH, USA
Sadhana Kannan	Tata Memorial Centre, Mumbai
Ruth Langley	MRC-Clinical Trials Unit at University College London
Vikram Mathews	Christian Medical College, Vellore
Hari Menon	Cytecare Hospitals, Bangalore
Mahesh Parmar	MRC-Clinical Trials Unit at University College London
C S Pramesh	Tata Memorial Centre, Mumbai
Arnie Purushotham	King's College, London
Preetha Rajaraman	Centre for Global Health, NCI, USA
Priya Ranganathan	Tata Memorial Centre, Mumbai
Manju Sengar	Tata Memorial Centre, Mumbai
Subir Sinha	Tata Medical Centre, Kolkata
James Spicer	King's College, London
Martin Stockler	University of Sydney, Australia
Ian Tannock	Princess Margaret Cancer Centre, Toronto, Canada
Shivakumar Thiagarajan	Tata Memorial Centre, Mumbai

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About the faculty

Rajendra Badwe is Professor, Surgical Oncology & Director, Tata Memorial Centre, Mumbai, India. After qualifying in surgery from the KEM Hospital, Mumbai, he trained in cancer surgery at the Royal Marsden Hospital, London and at Guy's Hospital, London. His original research carried out at Guy's Hospital, London on 'Timing of Surgery during the menstrual cycle for Operable Breast Cancer' has changed the treatment planning in England and East Coast of USA. He is a reviewer for Lancet, British Journal of Cancer, Cancer, International Journal of Surgery, Annals of Oncology, Indian Journal of Surgery, and Indian Journal of Cancer and has several peer-reviewed publications to his credit. Among various other awards, he has received the Padma Shri National award conferred by the President of India for the contribution to the field of Medicine and the Lal Bahadur Shastri National award conferred by President of India for Excellence in Public Administration, Academics and Management.

Christopher Booth is a Medical Oncologist and Health Services Researcher at Queen's University in Kingston, Canada. He is an Associate Professor of Oncology and holds the Canada Research Chair in Population Cancer Care. Dr. Booth studied medicine at Queen's University and did postgraduate training in Internal Medicine and Medical Oncology at the University of Toronto. Upon completing his clinical training, he spent two years as a research fellow with the NCIC Clinical Trials Group. In his clinical practice he provides care to patients with gastrointestinal and genitourinary cancers. Dr. Booth has an active program in population-based cancer research. The focus of his research program is to evaluate the effectiveness of new therapies in the general population and the quality of care delivered to patients in routine clinical practice. Dr. Booth is the Co-Chair of the CHALLENGE study (NCIC CTG CO21), an international RCT evaluating whether physical activity can improve survival among patients with early stage colon cancer. As a junior investigator he was awarded an inaugural Cancer Care Ontario Chair in Health Services Research. Dr. Booth has published over 100 peer-reviewed manuscripts and served as research supervisor for more than 25 trainees. In 2016 Dr. Booth spent a sabbatical as a visiting scientist at the Regional Cancer Centre in Trivandrum, India to develop a collaborative program in health services research.

Marc Buyse holds a ScD in biostatistics from the Harvard School of Public Health (Boston, MA). He worked at the EORTC in Brussels and at the Dana Farber Cancer Institute in Boston. He is the founder of the International Drug Development Institute (IDDI) and of CluePoints, two biostatistical service organizations based in the US and Europe. His interests include clinical trial design, meta-analysis, validation of biomarkers and surrogate endpoints, statistical methods in oncology, statistical detection of errors and fraud, statistical monitoring of clinical trials, and medical data sharing (http://publicationslist.org/marc.buyse).

Girish Chinnaswamy completed his medical school and post graduate training in paediatrics at Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER) Pondicherry. He further underwent subspeciality training in paediatric and adolescent oncology at the Royal London and Newcastle Upon Tyne Hospitals in the United Kingdom. He subsequently pursued research in paediatric cancer pharmacology at the Northern Institute of Cancer Research, Newcastle University studying the pharmacokinetics and pharmacogenomics of anticancer drugs in Children. He has previously worked as a faculty in paediatric oncology at Christian Medical college hospital Vellore and is presently working as a consultant at Tata Memorial Hospital. His special interests are paediatric neuro-oncology and bone tumors in children.

Gary Clark recently retired from Array BioPharma Inc. in Boulder, Colorado, USA, where he was Vice President of Biostatistics & Data Management. He has been actively involved in the development of targeted therapies for various cancers. His areas of expertise and interest include the identification and evaluation of prognostic and predictive biomarkers for breast cancer, lung cancer and other solid tumors, and the design and analysis of Phase I, II, III clinical trials of targeted therapies. Dr. Clark has an extensive list of publications in the area of early drug development and

has significantly contributed to the field of biomarkers in breast cancer and other solid tumours. He has been a member of numerous committees of the National Cancer Institute, AACR and ASCO, including several grant review and consensus development panels. He was co-director of the AACR/ASCO Workshop on Methods in Clinical Cancer Research in Vail, Colorado from 1996 to 2000, and co-director of the FECS/AACR/ASCO Workshop on Methods in Clinical Research in Flims, Switzerland, from 1999 to 2005. Dr. Clark has been an AACR representative and faculty member of the ACORD Workshop in Australia since 2008, and was a faculty member of the first CReDO Workshop in 2015.

Chris Frampton is Professor, Biostatistics, Department of Medicine/Psychological Medicine, University of Otago, and Director of a statistical consultancy company based in Christchurch, New Zealand. In addition, he is the statistical representative on New Zealand's regulatory committees the Standing Committee on Therapeutic Trials, Medicines Adverse Reactions Committee, and Medicines Assessment Advisory Committee and on a number of national and international data safety monitoring committees for ongoing randomised controlled trials. Professor Frampton has a specific interest in the design, conduct and analysis of phase I, II and III randomised controlled trials. With over 25 years of experience in biostatistics consultancy as applied to a wide range of clinical disciplines he has co-authored over 600 peer reviewed publications.

Durga Gadgil is currently a consultant with the Tata Memorial Administrative and Research Council (TRAC). She is the chief coordinator for the two-year MSc in Clinical Research course conducted by the Tata Memorial Centre under the Homi Bhabha National Institute. She has 31 years of experience in the pharmaceutical industry and retired in November 2015 as Area Head, Asia Pacific, Regional Medical Monitoring Organization, Pfizer. In this role, she was the line manager for medical monitors based in Australia, India, Singapore, Hong Kong, China, Korea, Taiwan and Philippines. The team was responsible for monitoring all global studies from Phase 2 to 4 for medical aspects, ensuring patient eligibility, protocol adherence, data integrity and quality, in compliance with local and global ethical principles. During her career span of 30+ years, she has worked in many pharmaceutical companies, all MNCs and one India company. She has experience in all fields related to a medical doctor's role in the industry, like medico-marketing support, regulatory activities, pharmacovigilance and safety reporting, clinical operations, medical monitoring, auditing and training.

Sarbani Ghosh-Laskar is a Professor and Consultant Radiation Oncologist in the Department of Radiation Oncology at the Tata Memorial Hospital, Mumbai, India. She specializes in the treatment of Head & Neck Cancers and Esophageal Cancers with special interest in nasopharyngeal cancer, reradiation, precision radiotherapy for head and neck cancers, brachytherapy for surface lesions and palliation in esophageal cancer. Her areas of interest include outcomes studies dealing with the multidisciplinary management of head and neck and esophageal cancers, the OCAT, 3DCRT vs IMRT, palliative ILRT in advanced esophageal cancer, to name a few. She has also been serving as the Secretary of the Data and Monitoring Sub Committee of the Ethics Committee of the Institute for the last 6 years and is currently the Member Secretary of the IEC-II at the TMH.

Allan Hackshaw is Professor of Epidemiology & Medical Statistics at University College London, and Deputy Director of the Cancer Research UK & UCL Cancer Trials Centre, one of the largest cancer trials units in the UK. He has >25 years' experience in the design, conduct and interpretation of clinical trials (phase I-III), observational studies (cohort and case-control) and systematic reviews/meta-analyses: for prevention, screening or treatment. The main areas of research have been cancer; antenatal & cancer screening; and tobacco and health. He has been a key co-investigator on successful grant funding applications (~£56 million in total), and published >150 articles in journals and book chapters, plus sole or first author of four textbooks. He leads modules on postgraduate courses (evidence-based medicine/clinical trials) at UCL, London School of Economics and Harvard. He has been a member

of national and international scientific grant funding and data monitoring committees. Since 2012 he is named as one of the top 40 academic role models in biomedicine at UCL.

Sally Hunsberger is a Mathematical Statistician with the Biostatistics Research Group at the National Institute of Allergy and Infectious Disease where one of her main focuses is Influenza research. She has worked at the National Institutes of Health for 25 years and has focused on clinical trials. She began her career in at the National Heart, Lung, and Blood Institute and then moved to the National Cancer Institute after 10 years. She worked at the National Cancer Institute for 12 years, specializing in breast cancer and pediatric clinical trial research.

Sadhana Kannan completed her postgraduation in Biostatistics from the Christian Medical College, Vellore and has been employed as Data Manager, Clinical Trials Unit, at the Advanced Centre for Treatment Research & Education in Cancer (ACTREC), Tata Memorial Centre, since 2001. She has trained in the areas of management and analysis of clinical trial data, molecular epidemiological data, systematic review and meta-analysis. She has over 62 publications in national and international peer-reviewed journals.

Ruth Langley is a medical oncologist with a particular interest in the design and management of clinical trials. Her training included time at the Joint Centre for Radiation Therapy, Boston USA studying for her PhD in radiation-induced apoptosis. She is based at the UK Medical Research Council Clinical Trials Unit in London where she jointly leads the Cancer Group. She has a particular interest in gastro-oesophageal malignancy and has coordinated a series of trials and associated translational studies, and has led the investigation of the use of transdermal oestrogen in the treatment of prostate cancer. A major focus of her recent work has been the development of an international trial to assess the effect of aspirin as an adjuvant agent in several common solid tumours. She has an honorary clinical consultant post at the Brighton and Sussex University Hospital where she has a small clinical practice.

Vikram Mathews is Professor and Head of the Department of Haematology, Christian Medical College, Vellore. His focus areas of research have been leukemia and stem cell transplantation. Based on his training, he is a physician-scientist and in addition to his clinical work, he runs his own laboratory which is mainly focused on research in acute myeloid leukemia and studying the role played by the microenvironment in mediating drug resistance. On the clinical side his major interest is in developing cost effective strategies to treat acute leukemia. There are significant context specific challenges in treating acute leukemia in India and he, along with his group, attempts to address such challenges. He has been involved in more than 100 peer reviewed publications and written 5 text book chapters.

Hari Menon, formerly Professor of Medical Oncology at the Tata Memorial Centre, is currently senior consultant, Medical oncology at Cytecare Hospitals, Bangalore. His field of interest is Leukemia-lymphoma, which he continues to pursue. Over the last eighteen years Dr. Menon has been actively involved with clinical research, clinical trials and has been a member of the Institutional review board for eight years until March 2016. He has been a participant in the ACORD clinical trial development workshop conducted by the Medical Oncology group of Australia and has been involved with the India Oxford (INDOX) clinical trial development program. He is a reviewer for both Indian and International Journals related to oncology and medicine and has been invited member on the advisory board for drug development involving multinational pharmaceutical industry. His niche area in the field of clinical trial is concept development, implementation and conduct of phase-I and phase-II studies.

Mahesh Parmar is a 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. He has been an Associate Director of the National Cancer Research Network since its inception in 2001, an organisation which has more than doubled the number of patients going into cancer studies in England. Max joined the MRC in 1987. He has more than 250 publications in peer reviewed journals, many of which have had direct impact on policy, clinical practice

and improving outcomes for patients. The Unit he directs is at the forefront of resolving internationally important questions, particularly in infectious diseases and cancer, and also aims to deliver swifter and more effective translation of scientific research into patient benefits. It does this by carrying out challenging and innovative studies and by developing and implementing methodological advances in study design, conduct and analysis.

C S Pramesh is a thoracic surgeon at the Tata Memorial Centre. He is also a member of the Clinical Research Secretariat of the hospital and the coordinator for the National Cancer Grid, a large network of 93 cancer centres in India. In the latter role, he works extensively on enabling creation of uniform standards of cancer care, promoting equity in access to care and rational use of healthcare resources. His primary clinical areas of interest include minimal invasive surgery and innovative treatment options in the management of esophageal and lung cancer. He is the Principal Investigator in several investigator-initiated research studies including randomised trials on cancer screening, surgical techniques, and neoadjuvant treatment of thoracic cancers. Professor Pramesh has strong interests in clinical trial designs, surgical trials, biostatistics and promoting collaborative research. He is passionate about promoting training of early career physicians and surgeons in clinical research methods and conducts several formal and informal courses on clinical research methodology, biostatistics and scientific writing.

Arnie Purushotham has been a Consultant Academic Surgeon for 22 years having worked in Glasgow, Cambridge and London. He is Professor of Breast Cancer at King's College London and Consultant Surgeon at Guy's and St Thomas NHS Foundation Trust in 2005. He is the Director of King's Health Partners Comprehensive Cancer Centre and Senior Clinical Advisor to Cancer Research UK. As a scientific researcher for the last 26 years, Professor Purushotham's goal has been to drive high quality clinical and translational research that directly impacts on breast cancer patients. Key areas of research are patterns of metastatic spread, pathophysiology of lymphoedema, sentinel lymph node biopsy, novel optical intra-operative imaging, window of opportunity targeted therapy trials and cancer outcomes. His specific areas of expertise include study design, ethics and regulatory permissions, research governance, user involvement, window of opportunity studies and randomized controlled trials.

Preetha Rajaraman is the South Asia Program Director for the NCI's Center for Global Health, and is the representative of the U.S. National Cancer Institute (NCI) in India. She is responsible for strategic planning to help define the NCI's portfolio and strategy in the South Asia region, and leads the development, oversight, and evaluation of regional programs for cancer research and training. Dr. Rajaraman is a cancer epidemiologist, with an additional affiliation at NCI's Division of Cancer Epidemiology and Genetics, where her research focuses on genetic susceptibility factors and their interaction with known or suspected environmental carcinogens, particularly with regard to the etiology of brain/central nervous system (CNS) tumors, and exposure to radiation from occupational and medical sources. Dr. Rajaraman received her Ph.D. in Epidemiology from the Johns Hopkins School of Public Health, with a concentration in cancer and molecular epidemiology. She has a Master's of Science in Environmental Health from the University of Washington, Seattle, and an undergraduate degree in Biology (Phi Beta Kappa) from Reed College, Portland OR.

Priya Ranganathan works as a consultant anaesthesiologist at the Tata Memorial Centre, Mumbai. She has a special interest in thoracic anaesthesia and is a member of the specialized thoracic anaesthesia working group. She completed her under-graduate and post-graduate training at the King Edward Memorial Hospital, Mumbai. She is a member of the Institutional Review Board at Tata Memorial Hospital and co-ordinates a post-graduate degree course in Clinical Research at TMC. She has organized several courses on biostatistics and clinical research methodology and is editor of the biostatistics section for the journal 'Perspectives in Clinical Research'.

Manju Sengar [MD (Medicine), DM (Medical Oncology)] is Professor, Adult hematolymphoid disease management group, Medical Oncology at the Tata Memorial Centre, Mumbai. She has done her post graduate diploma in clinical

trials from London School of hygiene and tropical medicine (external programme). She is an ACORD alumnus. She is a recipient of American Society of Hematology visitor training program fellowship at Duke University, Durham. Her main areas of clinical research are non Hodgkin lymphomas in HIV/AIDS and adult acute lymphoblastic leukemia. She is the principal investigator for several investigator-initiated studies and has participated in industry sponsored multi-centre clinical trials.

Subir Sinha is Scientific Officer, Statistics in Tata Medical Centre, Kolkata. He received his B Stat and M Stat from Indian Statistical Institute (Kolkata), and Master's from Carnegie Mellon University. He has worked at Novartis, Harvard School of Public Health and Alexion Pharmaceuticals. He has taught courses in Biostatistics in Boston School of Medicine and Harvard University. He has been an invited speaker at Indian Statistical Institute, Kolkata, Tata Memorial Centre, Mumbai and Indian Institute of Management, Ahmedabad.

James Spicer is Consultant in Medical Oncology at Guy's and St Thomas' Hospitals, and Professor of Experimental Cancer Medicine at King's College London. His clinical interests include the care of patients with thoracic malignancies, including lung cancer and mesothelioma, and clinical trials in these diseases. He set up and runs his hospital's Cancer Early Phase Trials programme. He is joint Lead of the King's Experimental Cancer Medicine Centre, funded by Cancer Research UK/National Institute for Health Research. His clinical interests include the care of patients with thoracic malignancies, including lung cancer and mesothelioma, and clinical trials in these diseases. His translational research focus is on novel immunotherapies and molecular diagnostics. He is a member of Cancer Research UK's New Agents Committee and other national funding panels.

Martin Stockler is Professor of Oncology and Clinical Epidemiology at The University of Sydney, a consultant medical oncologist at the Concord Repatriation General Hospital and Chris O'Brien Lifehouse RPA, and Oncology Co-Director at the NHMRC Clinical Trials Centre. After internal medicine and medical oncology training in Sydney, Australia he spent 3 years in Toronto, Canada doing a clinical research fellowship at the Princess Margaret Hospital and a Masters in Clinical Epidemiology at the University of Toronto with Ian Tannock and Pamela Goodwin. His research focuses on using clinical trials to improve quality of life, survival, prognostication, and doctor-patient communication for those affected by cancer, particularly from genitourinary, thoracic, and gynaecologic primaries. His clinical focus is on genitourinary cancer.

Ian Tannock is Emeritus Professor of Medicine and Medical Biophysics at Princess Margaret Cancer Centre and University of Toronto. His clinical research investigates methods related to cancer clinical trials, and he chaired trials for men with metastatic prostate cancer that led to licensing of previous (mitoxantrone) and current (docetaxel) standard chemotherapy. His laboratory research evaluates effects of the tumour microenvironment on outcome of cancer therapy. He is an editor of the Basic Science of Oncology textbook, now in its 5th edition that is used by trainees in all branches of oncology. Dr. Tannock was a member of the Board of Directors of the American Society of Clinical Oncology (ASCO) from 2001-2004. He chairs the scientific audit committee of the European Organisation for Research and Treatment of Cancer (EORTC) and is a member of the EORTC Board. Dr. Tannock was appointed a Member of the Order of Canada in December 2013.

Shivakumar Thiagarajan graduated from KIMS, Bangalore after which he did his post-graduation in Otolaryngology from the Indian AirForce Hospital, Bangalore. He further underwent sub-speciality training in Head and Neck Surgical Oncology from Kidwai Memorial Institute of Oncology, Bangalore and Tata Memorial Centre, Mumbai. He was actively involved in both clinical and translational research during his training. He is presently working as a faculty in the department of Head and Neck surgical oncology, Tata Memorial Centre, Mumbai, India. His primary clinical interest is in the management of oral, thyroid and skull base malignancies.

About the participants

	Name	Designation	Institute
1.	Rajeev Kumar	Scientist	Cachar Cancer Hospital & Research Centre, Silchar
2.	Narayana Subramaniam	Resident Surgical Oncology	Amrita Institute of Medical Sciences, Kochi
3.	Suma MN	Assistant Professor, Pathology	Kidwai Memorial Institute of Oncology, Bangalore
4.	Alok Goel	Resident, Medical Oncology	Tata Memorial Centre, Mumbai
5.	Ramandeep Arora	Consultant, Paediatric Oncology	Max Super Speciality Hospital, Saket, New Delhi
6.	Budhi Singh Yadav	Associate Professor, Radiation Oncology	Post Graduate Institute of Medical Education & Research, Chandigarh
7.	Gunjan Dwivedi	Trainee, Surgical Oncology	Tata Memorial Centre, Mumbai
8.	Aditi Chaturvedi	Resident, Surgical Oncology	Tata Memorial Centre, Mumbai
9.	Anand Raja	Associate Professor, Medical Oncology	Cancer Institute, Adayar, Chennai
10.	Caleb Harris	Assistant Professor, Department of Surgical Oncology	NEIGRIHMS, Shillong
11.	Aniket Shah	Fellow, Head and Neck Oncology	Kolhapur Cancer Centre
12.	Madhura Dukle	Fellow- Oncotherapeutics	ACTREC, Tata Memorial Centre, Mumbai
13.	Lingaraj Nayak	Resident, Medical Oncology	Tata Memorial Centre, Mumbai
14.	Smita Kayal	Assistant Professor, Medical Oncology	JIPMER, Pondichery
15.	Avinash Bonda	Resident, Medical Oncology	Tata Memorial Centre, Mumbai
16.	Balu Mahendra	Resident, Surgical Oncology	Tata Memorial Centre, Mumbai
17.	Odaiyappan Kannappan	Resident, Surgical Oncology	Tata Memorial Centre, Mumbai
18.	Vincent Singh Paramanandam	Physiotherapist	Tata Memorial Centre, Mumbai
19.	Uday Kulkarni	Assistant Professor, Haematology	Christian Medical College, Vellore
20.	Swati Mittal	Post-Doctoral Fellow, Gynaecological Oncology	Tata Medical Centre, Kolkata
21.	Kuldeep Kumar	Consultant, Surgical Oncology	Mahavir Cancer Sansthan, Patna, Bihar
22.	Nisha Hariharan	Consultant surgeon, Breast Oncology	Basavatarakam Indo American Cancer Hospital, Hyderabad
23.	Ashutosh Tondare	Senior Research Fellow, Breast Surgical Oncology	Tata Memorial Centre, Mumbai

24.	Garvit Chitkara	Research fellow, Breast Surgical Oncology	Tata Memorial Centre, Mumbai
25.	Anup Devasia	Assistant Professor, Dept of Clinical Hematology	Christian Medical College, Vellore
26.	Venkitaraman B	Assistant Professor, Surgical Oncology	Cancer Institute, Adayar, Chennai
27.	VidishaTuljapurkar	Resident, Surgical Oncology (Head and Neck Services)	Tata Memorial Centre, Mumbai
28.	Smita Asthana	Scientist	Indian Council of Medical Research, New Delhi
29.	SatishM S	Physiotherapist	Cancer Institute, Adayar, Chennai
30.	Naveena Kumar A N	Specialist Registrar (Surgical Oncology)	Tata Memorial Centre, Mumbai
31.	Vikram Chaudhari	Assistant Professor, Surgical Oncology	Tata Memorial Centre, Mumbai
32.	Vasudev Bhat	Resident, Paediatric Oncology	Tata Memorial Centre, Mumbai
33.	Poulome Mukherjee	Consultant, Surgical Oncology	Cachar Cancer Centre, Silchar
34.	Atul Sharma	Resident, Medical Oncology	AIIMS, New Delhi
35.	Jayashree Natarajan	Assistant Professor, Gynaecological Oncology	Amrita Institute of Medical Sciences, Kochi
36.	Vinod Sharma	Resident, Medical Oncology	AIIMS, New Delhi
37.	Shweta Baral	Consultant, Radiation Oncology	Bhakatpur Cancer Hospital, Nepal
38.	Satheesan B	Professor and Head, Surgical Oncology and Director	Malabar Cancer Centre
39.	Ashis Patnaik	Associate Professor, Neurosurgery	AIIMS, Bhubaneshwar
40.	Devayani Niyogi	Resident, Surgical Oncology	Tata Memorial Centre, Mumbai
41.	Pesona Grace Lucksom	Fellow, Gynaecological Oncology	Tata Medical Center, Kolkata
42.	Akshat Malik	Resident, Head and Neck Oncology	Tata Memorial Centre, Mumbai
43.	Aswathy Mathew	Resident, Radiation Oncology	Tata Memorial Centre, Mumbai
44.	Pavan Sugoor	Resident, Surgical Oncology	Tata Memorial Centre, Mumbai
45.	Apurva Ashok	Resident, Surgical Oncology	Tata Memorial Centre, Mumbai
46.	Vivek Mundale	Fellow, Surgical Oncology (Thoracic oncology)	Tata Memorial Centre, Mumbai
47.	Sonia Mathai	Fellow, Gynaecological Oncology	Tata Medical Center, Kolkata, India
48.	Amit Janu	Assistant Professor, Radiology	Tata Memorial Centre, Mumbai

49.	Hina Shah	Senior Project Engineer	Indian Institute of Technology, Mumbai
50.	Pallavi Vinarkar	Project Research Assistant	Indian Institute of Technology, Mumbai

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LDA, Lonavla
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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 50 participants from a total of 166 applicants. Preference was given to early or mid-career level researchers from academic institutions who demonstrated commitment to continuing research in oncology.

Each application was rated 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: 200 US dollars only
World Bank High income economies: 1000 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 4th February 2017
- Shuttle-bus service from the workshop venue to a pre-specified drop-off point in Mumbai or Mumbai airport on 10th February 2017
- Accommodation (twin sharing) in the workshop venue from 5th to 10th February 2017
- 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, volley ball, basketball, tennis, golf, carrom, chess, table tennis and snooker along with a gymnasium, spa, jacuzzi and sauna

Workshop sessions

The workshop sessions were carefully formulated to meet the objectives while stimulating interactive discussions and avoiding monotony. Learning sessions were in one of the following four formats:

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.

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 each, with each of these groups being mentored by 3-4 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.

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.

Small Group Discussion (SGD) sessions

SGD 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 small-group discussions

Methodological aspects of randomized trials
Novel trial designs
Epidemiological studies
Screening studies
Patient-reported outcomes and Quality of Life research
Implementation research
Questionnaire-based studies
Biomarker-based research
Research on targeted therapy and immunotherapy

Special session: visit from the Director-General of the Indian Council of Medical Research

Dr Sowmya Swaminathan, Director-General of the Indian Council of Medical Research attended the workshop on 9th February 2017 and interacted with participants and faculty. During her visit she gave a talk on the 'Current research scenario in India'

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, and to Dr Sowmya Swaminathan during a one-hour session on 9th February 2017.

Evaluation of participants

An online pre and post-test evaluation of participants was conducted to assess the impact of 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.

For the pre-test evaluation, the average rate of correct responses was 54 percent. This improved to 62 percent for the post-test evaluation. Statistical analysis showed a significant improvement in post-test scores as compared to the pre-test scores for more than fifty percent of questions

Feedback from participants

We conducted a post-workshop online survey to feedback to obtain feedback from the participants

The feedback form included following domains:

1. Quality of the teaching sessions: didactic lectures, small-group discussions, “meet the expert” sessions and protocol development break-out sessions
2. Satisfaction with workshop arrangements (venue, amenities, travel, food and overall arrangements)
3. Other suggestions

1. Quality of teaching sessions:

a) Didactic lectures: Overall, 93 % of respondents rated the didactic lectures as good to excellent.

b) Protocol development break-out sessions: 97% of respondents rated these sessions as good to excellent.

2. Satisfaction with workshop arrangements (venue, amenities, travel, food and overall arrangements)

More than 95% of respondents rated the arrangements as excellent

3. Other suggestions:

To include sessions on

a. Health economics
b. Publishing a paper
c. Statistical software and data management tools

"I wanted to express my gratitude and thanks to everyone for the wonderful workshop and this opportunity to learn. I learnt and did things which I didn't think I was capable of"

- Garvit Chitkara, Tata Memorial Centre

"I believe this workshop will definitively have an impact on my approach to medicine and research attitude"

- Odaiyappan Kannappan, Tata Memorial Centre

"Thank you for an excellent workshop. It was a unique learning experience. The concept of a healthy mix of Indian and international faculty was a great idea! It made the protocol extremely doable and still strong enough to stand to scrutiny in an international arena"

- Nisha Hariharan, Basavatarakam Indo American Cancer Hospital, Hyderabad

"The memories of the workshop and all the encouraging words of the wonderful faculty members are still lingering in my mind. Thank you for this phenomenal opportunity"

- Madhura Dukle, ACTREC, Tata Memorial Centre, Mumbai

"I would like to congratulate you and your team for organizing such a wonderful workshop"

- Aniket Shah, Kolhapur Cancer Centre

"CReDO was truly a beautiful experience- in terms of knowledge gained and concepts cleared but more importantly in terms of the inspiration. There is so much possibility and so much to be done. Thank you for opening up a whole new world for all of us"

- Devayani Niyogi, Tata Memorial Centre

"Thanks a lot for the wonderful workshop. It was indeed a great experience, came back with a lot of positive notes - I have started to disseminate the efficacy of this workshop with my colleagues"

- M S Satish, Cancer Institute, Adayar
-

"Thank you so much for the amazing workshop. Indeed a great learning experience"

- Swati Mittal, Tata Medical Centre, Kolkata

Feedback from faculty

"I am privileged to be part of CReDO. This year was, as we would say of French wines, "un grand cru". Wonderful atmosphere, very engaged group, great projects. What a pleasure it was to spend a week with such smart and committed individuals."

- Marc Buyse, International Drug Development Institute

"The whole week was an absolute privilege to be involved with, and perfectly organised at every step. You have created something that will really make a difference"

- James Spicer, Kings College, London

"The meeting, as always, was very well organized - I always learn a lot more than I contribute at these meetings."

- Vikram Mathews, Christian Medical College, Vellore, India

"All aspects of the organization were superb, including selection of candidates, organization of the program with lectures and small group discussions, and the logistics of travel and accommodation. I have participated in multiple ASCO-supported clinical methods workshops in United States (Vail), Europe (Flims) and Australia (ACORD), and I am happy to report that despite less resources in India, the knowledge, quality and enthusiasm of the participating young oncologists was equal or greater to those attending the above courses. This bodes well for increasing clinical cancer research in India and the surrounding developing countries, where the cancer problem is enormous. Given the large population it will facilitate answering important clinical problems more quickly as research infrastructure mature"

- Ian Tannock, Princess Margaret Cancer Centre, Toronto, Canada

"It was wonderful to be with you all and I wish I could have stayed longer. The quality of both faculty and participants was outstanding"

- Soumya Swaminathan, Director-General, Indian Council of Medical Research

Research ideas discussed at the workshop

1.	Active versus patient initiated follow-up in Oral cavity cancers: a randomized control trial.
2.	A phase III randomized, non-inferiority trial of neoadjuvant chemotherapy followed by radical cystectomy compared to bladder preservation protocol.
3.	A phase III open label multicentre RCT comparing low dose Antithymocyte Globulin (ATG) to placebo as part of reduced intensity conditioning regimen in Acute Myeloid Leukemia
4.	A prospective randomised trial for evaluating the role of chloroquine in improving the long term outcome of glioblastoma multiforme.
5.	Prospective randomized control trial to evaluate the impact of intensive monitoring (IM) versus symptomatic evaluation at follow up in women with first line metastatic breast cancer (MBC).
6.	Multicentric randomised control trial to evaluate the role of adjuvant chemotherapy vs observation in node positive penile cancer patients .
7.	Role of Areca nut and dietary habits in causing high incidence of Esophageal cancer in Northeast India: A Case-Control Study
8.	Role of perioperative immunonutrition in patients undergoing surgery for colorectal malignancy
9.	Outcomes and Prognostic factors in operable recurrent oral cavity cancer: A prospective observational study
10.	Randomised trial addressing post-operative radiotherapy for adverse pathological features in early stage oral cavity squamous cell carcinoma
11.	Impact of statin therapy on Pathological Complete response when given in concordance with neo-adjuvant chemo-radiotherapy in rectal cancers
12.	Wait and Watch (WW) versus Definitive radical surgical resection in Patients with locally advanced rectal cancer who achieved complete clinical response after Neoadjuvant Chemoradiotherapy (NACTRT)
13.	Investigating markers for treatment response with special emphasis on cancer stem cell associated pathways in carcinoma of upper alimentary tract
14.	A prospective multi-centre study in North India to assess feasibility and utility of identifying targetable alterations in children with CNS tumours
15.	Anxiety Depression in Cancer patients -impact of Psychotherapy Vs Yoga (AnDeCaPY)
16.	Cytoreductive Surgery Combined with Hyperthermic Intraperitoneal Chemotherapy (HIPEC) in the Treatment of Advanced Ovarian Cancer: Efficacy, Complications and Outcome.
17.	Randomised Control Trial to Evaluate the Role of Modified C.O.M.B.A.T maintenance regimen in children with High Risk Medulloblastoma
18.	Effect of preoperative nutritional supplementation on morbidity & Quality Of Life in patients with head & neck squamous cell cancers(HNSCC).
19.	Effectiveness of compression garment in preventing breast cancer related lymphedema - Randomized Controlled Trial
20.	A randomized controlled trial to evaluate the role of metformin (Mt) with or without a mTOR inhibitor in metastatic Triple negative breast cancer (TNBC)
21.	Docetaxel, cisplatin, 5-Fluorouracil (DCF) or Docetaxel, oxaliplatin, capecitabine (DOX) chemotherapy versus Epirubicin, cisplatin, 5-Fluorouracil (ECF) or Epirubicin, oxaliplatin, capecitabine (EOX) peri-chemotherapy in locally advanced gastric and gastr
22.	Indian patient perception of the benefit of new cancer therapies: A survey
23.	Randomized trial comparing the effect of consolidation followed by maintenance versus maintenance alone post-autotransplantation on progression risk in fit patients with myeloma having less than very good partial response pre-transplant
24.	Feasibility of Sentinel Lymph Node Mapping in Cervical Cancer
25.	A phase III randomized study comparing two adjuvant hypofractionated radiation schedules in patients with breast cancer

26.	Follicular variant of papillary thyroid carcinoma(FVPTC), revisited, with application of defined nuclear criteria and histomorphology aided with molecular studies to the encapsulated non-invasive type- A 5 year retrospective study
27.	To understand the pharmacokinetics of Colistin in patients with Febrile Neutropenia
28.	RIsk Score for PrEdicting Chemotherapy Toxicity in older adults with non-metastatic solid tumors: a multicenter collaborative study (Acronym : RISPECT
29.	Role of radical cholecystectomy in patients of carcinoma gall bladder with extensive liver invasion / or small para-aortic nodes (1cm) after neoadjuvant chemotherapy.
30.	A phase II trial to assess the efficacy of artesunate as pre-emptive therapy for cytomegalovirus infection in patients undergoing allogenic stem cell transplant
31.	Suction Versus Non-suction drainage after lung resection : A randomised trial
32.	Comparison of efficacy of voriconazole versus fluconazole as antifungal prophylaxis in acute leukemia patients undergoing induction chemotherapy
33.	Impact of structured exercises on cancer related fatigue among oral cavity cancer patients
34.	Neoadjuvant chemo- radiation in locally advanced carcinoma rectum- Locoregional response and sphincter preservation: Single institution study in Nepal
35.	A study on the influence of duration between neoadjuvant chemoradiotherapy and surgery on the pathological response and outcomes in locally advanced rectal cancer
36.	Does intensive monitoring change outcomes in patients with advanced lung cancer on palliative treatment? – a randomized trial
37.	Prospective randomized controlled study comparing elective contralateral neck treatment versus observation for oral cavity carcinoma.
38.	Follow-up strategies after non-surgical treatment for locally advanced cervical cancer
39.	An open label, non-randomized phase II study of Dasatinib with modified BFM-90 chemotherapy regimen in adolescent and adult Philadelphia positive Acute lymphoblastic leukemia.
40.	Randomised controlled trial comparing short course radiotherapy followed by consolidation chemotherapy versus neoadjuvant chemoradiotherapy in locally advanced poorly differentiated rectal cancer
41.	Use of tamoxifen maintenance therapy for advanced epithelial ovarian cancer patients with primary treatment
42.	Study of feasibility and role of video assisted thoracoscopy in advanced ovarian malignancy
43.	Phase 2 clinical trial to evaluate utility of Ciprofloxacin as an adjunct to cytotoxic chemotherapy in hormone refractory prostate cancer.
44.	Role of excision of the breast primary in patients who achieve complete response in the breast after neo adjuvant chemotherapy
45.	Neoadjuvant Chemotherapy in Locally Advanced Carcinoma Cervix-Will more chemotherapy improve outcomes?
46.	Poly Tobacco use and other risk factors associated with prostate cancer: A case control study
47.	Phase 3 randomized double blind placebo controlled trial comparing dexamethasone, 5HT3 antagonist, olanzapine versus dexamethasone, 5HT3 antagonist, olanzapine, NK1 receptor anatgonist in highly emetogenic chemotherapy regimen in solid cancer patients.
48.	Patient survey to understand the extent to which the Indian patients want information about disease prognosis and estimated survival.

Acknowledgements

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Indian Council of Medical Research

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Endorsing agencies

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Cancer Research UK

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CReDO 2017 workshop scientific programme

SUNDAY – 5th Feb 2017	MONDAY – 6th Feb 2017	TUESDAY – 7th Feb 2017	WEDNESDAY – 8th Feb 2017	THURSDAY – 9th Feb 2017	FRIDAY – 10THFeb 2017
	8.30 - 9 am: Phases of trials and Drug development process – Manju Sengar	8.30 - 9.15 am: Methodological aspects of phase III randomized trials - C S Pramesh	8.30 - 9.15: Observational study designs – case-control and cohort studies - Chris Frampton	8.30 - 9 am: Predictive and prognostic factors-Gary Clark	8.30 - 9: Systematic reviews and meta-analysis–Marc Buyse
8.45 to 9.45 am: Pretest	9 - 9.45 am: Phase I and Phase II trials - James Spicer	9.15 - 9.45 am: Non-inferiority and Equivalence trials - Mahesh Parmar	9:15 - 9:45: Screening studies Preetha Rajaraman	9 - 9.45 am: Quality of life and patient-rated outcomes in cancer research – Martin Stockler	9 - 9.30: Writing a research grant proposal - Arnie Purushotham
9.45 - 10.30 am: Participant registration	9.45 - 10.30 am: Stats for Phase 1 and 2 trials - Allan Hackshaw	9.45 - 10: 30 am: Stats for randomized phase III trials - Chris Frampton	9.45 - 10.30 am: Implementation research - Christopher Booth	11.15 – 11.45: Multiple testing - Marc Buyse	9.30 - 10: Funding for research - Vikram Mathews 10 - 10.30: Conducting your research – practical aspects - Ruth Langley
10.30 – 11 Tea break	**10.30 – 11 Tea break**	**10.30 – 11 Tea break**	**10.30 – 11 Tea break**	**10.15 - 11.15 Tea break (Group Photos)**	**10.30 – 11 Tea Break**
11 - 11.30 am: Faculty briefing - C S Pramesh Study designs - Priya Ranganathan	11 - 11.30 am: Incorporating biomarkers into early and late phase trials- James Spicer	11 - 11.40 am: Adaptive study designs - Mahesh Parmar	11 - 11.30 am: Diagnostic tests - Preetha Rajaraman	11.15 – 11.45: Handling missing data – Sally Hunsberger	11 - 11.30: Publishing and presenting your research paper - Ian Tannock
11.30 - 12: Introduction Overview of workshop – Priya 12 - 12.30: Feedback from previous CReDO participants	11.30 am - 12.30 pm: Basic statistics for the clinical researcher - Gary Clark	11.40 - 12.15: Protocol writing: Outcomes and endpoints including Surrogate endpoints, Composite end-points - Marc Buyse	11.30 - 12 noon: Ethics in Clinical Research – Shivakumar Thiagarajan 12 - 12.30 pm: Informed consent document and process - Durga Gadgil	11.45 - 12: Surgical trials - C S Pramesh 12 – 12.15 pm: Radiation trials – Sarbani Ghosh Laskar	11.30 - 12.00: Critical appraisal of published papers – Manju Sengar
12.30 - 1 pm: Keynote address: Why do we need clinical research? Ian Tannock	12.30 - 1.15: Protocol writing: Methods (Design /inclusion / exclusion / randomization / interventions) – Martin Stockler	12.15 - 1 pm: Survival analysis - Priya Ranganathan	12.30 - 1 pm: Monitoring and adverse event reporting – Durga Gadgil	12.15 -1 pm: Common mistakes in statistics - Marc Buyse	12 - 1: Post test Faculty feedback and wrap-up
1 - 2 pm Lunch	**1.15 - 2pm: Lunch**	**1 - 2 pm Lunch**	**1 - 2 pm Lunch**	**1 - 2 pm Lunch**	**1 - 2 pm Lunch**
2 - 2.45 pm: Protocol writing: Introduction / Hypothesis/ Aims / Objectives – Girish Chinnaswamy 3 - 5.30 pm (tea included) Break out session –Background/ title / aims / objectives All faculty	2 - 4.30 pm: Break-out session: Population & setting, Interventions, Study design All faculty	2 - 4.30 pm: Break-out session: Outcomes & measures, Study procedures, Statistical considerations All faculty	2 - 4 pm: Break-out session: protocol development All faculty	2 - 3.30 pm: Break-out session: Final discussions All faculty	
	4.30 - 5 pm: Tea Break	**4.30 - 5 pm: Tea break**	**4 - 4.30 pm: Tea break**	Free time for protocol completion	
5.45 - 6.30 pm: Focused small-group sessions	**5 - 6.30 pm: Team-building activity** All faculty and participants	5 – 6 pm : Meet the expert sessions (Office hours) By prior booking only	4.30 - 5.15 pm: Focused small-group sessions 5.30 - 6.30 pm: Meet the expert sessions (Office hours)		
Homework: Concept outline	**Homework**: Background/rationale, Aim, objectives & hypothesis, Study design, Population & setting, Study Interventions	**Homework**: Outcomes, endpoints & measures, Study procedures, Assessment plan, Statistical considerations	**Homework**: Ethics, Safety reporting, Informed consent document	**Homework**: Final protocol due	
INAUGURAL DINNER				6.30 pm onwards: Best projects and Participant feedback followed by **GALA DINNER**	