WORKSHOP SUMMARY

International Collaboration for Research methods Development in Oncology (CReDO) workshop

22nd to 26th November 2015

Lonavla, Maharashtra

CReDO

Shaping research ideas

Organized by:
Tata Memorial Centre, Mumbai
National Cancer Grid of India

Supported by
Tata Trusts, Mumbai
Tata Memorial Centre, Mumbai
National Cancer Institute, USA
King's College, London

TATA TRUSTS

Collaborating partner

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

This conference was organized under the auspices of the **EORTC**

Endorsed by

Medical Research Council - Clinical Trials Unit at University College London

Cancer Research UK

American Society of Clinical Oncology

About the workshop

The Tata Memorial Centre, Mumbai and the National Cancer Grid of India conducted a five-day residential workshop on clinical research protocol development at Lonavla, near Mumbai between 22nd and 26th November 2015. This intensive protocol development workshop was the first in a series of workshops and was modeled on similar workshops held in the United States (Vail), Europe (Flims) and Australia (ACORD).

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 Maharashtra Medical Council granted four CME credit points for participants attending this workshop

The Tata Memorial Centre and The National Cancer Grid of India

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 (NCG) of India is a collaboration of 63 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 5 research proposals submitted for the workshop are being considered for funding by the National Cancer Grid, as multi-centric trials.

The Tata Memorial Centre and The National Cancer Grid of India

Workshop advisory board

Rakesh Aggarwal	SGPGI, Lucknow
Rajendra Badwe	Tata Memorial Centre, Mumbai
Marc Buyse	IDDI, Belgium
Chris Frampton	University of Otago, New Zealand
Bogda Koczwara	Flinders University, Australia
Mahesh Parmar	MRC-CTU at University College London
C S Pramesh	Tata Memorial Centre, Mumbai
Arnie Purushotham	King's College, London
Priya Ranganathan	Tata Memorial Centre, Mumbai
Sabine Tejpar	EORTC, Belgium
Jack Welch	National Cancer Institute, USA

Workshop faculty

Rakesh Aggarwal	SGPGI, Lucknow
Rajendra Badwe	Tata Memorial Centre, Mumbai
Louise Brown	MRC-CTU at University College London
Marc Buyse	IDDI, Belgium
Sanjoy Chatterjee	Tata Medical Center, Kolkata
Girish Chinnaswamy	Tata Memorial Centre, Mumbai
Gary Clark	Array Biopharma, USA
Chris Frampton	University of Otago, New Zealand
Gareth Griffiths	Southampton Clinical Trials Unit
Amit Khot	Peter MacCallum Cancer Centre, Melbourne
Ruth Langley	MRC-CTU at University College London
Vikram Mathews	Christian Medical College, Vellore
Hari Menon	Tata Memorial Centre, Mumbai
C S Pramesh	Tata Memorial Centre, Mumbai
Arnie Purushotham	King's College, London
D Raghunadharao	Homi Bhabha Cancer Hospital, Visakhapatnam
Preetha Rajaraman	National Cancer Institute - Center for Global Health
Priya Ranganathan	Tata Memorial Centre, Mumbai
Debashis Sarker	King's College, London
Manju Sengar	Tata Memorial Centre, Mumbai
James Spicer	King's College, London
Martin Stockler	University of Sydney, Australia
Sabine Tejpar	EORTC, Belgium

About the faculty

Rakesh Aggarwal is a Professor of Gastroenterology at the Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India. He trained in medicine and gastroenterology at the All India Institute of Medical Sciences, New Delhi, and at the Post-Graduate Institute of Medical Education and Research, Chandigarh. In addition, he has a Master's degree in Epidemiology from the LSHTM, London. His research work is in the area of liver disease, in particular viral hepatitis. Besides this, he has been involved in teaching research methodology, epidemiology, biostatistics and health economics.

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.

Louise Brown is a Principal Research Associate in Medical Statistics at the MRC Clinical Trials Unit at University College London. She works mainly on cancer trials and has a particular interest in stratified medicine and biomarker clinical validation studies focussing much of her time as the project lead for FOCUS4, a molecularly stratified adaptive trial programme in advanced colorectal cancer. She also has an interest in diagnostic studies and runs the PROMIS study, which is investigating the role of MRI in screening and diagnosis of prostate cancer. She originally trained in mechanical engineering but after completing a Master's degree in medical statistics at the London School of Hygiene and Tropical Medicine she went on to complete her PhD in statistics at Imperial College London. Prior to working at the MRC CTU, she worked as a statistician at Imperial College, primarily in cardiovascular surgery trials and with a particular interest in abdominal aortic aneurysm.

About the faculty

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).

Sanjoy Chatterjee is a clinical oncologist, with an interest in the management of Head and Neck and Breast Cancers. He graduated from Medical College: Kolkata (1998), thereafter completed his post graduation in General Medicine (MRCP 2001) and Clinical Oncology FRCR (2006). He has experience in clinical research since 2001, initially participating in multi centre sponsored studies and then as the site principal investigator for various international multi centre studies. Thereafter, he has formulated protocols and successfully secured funding for investigator initiated studies, including that from International grant organisations like the Royal College of Radiologists of UK. Currently he is the principal investigator in four investigator initiated studies (breast and head and neck cancers) along with acting as site specific PI of multicentric sponsored drug studies. He is also the Member Secretary of the IRB of Tata Medical Centre: Kolkata, where he works as a senior consultant clinical oncologist.

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.

About the faculty

Gary Clark, PhD is Vice President of Biostatistics & Data Management at Array BioPharma Inc in Boulder, Colorado, USA, where he is actively involved in the development of targeted therapies for various cancers. Prior to joining industry, he spent many years in academia. He 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 tumors. 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. He has been a faculty member of the ACORD Workshop in Australia since 2008. His areas of expertise include identification and evaluation of prognostic and predictive biomarkers, design and analysis of Phase I, II, III clinical trials of targeted therapies, research in breast cancer and lung cancer

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.

Gareth Griffiths is Professor of clinical trials at the University of Southampton in the UK and the Director of the Southampton Clinical Trials Unit which is core funded by Cancer Research UK. Gareth is a statistician by training, and has over 20 years experience in cancer clinical trials. Within cancer his interests lie in cancer therapies (including novel agents), primary care oncology and supportive care. Professor Griffiths is internationally recognised in the area of bladder cancer clinical trials and nationally in upper gastro-intestinal cancer and palliative and supportive care.

About the faculty

Amit Khot graduated from the University of Pune, India and then trained in Internal Medicine in India and the UK, where he qualified as a Member of the Royal College of Physicians. He completed training in laboratory and clinical Haematology in London, UK, obtaining a Fellowship from the Royal College of Pathologists. This was followed by a clinical research fellowship involving early phase clinical trials in cell therapies and myeloma at the Peter MacCallum Cancer Centre, Melbourne, Australia. Dr Khot has published in international journals and presented in international conferences in his fields of interest of cell therapies, haematopoietic progenitor cell transplantation, myeloma and early phase clinical trials. He currently works as a Consultant Haematologist at the Peter MacCallum Cancer Centre and Bendigo Health and is an investigator in clinical trials involving novel agents in myeloma and advanced haematologic malignancies.

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 co-ordinated 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.

Hari Menon is Professor of Medical Oncology and is consultant in the Adult Leukemia-lymphoma services at the Tata Memorial Centre, Mumbai, India. Having completed post graduation in Internal Medicine at the King Edward Memorial Hospital he proceeded to complete specialization in Medical Oncology at The All India Institute of Medical Sciences, New Delhi in 2004 following which he joined as Faculty at Tata Memorial Centre where he is focused in the area of Leukemia and Lymphoma. Over the last seventeen years Dr. Menon has been actively involved with clinical research, clinical trials and has been a member of the Institutional review board for past seven years. After being exposed as a student to multi-centric global studies he has persevered with his interest in clinical trial conduct, methodology, and designing of studies thereby gaining useful experience in the field. Besides being a

busy clinician he is a guide in studies involving junior faculty, post-graduate fellows and PhD students, helping them design and implement projects both in the clinical and laboratory fields. He has been a recipient of 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- and phase-II studies.

Pramesh C S is Professor and Head of Thoracic Surgery and past convener of the Thoracic Oncology Disease Management Group at the Tata Memorial Centre, Mumbai. He serves on the core committee of the Clinical Research Secretariat of the hospital. He is also the coordinator for the National Cancer Grid, a large collaborative network of 63 major cancer centres, research institutes, patient advocacy groups and charitable organizations in India. His primary clinical areas of interest include the treatment of esophageal and lung cancers and minimally invasive surgery. He is the Secretary of the Indian Society for Diseases of the Esophagus and Stomach (ISES) and is a Directorate member of the International Society for Diseases of the Esophagus. He is the Principal Investigator in several investigator-initiated research studies including randomized trials on cancer screening, surgical techniques, and neoadjuvant treatment of thoracic cancers. He has written more than 150 peer-reviewed journal articles and book chapters on topics in his specialty, including esophageal and lung cancers, minimally invasive surgery, tracheal, mediastinal and chest wall tumors, clinical research methods, biostatistics, translational research in oncology and cancer policy. Pramesh has strong interests in clinical trial designs, specific issues with surgical trials, biostatistics, promoting collaborative research and cancer policy. He is keen on 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. He is passionate about reducing inequities in cancer care and making cancer treatment accessible to all strata of society.

Arnie Purushotham has been a Consultant Academic Surgeon for 20 years having worked in Glasgow, Cambridge and London. He was the Director of Breast Services at Addenbrookes Hospital, Cambridge for 7 years prior to becoming Professor of

About the faculty

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 Cancer Centre and Vice-Dean International for the Faculty of Life Sciences and Medicine, King's College London. He is also a Senior Clinical Advisor to Cancer Research UK. As a scientific researcher for the last 25 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

Raghunadharao Digumarti is Director of the Homi Bhabha Cancer Institute at Vishakapatnam. Apart from being the principal investigator in over 80 clinical trials, he has chaired the formulation of standard operating instructions for clinical investigators for the Indian Cooperative oncology Network. He qualified in Grant Writing through an ICMR workshop at JIPMER and later went onto help train members of Ethics Committees as well as to establish several review boards and ethics committees across the country. He has also coordinated the mandatory course in clinical research and medical statistics for all post graduate and sub-specialty students of NIMS, Hyderabad. He has had the credit of bringing several phase 3 cancer drugs into the Indian market. He is a certified member of ACRP as well as the ISCR. His main interest is training research staff, translational research and early phase trials in oncology.

Preetha Rajaraman currently serves as 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 received her Ph.D. (Hon) in Epidemiology from the Johns Hopkins School of Public Health, with a concentration in cancer and molecular epidemiology. She was previously a principal investigator at NCI's Division of Cancer Epidemiology and Genetics, where her research focused 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 has previously

served on the Scientific Advisory Committees of the International Brain Tumor Epidemiology Consortium (BTEC), and the U.S. Childhood Cancer Survivor Study. She is an expert member of Committee 1 (Biological Effects) of the International Commission of Radiation Protection.

Priya Ranganathan works as a consultant anaesthesiologist at the Tata Memorial Centre, Mumbai. 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'

Debashis Sarker is Senior Lecturer in Medical Oncology at Kings College London and Honorary Consultant at Guy's, St Thomas' and King's College Hospitals. Dr Sarker graduated in medicine from the University of Liverpool in 1997, and subsequently trained in internal medicine and medical oncology. In 2003 he received a Cancer Research UK Clinical Research Fellowship in the Drug Development Unit of The Royal Marsden Hospital and Institute of Cancer Research, leading to the award of a PhD. His laboratory work was supervised by Professor Paul Workman and focused on development of novel PI3K inhibitors. He completed his medical oncology training at The Royal Marsden in 2010. Debashis' research interests are in early phase clinical trials, with a focus on novel combination therapies, predictive and pharmacodynamic biomarkers and application of molecular imaging. His clinical interests are in liver, pancreatic and neuroendocrine cancers.

Manju Sengar [MD (Medicine), DM (Medical Oncology)] is Professor, Adult hematolymphoid disease management group, Medical Oncology at the Tata Memorial Centre, Mumbai. Dr Sengar completed her training in Medical Oncology from All India Institute of Medical Sciences, New Delhi. 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.

About the faculty

James Spicer is Consultant in Medical Oncology at Guy's and St Thomas' Hospitals, and Reader 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 co-leads 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 Cancer Medicine and Clinical Epidemiology at The University of Sydney, Co-Director of Oncology at the NHMRC Clinical Trials Centre, and medical oncologist at the ConcordCancer Centre and the Chris O'Brien Lifehouse RPA. After internal medicine training at the Prince of Wales and Prince Henry Hospitals, and medical oncology training at the Royal Prince Alfred Hospital all in Sydney, he trained with Ian Tannock and Pamela Goodwin doing a clinical research fellowship at the Princess Margaret Hospital and a Masters in Clinical Epidemiology at the University of Toronto. His research focuses on improving survival, quality of life, and doctor-patient communication for those affected by cancer, particularly arising from genitourinary, breast, gynaecologic, and thoracic primaries. “The first protocol I wrote was for a randomised trial incorporating quality of life assessment in routine clinical practice - alas, this trial never happened. My first successful protocol was for a small (tiny), placebo-controlled, crossover trial of paracetamol (acetaminophen) for people with advanced cancer and troublesome pain despite a strong opioid regimen (J Clin Oncol 2004: 22; 3389).”

Sabine Tejpar is a trained gastro enterologist and oncologist with a PhD in molecular biology. She works as a part-time clinician and part-time researcher (Senior Clinical Investigator of the Fund for Scientific Research- Flanders), with a focus on basic and translational research in colorectal cancer. Her current positions are as Associate Professor of Medicine – Head of the Laboratory of Molecular Digestive Oncology, KU Leuven and Adjunct Clinical Head - Dept of Gastroenterology, Digestive Oncology Unit, University Hospital Gasthuisberg, Leuven. She is Chair of the Translational Research Committee, European Organisation for the Research and Treatment of Cancer (EORTC) and board member since 2012. From 2014 onwards, she has been

the founder of the molecular screening platforms (SPECTA) at EORTC. She is Chair of the NCI-AACR-EORTC-EMA run course on biomarker discovery and validation. Her areas of expertise in translational research consist of a large scale molecular interrogation of human colorectal cancer samples (polyps, tumors and mets) for mapping of subgroup, pathway alterations and oncogenic events and testing of these features in clinical trial series for prognostic and predictive marker discovery.

Workshop participants

	Name	Institute
1.	Anand K C	Tata Memorial Centre, Mumbai
2.	Moses Arunsingh	Tata Medical Center, Kolkata
3.	Latha Balasubramani	GKNM Hospital Coimbatore
4.	Gauri Chinchalker	Tata Memorial Centre, Mumbai
5.	Neha Choudhary	Tata Memorial Centre, Mumbai
6.	Anuja Damani	Tata Memorial Centre, Mumbai
7.	Manikandan Dhanushkodi	Cancer Institute, Adayar, Chennai
8.	Veronique Dinand	Gangaram Hospital, New Delhi
9.	Santosh Dixit	Pragati Cancer Care Mission, Pune
10.	Jeson Doctor	Tata Memorial Centre, Mumbai
11.	Biswajit Dubashi	JIPMER, Pondicherry
12.	Sivaram Gavini	Venkateswara Institute, Tirupati
13.	Sanjay Hake	Boehringer-Ingelheim, Mumbai
14.	Roopa Hariprasad	Institute of Cytology and Preventive Oncology, Noida
15.	Vinita Kumar Jaggi	Delhi State Cancer Institute
16.	Hasmukh Jain	Tata Memorial Centre, Mumbai
17.	Shalaka Joshi	Tata Memorial Centre, Mumbai
18.	Kalayarasan	JIPMER, Pondicherry
19.	Ravi Kannan	Cachar Cancer Hospital and Research Centre, Silchar
20.	Vikram Kekatpure	Mazumdar-Shaw Cancer Centre, Bangalore
21.	Arvind Krishnamurthy	Cancer Institute, Adayar, Chennai
22.	Manish Mair	Tata Memorial Centre, Mumbai
23.	Sivasanker Masillamany	Tata Memorial Centre, Mumbai
24.	Abhishek Mitra	Tata Memorial Centre, Mumbai
25.	Vishwas Pai	Kerudi Cancer Hospital and Research Centre, Bagalkot

Workshop participants

26.	Subhas Pandit	B P Koirala Hospital, Nepal
27.	Shraddha Patkar	Tata Memorial Centre, Mumbai
28.	Prashant Penumadu	JIPMER, Pondicherry
29.	Avinash Pilar	Tata Memorial Centre, Mumbai
30.	Prahlad H Y	Shirdi Sai Baba Cancer Hospital, Manipal
31.	Venkatraman Radhakrishnan	Adayar Cancer Institute, Chennai
32.	Ajay Sasidharan	Tata Memorial Centre, Mumbai
33.	Noopur Sawarkar	Tata Memorial Centre, Mumbai
34.	Naman Shah	Johnson and Johnson Pvt Ltd., Mumbai
35.	Shilpi Sharma	Tata Memorial Centre, Mumbai
36.	Praveen Kumar Shenoy	Cancer Institute, Adayar, Chennai
37.	Pankaj Singhai	Tata Memorial Centre, Mumbai
38.	Krithiga Sridhar	Centre for Chronic Conditions and Injuries, Gurgaon
39.	Sneha Tandon	Tata Memorial Centre, Mumbai
40.	Ritesh Tapkire	Cachar Cancer Hospital and Research Centre, Silchar
41.	Priya Tiwari	AIIMS, New Delhi

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 41 participants from a total of 68 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 Five thousand only
Industry participants: Indian Rupees One lakh only

Participants from outside India:
World Bank Low, lower-middle and upper-middle income economies: 100 US dollars only
World Bank High income economies: 500 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 21st November 2015
- Shuttle-bus service from the workshop venue to a pre-specified drop-off point in Mumbai or Mumbai airport on 26th November 2015
- Accommodation (twin sharing) in the workshop venue from 21st to 26th Nov 2015
- 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, basket ball, 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 five 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.

	Group A	Group B	Group C	Group D	Group E
FACULTY	Martin Stockler	Chris Frampton	Marc Buyse	Louise Brown	Gary Clark
	Gareth Griffiths	James Spicer	Arnie Purushotham	Debashis Sarker	Ruth Langley
	Girish Chinnaswamy	Amit Khot	Raghunadharao	Manju Sengar	Rakesh Aggarwal
		Sanjoy Chatterjee	Hari Menon	C S Pramesh	Vikram Mathews
PARTICIPANTS	Vinita Kumar Jaggi	Priya Tiwari	Vishwas Pai	Kalayarasan	Moses Arunsingh
	Roopa Hariprasad	Ravi Kannan	Sneha Tandon	Veronique Dinand	Subhas Pandit
	Vikram Kekatpure	Noopur Sawarkar	Sivasanker	Sivaram	Prashant Penumadu
	Gauri Chinchalker	Praveen Shenoy	Shalaka Joshi	Shilpi Sharma	Pankaj Singhai
	Biswajit Dubashi	Prahlad H Y	Neha Choudhary	Manish Mair	Anuja Damani
	Anand K C	Hasmukh Jain	Latha Balasubramani	Manikandan	Venkatraman
	Abhishek Mitra	Avinash Pilar	Jeson Doctor	Krithiga Sridhar	Naman Shah
	Sanjay Hake	Ajay Sasidharan	Ritesh Tapkire	Arvind Krishnamurthy	Shraddha Patkar
		Santosh Dixit			

Workshop 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.

Early phase trials – Design, Endpoints, Statistics	Lead faculty: Debashis Sarker Other faculty: Gareth Griffiths, D. Raghunadharao, Girish Chinnaswamy
Randomized trials: Techniques, limitations, endpoints, practical issues	Lead faculty: Gary Clark Other faculty: Ruth Langley, Louise Brown, Hari Menon
Alternative trial designs (Non-inferiority, Equivalence, Adaptive)	Lead faculty: Marc Buyse Other faculty: C S Pramesh, Manju Sengar Priya Ranganathan
Quality of life research	Lead faculty: Chris Frampton Other faculty: Martin Stockler, Rakesh Aggarwal
Biomarker-based research (Only on 22nd November)	Lead faculty: Sabine Tejpar Other faculty: Amit Khot, Vikram Mathews
Translational research (only on 24th November)	Lead faculty: James Spicer Other faculty: Arnie Purushotham, Amit Khot, Vikram Mathews

Workshop sessions

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 46 percent. This improved to 58 percent for the post-test evaluation. Statistical analysis showed a significant improvement in post-test scores as compared to the pre-test scores

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

Of the 41 participants, 36 participants submitted their responses for all the above-mentioned domains.

1. Quality of teaching sessions:

a) Didactic lectures: Overall 72.5 % of respondents rated the didactic lectures as excellent. 25.7 % of lectures were rated as good and 1.9 % as average.

b) Small group discussions: All the participants attended various small group discussions. Overall 60.2% of respondents rated these discussions as excellent, 35.5% as good and 4.3% as average

c) Meet the expert sessions: All the participants attended the discussion session with the different experts. Overall 69.5% respondents rated the discussion session with expert as excellent, 18.0% rated as good and 12.5% rated as average.

d) Protocol development break-out sessions: 92% of respondents rated these sessions as excellent and the remaining rated them as good.

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

All respondents (100%) rated the arrangements as excellent

3. Other suggestions

- More than 70% of participants suggested having one additional day for the workshop.
- More interactive session with the statistician on a one-to-one basis rather than meet the expert session only.
- To train local biostatisticians so they can troubleshoot the protocol-related issues later.
- To give a common template for concept line and protocol writing.

Research ideas discussed at the workshop

Neoadjuvant chemoradiation for resectable pancreatic head cancer: a phase III randomized control trial

Conventional X-ray based 2D Vs 3D MR-Image Based Brachytherapy in Locally Advanced Cervical Cancers A Phase III Randomized Control Trial

A Prospective Randomised Open Labelled Study of Safety , Efficacy , Cost Effectiveness and Quality of Life with Peg Filgrastim versus Filgrastim prophylaxis in children receiving Myelosuppressive Chemotherapy

Effect of nebulised furosemide for management of dyspnea in advanced cancer: A single blind, randomized placebo controlled trial

A Randomised controlled trial of Neoadjuvant chemoradiotherapy versus Neoadjuvant Chemotherapy for resectable carcinoma esophagus

Neoadjuvant chemotherapy followed by concurrent chemo-radiotherapy versus chemo-radiotherapy alone in PET CT staged non metastatic locally advanced nasopharyngeal cancers treated with IMRT.

Comparison of efficacy of Neoadjuvant chemotherapy FEC – Docetaxel versus Docetaxel and Carboplatin in Triple negative breast cancer-A Randomized Clinical study

Effect of sleep hygiene on quality of sleep in advanced cancer in palliative medicine setting-a randomized controlled trial

A study to evaluate the prevalence of occult HBV infection and Hepatitis B reactivation in patients of adult acute lymphoblastic leukemia on chemotherapy.

To study the correlation between the duration of fasting and gastric pH and volume in patients undergoing elective oncological surgery.

Prognostic role of estrogen receptor beta expression in patients with esophageal cancer receiving neoadjuvant chemoradiotherapy

Clinical and bio-chemical effects of combined natural carotenoids in oral pre-cancer-A randomized controlled trial

Self collection using Care HPV as a strategy for cervical cancer screening in South India.

Prospective study of early switch to Nilotinib in patients with Chronic Myeloid Leukemia on Imatinib

Sentinel node biopsy(SNB) guided neck dissection versus elective neck dissection(END) for the management of clinically negative neck in early (T1 and T2) oral cancer: Proposal for a randomized control trial

Optimising follow up visits in Early Breast cancers and DCIS - Yearly follow up visit at the time of mammography.

An observational, post-marketing surveillance of Ibrutinib in Indian patients with CLL or MCL who have received at least one prior therapy

A Randomized Controlled Trial to asses the role of Loco-Regional Treatment of primary breast tumor and metastatic sites in De Novo Oligo-Metastatic Breast Cancer OMBC patients

Adjuvant Radiotherapy in Early Stage Oral Tongue Cancers (AREST) – a prospective randomized control trial

Effect of early integration of Palliative care into standard oncologic treatment on the quality of life in patients with advanced head and neck cancers- A randomized controlled trial

Randomised trial of standard dose conformal radiotherapy vs. escalated dose conformal radiotherapy in advanced esophageal carcinomas treated with definitive chemo-radiotherapy

Phase II Randomized control trial comparing Paclitaxel and Cisplatin with or without Capecitabine in locally advanced borderline operable oral cavity cancer

Randomised Control Trial Examining Benefit of Consolidative Radiation in Stage I and II Diffuse Large B-cell Lymphoma

Comparison of various dosing schedules of sunitinib

Molecular and cellular characterization of cancer stem cells and their clinical impact in squamous cell malignancies of upper alimentary tract

To study the difference in molecular profile of young and elderly rectal cancer patients and their response to chemoradiation.

Impact of health education intervention on knowledge and perception of common cancers in the country in rural communities in Gautam Budh Nagar District, UP.

Evaluation of a Mobile Mammography Unit-based Diagnostic Program for Breast Cancer

A prospective study to evaluate the safety of type II oncoplasties in breast conservation surgeries with respect to its impact on in-breast tumour recurrence

Role of neoadjuvant Chemotherapy (NACT) in Mandibular Preservation

Perioperative Chemotherapy/Chemoradiation In Locally Advanced Carcinoma Gall Bladder (POLCA –GB)

Randomized control trial comparing conventional gastrojejunostomy and partial stomach partitioning for the treatment of Gastric outlet obstruction in unresectable distal gastric cancer

A randomised phase III trial comparing neoadjuvant chemotherapy followed by definitive therapy versus upfront definitive treatment in locally advanced hypopharyngeal cancers.

A Prospective Open-labeled Randomized Control Trial of Proactive Enteral Nutrition Versus Standard of Care in Children with Cancer and High Nutritional Risk

Comparative study of two different chemotherapy schedules in treatment of Head & Neck Squamous Cell Carcinoma

Phase 3 randomised control trial comparing radiotherapy versus chemoradiotherapy with weekly cisplatin or carboplatin in locally advanced head and neck squamous cell cancer patients above the age of 60 years

Double blinded randomized controlled trial of zinc versus placebo in children receiving chemotherapy to assess the role of zinc as an immunomodulator in febrile neutropenia

Phase III Randomized Study to Determine Efficacy of Curcumin and Metformin in Reducing Incidence of Second Primary Tumors of Aero-digestive Tract in Patients with Head and Neck Squamous Cell Carcinoma

Quantifying ovarian cancer disease burden by imaging, tumor markers, genetic analysis, intraoperative mapping, immune histochemistry and correlating quantity of residual disease with

survival outcomes in applicable and reproducible manner

Prophylactic use of Glycopyrrolate in reducing oro cutaneous fistula after surgery for oral cavity cancer– A prospective study.

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