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AAZPIRE

WORKSHOP ON CLINICAL RESEARCH METHODS



28th April - 1st May 2022 | 9:15 am - 4:00 pm



Dr. Sudeep Gupta
Director, ACTREC
Professor of Medical Oncology
Tata Memorial Centre
Mumbai



Dr. Vikram Gota
Program Director - AAZPIRE 2022
Professor & Officer-in-charge
Department of Clinical Pharmacology
ACTREC, Mumbai



Dr. Jayant Goda
Joint Program Director
Professor, Department of
Radiation Oncology
Tata Memorial Centre
Mumbai

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Welcome Note

It gives us immense pleasure to welcome you to the 2nd AAZPIRE Workshop on clinical research methods and protocol development to be held from 28th April, 2022 - 1st May 2022 under the aegis of ACTREC, Tata Memorial Centre. This workshop was originally conceived and designed to train oncologists at entry level who have completed their specialty training in oncology in the last 3 years. The last couple of decades has seen tremendous innovation in clinical research methods. Oncology training at most centres, having a firm focus on imparting clinical skills, may not prepare young oncologists for clinical research. This workshop is designed to bridge this gap and put early career oncologists on the path to generating evidence that will feed into future standards of care. In addition, in this edition, the organizers also invite applications from early career non oncologists (Clinicians/PhDs or those with equivalent degrees) who are interested in developing an idea related to the field of oncology.

The workshop provides a unique opportunity to develop your own idea into a full length protocol. The course comprises of a mix of didactic lectures and breakout sessions. The lecture sessions will address a variety of topics including how to develop a research question, clinical study designs, protocol writing, biostatistics and clinical trial operations. The breakout sessions will enable you to develop ideas into protocols in consultation with experts in the field. The workshop faculty from India and abroad are accomplished researchers with a track record of conducting practice changing trials and publishing them in reputed journals. More importantly, their penchant for training and education makes them uniquely suited to conduct this workshop.

The best research idea will also receive a grant of Rs. 10 lakhs from AstraZeneca to complete the project.

We hope you will make use of this opportunity created exclusively for 'young practicing oncologists and cancer researchers'. Before we sign off, we would like to thank AstraZeneca for providing educational grant to conduct this workshop along with the research grant for the best project.

Regards,

Dr. Sudeep Gupta

Dr. Vikram Gota

Dr. Jayant Goda

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Confirmed Faculty

Dr. Balu Krishna S Nair

Professor Radiation Oncology,
Christian Medical College,
Vellore

Dr. Gary Clark

Biostatistical consultant,
Gary Clark Statistical Consulting LLC,
Colorado, USA

Dr. Indranil Mallick

Professor & Sr. Consultant
Radiation Oncologist
Tata Medical Center, Kolkata

Dr. Jayant Goda

Professor, Department of
Radiation Oncology,
Tata Memorial Centre, Mumbai

Dr. Kumar Prabhash

Professor & Head, Department of
Medical Oncology,
Tata Memorial Centre, Mumbai

Dr. Supriya Chopra

Professor, Department of
Radiation Oncology
ACTREC, Mumbai

Sajan Khosla

Executive Director,
Real World Evidence,
AstraZeneca

Dr. Victoria Chiou

Head, Clinical Excellence and Innovation,
Late Development Oncology,
AstraZeneca

Dr. Vikram Gota

Professor & Officer-in-charge,
Department of Clinical Pharmacology,
ACTREC, Mumbai

Mrs. Sadhana Kannan

Scientific Officer F (Biostatistics)
Tata Memorial Centre,
Mumbai

Dr. Santam Chakraborty

Sr. Consultant Radiation Oncologist,
Tata Medical Center,
Kolkata

Dr. Vanita Noronha

Professor, Department of
Medical Oncology,
Tata Memorial Centre, Mumbai

Dr. Vijay Patil

Professor, Department of
Medical Oncology,
Tata Memorial Centre, Mumbai

Dr. Andrew Martin

Associate Professor,
NHMRC Clinical Trials Centre,
Sydney, Australia

Dr. Irina Stepanov

Mayo Professor in Public Health,
University of Minnesota School of
Public Health, Minneapolis,
Minnesota, United States

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List of Mentors for Protocol Development Sessions



Dr. Vikram Gota

Professor & Officer-in-charge,
Department of Clinical
Pharmacology, ACTREC,
Mumbai



Dr. Jayant S Goda

Professor, Department of
Radiation Oncology,
Tata Memorial Centre,
Mumbai



Dr. Vanita Noronha

Professor, Department of
Medical Oncology,
Tata Memorial Centre,
Mumbai



Dr. Girish Chinnaswami

Associate Professor of
Paediatric Oncology,
TATA Memorial Centre,
Mumbai



Dr. Balukrishna S Nair

Professor Radiation Oncology,
Christian Medical College,
Vellore



Dr. Mahesh Iyer

Head, Stats and Programming,
PAREXEL,
India



Ms. Sadhana Kannan

Scientific Officer F (Biostatistics)
Tata Memorial Centre,
Mumbai



Dr. Tejpal Gupta

Professor,
Department of Radiation Oncology
Tata Memorial Centre,
Mumbai



Dr. Kalaivani Mani

M.Sc., Biostatistics
Scientist-IV
Dept. of Biostatistics
AIIMS, New Delhi

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Eligibility Criteria

Eligibility:

1. Morning Lecture Sessions: The morning lecture sessions are open for a wide audience of oncology researchers including those pursuing basic, translational or clinical research in cancer in any capacity. Those undergoing training in various specialties of oncology or involved in patient care in any capacity can also apply.

2. Protocol Development Sessions: The protocol development sessions will be held post-lunch from 1.30 PM to 4 PM on all four days. These sessions are exclusive for 'young practicing oncologists and cancer researchers' who have completed their specialty training in the last 3 years. It is mandatory for eligible candidates applying for the protocol development sessions to also attend the lecture sessions in the morning. Only 30 proposals will be selected for protocol development based on the quality of the proposal, curriculum vitae of the applicant and a personal statement. In this regard, the decision of the steering committee will be final and binding.

3. It is desirable to submit concept notes in the following areas.

- Interventional Clinical Studies (Phase I - IV) involving AstraZeneca authorized medicines OR
- Observational Research (i.e. Real World Evidence (RWE)) - research utilising data collected through observation of current clinical practice and/or patient reported experience OR
- Research on human biological samples or imaging (Eg. biomarkers, diagnostic studies)
- The research proposal should be aligned with one of the areas of focus for AZ oncology e.g. lung cancer, breast cancer, ovarian cancer, B-cell malignancies, prostate cancer, and hepatocellular cancer.

Note: The link for submission of the concept note may be found at the bottom of this page.

Click the link below to submit Concept Note
<https://rrcgvir.com/aazpire>

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Steering Committee

Dr. Vikram Gota

Dr. Jayant Goda

Dr. Santam Chakraborty

Mrs. Sadhana Kannan

Note:

The last Date for submission of the concept note is
20th March 2022

Venue

Venue for the Lecture Session

Virtual

**Venue for the the
Protocol Developement Session**

**ACTREC,
Tata Memorial Centre, Mumbai**

**'With provision for a virtual mode
workshop based on prevailing conditions'**

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WORKSHOP ON CLINICAL RESEARCH METHODS

28th April - 1st May 2022 | 9:15 am - 4:00 pm

Scientific Program

Day 1: 28th April 2022 | 09:15 - 04:00 PM

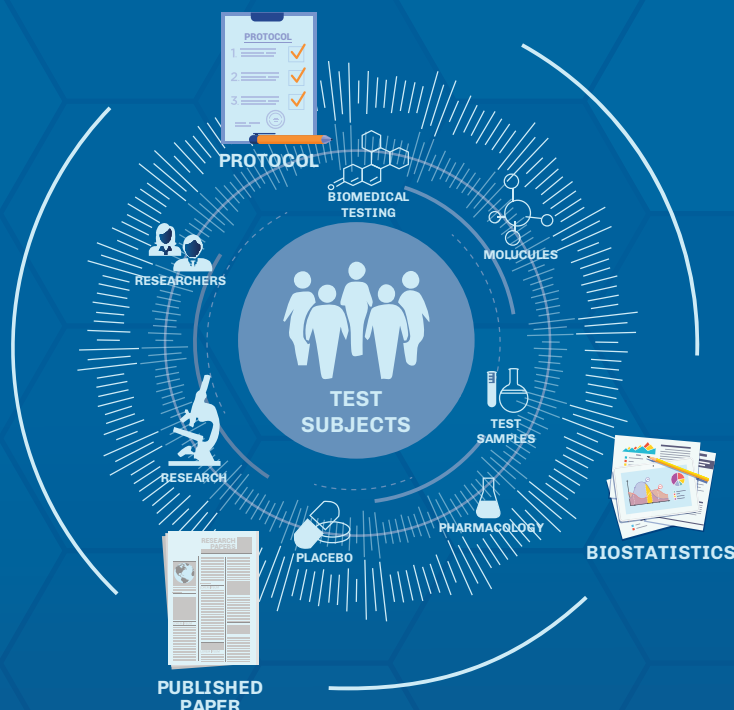
Time	Topic
09:15 am-09:30 am	Program overview Dr. Vikram Gota
09:30 am-10:15 am	Developing a research question Dr. Kumar Prabhash
10:15 am-11:00 am	Research objectives and clinical endpoints Dr. Indranil Mallick
11:00 am-11:15 am	Break
11:15 am-12:00 pm	Protocol writing: Introduction/Background and objectives Dr. Vijay Patil
12:00 pm-12:45 pm	Study designs in clinical research- Cross-sectional & Case-Control studies Dr. Irina Stepanov
12:45 pm-01:30 pm	Lunch
01:30 pm-04:00 pm	Break-out session (Framing the research questions, objectives and endpoints)

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28th April - 1st May 2022 | 9:15 am - 4:00 pm

Scientific Program

Day 2: 29th April 2022 | 09:15 - 04:00 PM

Time	Topic
09:15 am - 09:30 am	Q&A
09:30 am - 10:15 am	Study designs in clinical research- Cohort studies Dr. Santam Chakraborty
10:15 am - 11:00 am	Phase II trial designs Dr. Andrew Martin
11:00 am - 11:15 am	Break
11:15 am - 12:00 pm	Real-World Evidence (RWE) study designs Dr. Sajan Khosla
12:00 pm - 12:45 pm	Protocol writing – Study design & methodology Dr. Balukrishna S Nair
12:45 pm - 01:30 pm	Lunch
01:30 pm - 04:00 pm	Break-out session (Study design and methodology)

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WORKSHOP ON CLINICAL RESEARCH METHODS

28th April - 1st May 2022 | 9:15 am - 4:00 pm

Scientific Program

Day 3: 30th April 2022 | 08:45 - 04:00 PM

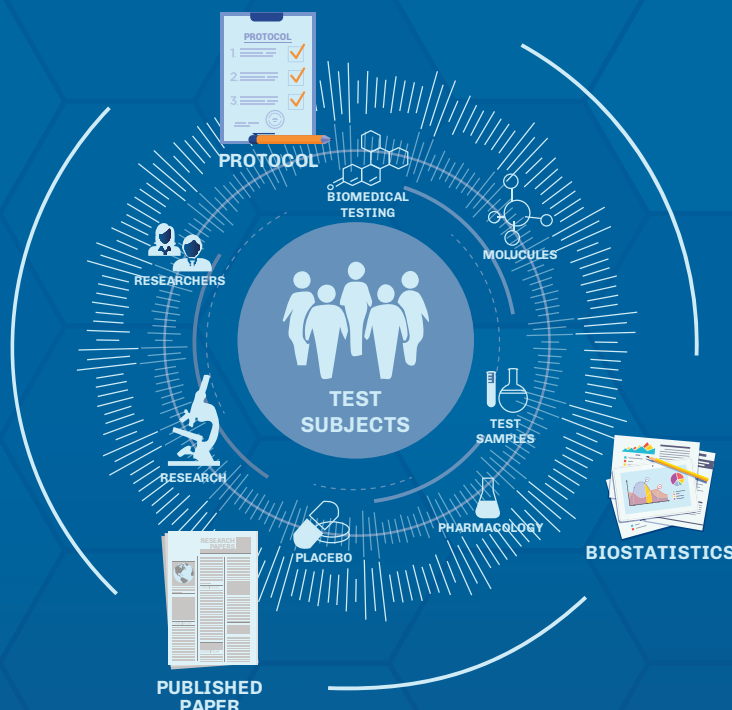
Time	Topic
08:45 am - 09:30 am	Digital disruption in oncology trials Dr. Victoria L Chiou
09:30 am - 10:15 am	Basic statistics for clinical research Dr. Andrew Martin
10:15 am - 11:00 am	Intermediate/Advanced Biostatistics Dr. Mahesh Iyer
11:00 am - 11:15 am	Break
11:15 am - 12:00 pm	Sample Size calculation- prospective and retrospective studies Dr. Sadhana Kannan
12:00 pm - 12:45 pm	Statistical Analysis Plan- Examples Dr. Vanita Noronha
12:45 pm - 01:30 pm	Lunch
01:30 pm - 04:00 pm	Break-out session (Sample size & Statistical Analysis plan)

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28th April - 1st May 2022 | 9:15 am - 4:00 pm

Scientific Program

Day 4: 1st May 2022 | 09:15 - 04:00 PM

Time	Topic
09:15 am - 09:30 am	Q&A
09:30 am - 10:15 am	Phase III trial designs – Superiority trials Dr. Supriya Chopra
10:15 am - 11:00 am	Phase III trial designs – Non-inferiority/Equivalence trials Dr. Vikram Gota
11:00 am - 11:15 am	Break
11:15 am - 12:00 pm	Biomarkers in oncology trials Dr. Gary Clark
12:00 pm - 12:45 pm	CRF and data management Dr. Sadhana Kannan
12:45 pm - 01:30 pm	Lunch
01:30 pm - 04:00 pm	Protocol presentations

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Conference Secretariat & Webinar Management

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