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# AAZPIRE

## WORKSHOP ON CLINICAL RESEARCH METHODS



**28<sup>th</sup> April - 1<sup>st</sup> 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 2<sup>nd</sup> AAZPIRE Workshop on clinical research methods and protocol development to be held from 28<sup>th</sup> April, 2022 - 1<sup>st</sup> 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

### **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. Irina Stepanov**

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

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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  
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## WORKSHOP ON CLINICAL RESEARCH METHODS

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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  
20<sup>th</sup> 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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## Scientific Program

Day 1: 28<sup>th</sup> April 2022 | 09:15 - 04:00 PM

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

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## Scientific Program

Day 2: 29<sup>th</sup> April 2022 | 09:15 - 04:00 PM

Time	Topic
09:15-09:30 am	Q&A
09:30-10:15 am	Study designs in clinical research- Cohort studies
10:15-11:00 am	Phase II trial designs
11:00-11:15 am	Break
11:15-12:00 pm	Real-World Evidence (RWE) in Oncology
12:00-12:45 pm	Protocol writing – Study design & methodology
12:45-01:30 pm	Lunch
01:30-04:00 pm	Break-out session (Study design and methodology)

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### Scientific Program

Day 3: 30<sup>th</sup> April 2022 | 08:45 - 04:00 PM

Time	Topic
08:45-09:30 am	Digital disruption in oncology trials
09:30-10:15 am	Basic statistics for clinical research
10:15-11:00 am	Intermediate/Advanced Biostatistics
11:00-11:15 am	Break
11:15-12:00 pm	Sample Size calculation- prospective and retrospective studies
12:00-12:45 pm	Statistical Analysis Plan- Examples
12:45-01:30 pm	Lunch
01:30-04:00 pm	Break-out session (Sample size and Statistical Analysis plan)

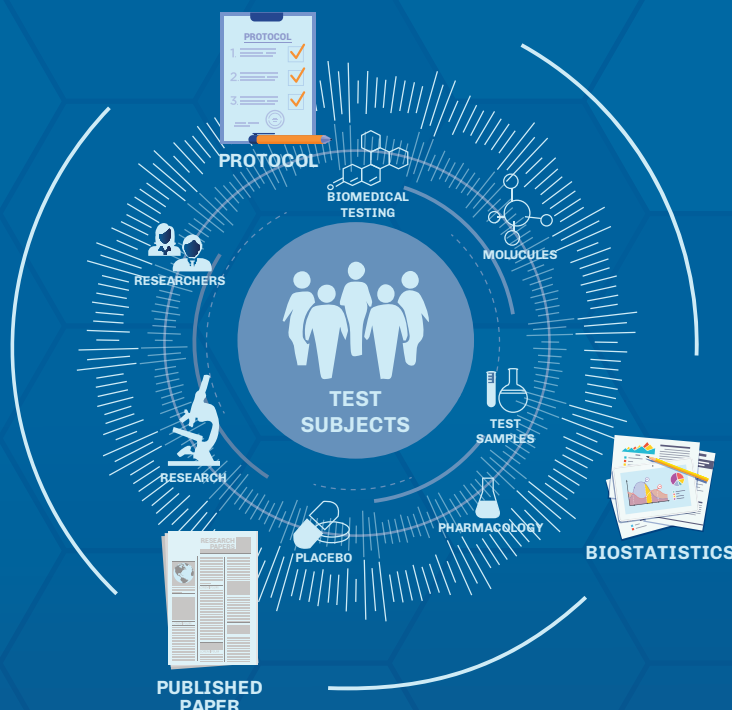
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### Scientific Program

Day 4: 1<sup>st</sup> May 2022 | 09:15 - 04:00 PM

Time	Topic
09:15-09:30 am	Q&A
09:30-10:15 am	Phase III trial designs – Superiority trials
10:15-11:00 am	Phase III trial designs – Non-inferiority/Equivalence trials
11:00-11:15 am	Break
11:15-12:00 pm	Biomarkers in oncology trials
12:00-12:45 PM	CRF and data management
12:45-01:30 pm	Lunch
01:30-04:00 pm	Protocol presentations

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Conference Secretariat & Webinar Management

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