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# AAZPIRE 2023

## Workshop on Clinical Research Methods & Protocol Development



**30<sup>th</sup> MARCH - 02<sup>nd</sup> APRIL 2023**



**Dr. Sudeep Gupta**

Patron - AAZPIRE 2023  
Director, ACTREC  
Professor of Medical Oncology,  
Tata Memorial Centre,  
Mumbai



**Dr. Vikram Gota**

Program Director -  
AAZPIRE 2023  
Professor & Officer-in-charge  
Dept. of Clinical Pharmacology,  
ACTREC,  
Mumbai



**Dr. Jayant Goda**

Joint Program Director -  
AAZPIRE 2023  
Professor,  
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## Workshop on Clinical Research Methods & Protocol Development

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### Welcome Note

It gives us immense pleasure to welcome you to the **3<sup>rd</sup> AAZPIRE Workshop on Clinical Research Methods and Protocol Development** to be held from March 30<sup>th</sup> to April 2<sup>nd</sup>, 2023, under the aegis of ACTREC, Tata Memorial Centre. We have conducted two successful workshops so far, and feedback from participants has been very encouraging. The idea of AAZPIRE was originally conceived and designed to train oncologists at the entry level who have completed their specialty training in oncology in the last three years. The past few decades have witnessed tremendous innovation in clinical research methods. Oncology training at most centers, with its firm focus on imparting clinical skills, may not prepare young oncologists for clinical research. Therefore, 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. We also encourage applications from early-career non-oncologists (Clinicians, PhDs, or those with equivalent degrees) who are interested in developing an idea in the field of oncology.

This workshop aims to provide a unique opportunity to develop an idea into a full-length protocol. The course comprises a mix of didactic lectures and breakout sessions. The lecture sessions will address a variety of topics, including how to develop a research question, design a clinical study, write a protocol, understand biostatistics, and conduct clinical trials. Breakout sessions will enable you to mature ideas into protocols in consultation with experts in the field. This year, we have introduced novel topics such as diagnostic research methods and data management to provide a well-rounded look to the curriculum. Another highlight of this year's edition is a mini-workshop on advanced tools for manuscript writing, introduced primarily to enable you to overcome the writer's block. The workshop faculty are accomplished researchers from India and abroad 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 an Rs. 10 lakh grant from AstraZeneca to complete the project.

We hope that you will make use of this opportunity curated exclusively for young practicing oncologists and cancer researchers. Before we sign off, we would like to thank AstraZeneca for providing an 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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### Eligibility Criteria

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

**Protocol Development Sessions:** Protocol development sessions will be held post-lunch from 1.30 PM to 4 PM on all four days. These sessions are exclusive to young practicing oncologists and cancer researchers who have completed their specialty training in the last three years. It is mandatory for eligible candidates who apply for protocol development sessions to attend lecture sessions in the morning. Only 30 proposals will be selected for protocol development based on the quality of the proposal, the curriculum vitae of the applicant, and a personal statement. In this regard, the decision of the steering committee will be final and binding. 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 utilizing data collected through observation of current clinical practice and/or patient-reported experience
- OR
- Research on human biological samples or imaging (e.g., biomarkers and 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.

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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  
10<sup>th</sup> March 2023**

**Venue for the Lecture Session**

**Virtual**

**Venue for the the  
Protocol Developement Session**

**ACTREC,  
Tata Memorial Centre, Mumbai**

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## Workshop on Clinical Research Methods & Protocol Development

**30<sup>th</sup> MARCH - 02<sup>nd</sup> APRIL 2023**

**Day 1** 30<sup>th</sup> March 2023 (Thursday)

### What is Research?

09:00 - 09:05 am	Program Overview <b>Dr. Sudeep Gupta</b>
09:05 - 09:10 am	Introduction <b>Mr. Sanjeev Panchal</b>
09:10 - 09:30 am	Program Overview <b>Dr. Vikram Gota</b>
09:30 - 10:15 am	Hypothesis & Research Question - Getting it Right Speaker: <b>Dr. Kumar Prabhash</b>
10:15 - 11:00 am	Collaborative Research Framework in Oncology Speaker: <b>Dr. Samir Khariwala</b>

**11:00 - 11:15 am** **Tea-Break**

11:15 - 12:00 pm Research Objectives & Clinical  
Endpoints  
Speaker: **Dr. Indranil Mallick**

12:00 - 12:45 pm Protocol Writing : Introduction /  
Background & Objectives  
Speaker: **Dr. Supriya Chopra**

**12:45 - 01:30 pm** **Lunch**

01:30 - 04:00 pm Break-out Session  
(Framing the research questions,  
objectives & endpoints)

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**Day 2**

**31<sup>st</sup> March 2023 (Friday)**

### Key Points in Methodology

09:30 - 10:10 am Study Designs in Clinical Research -  
Observational Studies  
Speaker: **Dr. Santam Chakraborty**

10:10 - 10:50 am Study Designs in Clinical Research -  
Interventional Studies - Phase - II  
Speaker: **Dr. Andrew Martin**

10:50 - 11:00 am **Tea-Break**

11:00 - 11:40 am Real World Evidence - How can we  
Contribute?  
Speaker: **Dr. Vijay Patil**

11:40 - 12:20 pm Biomarkers in Oncology Trials  
Speaker: **Dr. Gary Clark**

12:20 - 01:00 pm Protocol Writing -  
Study Design & Methodology  
Speaker: **Dr. Balukrishna S. Nair**

01:00 - 01:45 pm **Lunch**

01:45 - 04:00 pm Break-out Session  
(Study design & methodology)

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## Workshop on Clinical Research Methods & Protocol Development

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**Day 3**

**01<sup>st</sup> April 2023 (Saturday)**

### Data Analysis

09:30 - 10:15 am Basics Statistics for Clinical Research  
Speaker: **Dr. Andrew Martin**

10:15 - 11:00 am Survival Analysis  
Speaker: **Dr. Vikram Gota**

11:00 - 11:15 am **Tea-Break**

11:15 - 12:00 pm Sample Size Calculation  
Speaker: **Dr. Sadhana Kannan**

12:00 - 12:45 pm Protocol Writing - Statistical Analysis  
Plan in Oncology Research  
Speaker: **Dr. Vanita Noronha**

12:45 - 01:30 pm Panel Discussion - Challenges in  
conducting clinical research/trials for  
early career oncologists  
Moderator: **Dr. Vanita Noronha**  
Panelists: **Dr. Kartik Udupa,**  
**Dr. Balu Krishna Nair, Dr. Vijay Patil,**  
**Dr. Santam Chakraborty,**  
**Dr. Shona Nag, Dr. Shalaka Joshi,**  
**Dr. Bharat Rekhi**

01:30 - 02:15 pm **Lunch**

02:15 - 04:00 pm Break-out Session  
(Sample size & statistical analysis plan)

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**Day 4**

**02<sup>nd</sup> April 2023 (Sunday)**

### Workshop - Practical Aspects of Research

09:30 - 10:15 am	Data Management - Tips & Tricks Speaker: <b>Dr. Sadhana Kannan</b>
10:15 - 10:45 am	Outline of a Manuscript Speaker: <b>Dr. Vedang Murthy</b>
10:45 - 11:00 am	<b>Tea-Break</b>
11:00 - 01:00 pm	Advanced Tools for Manuscript Writing Speakers: <b>Dr. Anand Srinivasan,</b> <b>Mr. Ryan Varghese</b>
01:00 - 01:45 pm	<b>Lunch</b>
01:45 - 04:00 pm	Protocol Presentations Award Declaration & Closing Remarks

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# Workshop on Clinical Research Methods & Protocol Development



Link for Registration



<https://cutt.ly/D3IVyNo>

Link for submission of Concept Note



<https://rrcgvir.com/aazpire>

**Note: The deadline for submission of the  
concept note is 10<sup>th</sup> March 2023**

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Conference Secretariat & Webinar Management

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