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Workshop on Clinical Research Methods & Protocol Development



30th MARCH - 02nd 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,
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Mumbai



Dr. Jayant Goda

Joint Program Director -
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Mumbai

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Welcome Note

It gives us immense pleasure to welcome you to the **3rd AAZPIRE Workshop on Clinical Research Methods and Protocol Development** to be held from March 30th to April 2nd, 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
10th 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

30th MARCH - 02nd APRIL 2023

Day 1 30th March 2023 (Thursday)

What is Research?

09:15 - 09:30 am	Program Overview Dr. Vikram Gota
09:30 - 10:15 am	Hypothesis & Research Question - Getting it Right Speaker: Dr. Kumar Prabhash
10:15 - 11:00 am	Collaborative Research Framework in Oncology Speaker: Dr. Samir Khariwala

11:00 - 11:15 am Tea-Break

11:15 - 12:00 pm	Research Objectives & Clinical Endpoints Speaker: Dr. Indranil Mallick
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12:00 - 12:45 pm	Protocol Writing : Introduction / Background & Objectives Speaker: Dr. Supriya Chopra
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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

31st 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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Day 3 **01st 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. Senthil Rajappa**

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
Oncology Research
Moderator: **Dr. Vanita Noronha**
Panelists: **Dr. Kartik Udupa,**
Dr. Balu Krishna Nair, Dr. Vijay Patil,
Santam Chakraborty, Dr. Shona Nag,
Dr. Shalaka Joshi, 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

02nd April 2023 (Sunday)

Workshop - Practical Aspects of Research

09:30 - 10:15 am Data Management - Tips & Tricks
Speaker: **Dr. Sadhana Kannan**

10:15 - 10:45 am Outline of a Manuscript
Speaker: **Dr. Vedang Murthy**

10:45 - 11:00 am **Tea-Break**

11:00 - 01:00 pm Advanced Tools for Manuscript Writing
Speakers: **Dr. Sudhir Nair,**
Mr. Ryan Varghese

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

01:45 - 04:00 pm Protocol Presentations
Award Declaration & Closing Remarks

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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 10th March 2023**

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Conference Secretariat & Webinar Management

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