





### **WORKSHOP ON**

### CLINICAL RESEARCH METHODS & PROTOCOL DEVELOPMENT

25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)









Data Analysis







**Dr. Sudeep Gupta**Patron, Director
Tata Memorial Centre
Mumbai



Dr. Vikram Gota
Program Director
AAZPIRE 2024
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

Registration Link
Click on below link to register:
<a href="https://tinyurl.com/2vpaunnb">https://tinyurl.com/2vpaunnb</a>

Scan QR Code for Registration



All registered delegates will receive the attendee joining link on your registered email id.

Please send your queries related to the Workshop on <a href="mailto:azzpire2024@gmail.com">azzpire2024@gmail.com</a>























25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)

#### **Welcome Note**

We are delighted to welcome you all for the 4<sup>th</sup> AAZPIRE workshop on clinical research methods and protocol development under the auspices of ACTREC, Tata Memorial Centre to be held from April 25<sup>th</sup> to April 28<sup>th</sup> 2024. The goal of this workshop is to equip young oncologists with the essential skills required to conduct clinical research in the field of oncology. In addition, we also welcome clinicians, PhDs or those with equivalent degrees interested in oncology research to take part in this workshop. The workshop program is meticulously curated with a variety of academic sessions ensuring that all learning needs are addressed, including conception, design, execution, and analysis of research studies.

Broadly, the workshop will be delivered through a lecture series in hybrid mode for all participants and breakout sessions for a select group of participants aspiring to develop clinical research protocols. The breakout sessions will facilitate the development of research ideas into protocols under the guidance of experienced faculty within assigned groups comprising a maximum of 10-12 participants. An accomplished group of national and international experts will provide the knowledge, skills, experience and global perspectives needed to produce high-quality clinical cancer research. Besides there is an opportunity to network and establish long-term, research collaborations with co-participants. In addition, the best research proposal will be selected by steering committee and awarded 10 lakhs from AstraZeneca to support the fulfilment of the project.

Travel and accommodation will be provided for all candidates selected for protocol development.

We earnestly hope that you will make use of this opportunity to expand your horizons, foster connections, and drive innovation. We express our deepest gratitude to AstraZeneca for their invaluable support, which has made this workshop possible.

Sincerely,

**Dr. Sudeep Gupta** 

**Dr. Vikram Gota** 

**Dr. Jayant Goda** 























25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)

### **Eligibility Criteria**

The AAZPIRE Workshop brings oncology researchers with new research ideas to participate.

Morning Lecture Sessions: These sessions are open to a broad audience with an interest in oncology research. This includes individuals pursuing basic, translational, or clinical cancer research in any capacity. Additionally, trainees specialising in various oncology fields and individuals involved in patient care are encouraged to attend.

Protocol Development Sessions: Offered exclusively for a limited group, these sessions will take place after lunch (1:30 PM to 4:00 PM) on all four days of the workshop. Eligibility for these sessions is restricted to young, practicing oncologists and cancer researchers who have completed their speciality training within the past three years. Attendance at the morning lecture sessions is mandatory for all applicants seeking participation in the protocol development sessions.

**Selection Process:** A rigorous selection process will be implemented to select up to 30 participants for the protocol development sessions. Selection will be based on a comprehensive evaluation, considering the quality of the submitted research proposal, the applicant's curriculum vitae, and a personal statement. The decisions of the steering committee regarding participant selection will be final and binding.

**Concept Note Submission:** To be considered for selection, applicants must submit a concept note aligned with one of the following focus areas:

- A. Interventional Clinical Studies (Phases I-IV)
- **B.** Observational Research (Real-World Evidence [RWE]): Research utilising data collected through observation of current clinical practice and/or patient-reported experiences.
- **C.** Research on human biological samples or imaging (e.g., biomarkers and diagnostic studies).

Research Focus Alignment: Importantly, the proposed research should demonstrably align with one of oncology's key areas of focus, including Lung cancer, Breast cancer, Gastrointestinal cancer, Gynaecological cancer and GenitoUrinary cancer aligned to AstraZeneca strategy and pipeline.























25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)

### **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 31<sup>st</sup> March 2024

**Venue for the Lecture Session** 



Venue for the **Protocol Development Session** 

Royal Tulip Hotel, Kharghar Navi Mumbai























25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)



Dr. Vikram Gota
Program Director
AAZPIRE 2024
Professor & Officer-in-charge
Department of
Clinical Pharmacology
ACTREC, Mumbai

### **Faculty**



**Dr. Kumar Prabhash**Professor, Medical Oncology
Tata Memorial Centre
Mumbai



Dr. Jayant Goda
Joint Program Director
AAZPIRE 2024
Professor, Department of
Radiation Oncology
Tata Memorial Centre
Mumbai



Dr. Shrikant Bangdiwala
PhD Professor
Department of Health Research Methods
Evidence, and Impact McMaster University
Hamilton, Ontario.
Director of Statistics and Senior Scientist at
the Population Health Research Institute

Canada



Dr. Pankaj Kumar Panda
Senior Research Officer
Clinical Trials and
Epidemiological Sciences
National Cancer Centre Singapore
(NCCS), Singapore



Dr. Indranil Mallick
Senior Consultant
Department of Radiation Oncology
Tata Medical Center
Kolkata



**Dr. Vijay Patil**Consultant, Medical Oncology
P. D. Hinduja Hospital
Mumbai



Dr. Supriya Chopra
Professor, Radiation Oncology
ACTREC
Tata Memorial Centre
Mumbai



Dr. Santam Chakraborty
Consultant, Radiation Oncology
Tata Memorial Centre
Kolkata





















25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)



Dr. Denis Xavier MD, MSc
Professor & Head
Dept. of Pharmacology
Head, Division of Clinical Research
and Training, St. John's Medical College
and Research Institute
Bangalore

### **Faculty**



Dr. Amit Dutt
Principal Investigator/
Scientist F Tata Memorial Centre
ACTREC
Navi Mumbai



Dr. Balu Krishna Sasidharan Nair Professor, Radiation Oncology Christian Medical College Vellore



Mrs. Sadhana Kannan Scientific Officer F Statistician, ACTREC Tata Memorial Centre Navi Mumbai



**Dr. Vanita Noronha**Professor, Medical Oncology
Tata Memorial Hospital
Mumbai



Dr. Sudhir Nair
Professor & HOD
Surgical Oncology
Tata Memorial Centre
Mumbai



Dr. Sarbani Laskar
Professor & Radiation Oncologist
Tata Memorial Hospital
Mumbai



**Dr. Prabhat Bhargava**Professor, Medical Oncology
Tata Memorial Hospital
Mumbai



Dr. Shankar Viswanathan
Associate Professor
Department of Epidemiology &
Population Health
Albert Einstein College of Medicine
NY, USA





















Design



25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)



Dr. Bharat Rekhi
Professor Pathology
(Surgical Pathology and Cytopathology)
Tata Memorial Centre
Mumbai.

### **Faculty**



Dr. Shwetabh Sinha
Assistant professor
Radiation oncology
Tata Memorial Centre
Mumbai.



Professor
Medical oncology
Tata Memorial Centre
Mumbai



Ms. Deepa Ramani Member IEC committee Member Stem cell committee ACTREC Navi Mumbai



Dr. Mahesh lyer
Head, Statistics, Al/ML
Quantitative and Digital Sciences,
& Innovation, India and Phillipines,
Hyderabad





















25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)

### Mentors



Dr. Vikram Gota
Program Director
AAZPIRE 2024
Professor & Officer-in-charge
Department of
Clinical Pharmacology
ACTREC, Mumbai



Dr. Jayant Goda
Joint Program Director
AAZPIRE 2024
Professor, Department of
Radiation Oncology
Tata Memorial Centre
Mumbai



Dr. Denis Xavier MD, MSc
Professor & Head
Dept. of Pharmacology
Head, Division of Clinical Research
and Training, St. John's Medical College
and Research Institute
Bangalore



Dr. Balu Krishna Sasidharan Nair Professor, Radiation Oncology Christian Medical College Vellore



**Dr. Kumar Prabhash**Professor, Medical Oncology
Tata Memorial Centre
Mumbai



Dr. Shrikant Bangdiwala
PhD Professor
Department of Health Research Methods
Evidence, and Impact McMaster University
Hamilton, Ontario.
Director of Statistics and Senior Scientist at
the Population Health Research Institute
Canada



Dr. Sudhir Nair
Professor
Tata Memorial Centre
Mumbai



Dr. Girish Chinnaswamy
Professor, Paediatric Oncology
Tata Memorial Centre
Mumbai



Dr. Mahesh Iyer
Head, Statistics, AI/ML
Quantitative and Digital Sciences,
& Innovation, India and Phillipines,
Hyderabad



Mrs. Sadhana Kannan Scientific Officer F Statistician, ACTREC Tata Memorial Centre Navi Mumbai



Dr. Gaurav Chatterjee
Associate professor
Hematopathology Laboratory
Tata Memorial Centre,
Mumbai



Dr. P. G Subramanian
Professor & Officer-in-charge
Hematopathology
Tata Memorial Centre
Mumbai





















25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)

### **Agenda**

### Day 1 25<sup>th</sup> April 2024, Thursday

### A Research of Several Months Begins with a Single Question

09:00 am - 09:15 am Workshop Inauguration

09:15 am - 09:30 am Program overview

**Dr. Vikram Gota** 

09:30 am - 10:15 am What is the big idea? - A HYPOTHESIS

to ignite research

Speaker **Dr. Kumar Prabhash** 

10:15 am - 11:00 am Understanding the language of

research OBJECTIVES and

**ENDPOINTS** 

Speaker Dr. Indranil Mallick

11:00 am - 11:15 am Tea Break

11:15 am - 12:00 pm Protocol writing - Background, aims &

objectives

Speaker Dr. Supriya Chopra

12:00 pm - 12:45 pm My approach to writing a Protocol

Speaker Dr. Prabhat Bhargava

01:00 pm - 02:00 pm Lunch

02:00 pm - 04:00 pm Action learning: craft your case -

Developing research question,

objectives and meaningful endpoints























25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)

### **Agenda**

### Day 2) 26<sup>th</sup> April 2024, Friday

#### From Concept to Creation

08:45 am - 09:30 am Beyond traditional approaches - Novel

methodologies in cancer clinical

research

Speaker **Dr. Shankar Viswanathan** 

09:30 am - 10:15 am Navigating the landscape of

observational study design

Speaker **Dr. Santam Chakraborty** 

10:15 am - 10:50 am Deep dive into the design of Phase II

interventional research

Speaker **Dr. Denis Xavier** 

11:15 am - 11:45 am Building on Real world evidence

Speaker Dr. Vijay Patil

11:45 am - 12:15 pm Diagnostic advances in research

(NGS, ctDNA, liquid biopsy, biomarker

discovery)

Speaker Dr. Amit Dutt

12:15 pm - 12:45 pm Protocol writing - Study design and

methodology

Speaker Dr. Balu Krishna Sasidharan Nair

01:00 pm - 02:00 pm Lunch

02:00 pm - 04:00 pm Action learning: A step wise approach

to build the study design and planning

the methodology























25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)

### **Agenda**

### Day 3 27<sup>th</sup> April 2024, Saturday

#### **Data - Negotiating the Maze** 09:30 am - 09:55 am Keep it simple - Biostatistics for beginners Dr. Vikram Gota Speaker 09:55 am - 10:20 am Make it simple, not simpler - Advanced biostatistics Speaker Mrs. Sadhana Kannan 10:20 am - 11:00 am Modeling disease progression and patient outcomes - survival analysis in oncology Speaker Dr. Mahesh Iyer 11:00 am - 11:15 am Tea Break EmPOWERing your research - choosing 11:15 am - 12:00 pm the right sample size **Dr. Shrikant Bangdiwala** Speaker 12:00 pm - 12:45 pm Leveraging data - statistical analysis plan Dr. Vanita Noronha Speaker 12:45 pm - 01:30 pm Meeting the challenges in oncology research - know it from the experts! Moderator **Dr. Vanita Noronha Panelists Dr. Shrikant Bangdiwala** Dr. Bharat Rekhi, Dr. Denis Xavier **Dr. Shwetabh Sinha** Dr. Balu Krishna Sasidharan Nair 01:30 pm - 02:00 pm Lunch 02:00 pm - 04:00 pm Action learning - A hands on workshop on



sample size and statistical analysis





















25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)

### **Agenda**

Day 4) 28<sup>th</sup> April 2024, Sunday

#### **Building your research toolkit!**

9:30 am - 10:15 am Unlocking the secrets of data

management

Speaker Mrs. Sadhana Kannan

10:15 am - 11:00 am May I help you? - Workshop on

advanced tools to assist research

publication

Speaker Dr. Pankaj Kumar Panda

11:00 am - 11:15 am Tea Break

11:15 am - 11:50 am May I help you? - Workshop on

advanced tools to assist research

publication

Speaker **Dr. Pankaj Kumar Panda** 

11:50 am - 12:30 pm But ethics first - An open discussion

on responsible conduct of research in

cancer

Moderator **Dr. Kumar Prabhash** 

Panelists Dr. Sudhir Nair

Dr. Sarbani Laskar Dr. Sachin Punatar Ms. Deepa Ramani

01:00 pm - 02:00 pm Lunch

02:00 pm - 04:00 pm Protocol Presentations, Award

**Declaration & Closing Remarks** 









**WORKSHOP ON** 

### CLINICAL RESEARCH METHODS & PROTOCOL DEVELOPMENT

25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)

















**Link for Registration** 

https://tinyurl.com/2vpaunnb





**Link for Submission of Concept Note** 

https://tinyurl.com/bp6w77br



Note: The deadline for submission of the concept note is 31<sup>st</sup> March 2024









**WORKSHOP ON** 

### CLINICAL RESEARCH METHODS & PROTOCOL DEVELOPMENT

25<sup>th</sup> - 28<sup>th</sup> April 2024 | 9:00 am - 4:00 pm (IST)















Managed by:



15 \*\*
Excellence

Rajesh Sharma

M: 9374073512

E: rajesh@miceideas.in