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# AAZPIRE 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)



Clinical  
Trials



Statistics



Research



Publications



Data  
Analysis



Study  
Design



RWE/  
RWD



**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:

<https://tinyurl.com/2vpaunnb>

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 [aazpire2024@gmail.com](mailto:aazpire2024@gmail.com)

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### 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

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**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.

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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**

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# AAZPIRE 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)

### Faculty



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



**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

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### Faculty



**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. 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 Vishwanathan**  
Associate Professor  
Department of Epidemiology &  
Population Health  
Albert Einstein College of Medicine  
NY, USA

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

### Faculty



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



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



**Dr. Sachin Punatar**  
Professor  
Medical oncology  
Tata Memorial Centre  
Mumbai



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



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

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### Mentors



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



**Dr. Jayant Goda**  
Joint Program Director  
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**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  
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### 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 <b>Dr. Vikram Gota</b>
09:30 am - 10:15 am	What is the big idea? - A HYPOTHESIS to ignite research Speaker <b>Dr. Kumar Prabhash</b>
10:15 am - 11:00 am	Understanding the language of research OBJECTIVES and ENDPOINTS Speaker <b>Dr. Indranil Mallick</b>
11:00 am - 11:15 am	Tea Break
11:15 am - 12:00 pm	Protocol writing - Background, aims & objectives Speaker <b>Dr. Supriya Chopra</b>
12:00 pm - 12:45 pm	My approach to writing a Protocol Speaker <b>Dr. Prabhat Bhargava</b>
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

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### 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	<b>Dr. Shankar Vishwanathan</b>
09:30 am - 10:15 am	Navigating the landscape of observational study design
Speaker	<b>Dr. Santam Chakraborty</b>
10:15 am - 10:50 am	Deep dive into the design of Phase II interventional research
Speaker	<b>Dr. Denis Xavier</b>
11:00 am - 11:15 am	Tea Break
11:15 am - 11:45 am	Building on Real world evidence
Speaker	<b>Dr. Vijay Patil</b>
11:45 am - 12:15 pm	Diagnostic advances in research (NGS, ctDNA, liquid biopsy, biomarker discovery)
Speaker	<b>Dr. Amit Dutt</b>
12:15 pm - 12:45 pm	Protocol writing - Study design and methodology
Speaker	<b>Dr. Balu Krishna Sasidharan Nair</b>
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

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### 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
Speaker	<b>Dr. Vikram Gota</b>
09:55 am - 10:20 am	Make it simple, not simpler - Advanced biostatistics
Speaker	<b>Mrs. Sadhana Kannan</b>
10:20 am - 11:00 am	Modeling disease progression and patient outcomes - survival analysis in oncology
Speaker	<b>Dr. Mahesh Iyer</b>
11:00 am - 11:15 am	Tea Break
11:15 am - 12:00 pm	EmPOWERing your research - choosing the right sample size
Speaker	<b>Dr. Shrikant Bangdiwala</b>
12:00 pm - 12:45 pm	Leveraging data - statistical analysis plan
Speaker	<b>Dr. Vanita Noronha</b>
12:45 pm - 01:30 pm	Meeting the challenges in oncology research - know it from the experts!
Moderator	<b>Dr. Vanita Noronha</b>
Panelists	<b>Dr. Shrikant Bangdiwala</b> <b>Dr. Bharat Rekhi, Dr. Denis Xavier</b> <b>Dr. Shwetabh Sinha</b> <b>Dr. Balu Krishna Sasidharan Nair</b>
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

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### 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	<b>Mrs. Sadhana Kannan</b>
10:15 am - 11:00 am	May I help you? - Workshop on advanced tools to assist research publication
Speaker	<b>Dr. Pankaj Kumar Panda</b>
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	<b>Dr. Pankaj Kumar Panda</b>
11:50 am - 12:30 pm	But ethics first - An open discussion on responsible conduct of research in cancer
Moderator	<b>Dr. Kumar Prabhash</b>
Panelists	<b>Dr. Sudhir Nair</b> <b>Dr. Sarbani Laskar</b> <b>Dr. Sachin Punatar</b> <b>Ms. Deepa Ramani</b>
01:00 pm - 02:00 pm	Lunch
02:00 pm - 04:00 pm	<b>Protocol Presentations, Award Declaration &amp; Closing Remarks</b>

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RWE/  
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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**

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