

Federation of Asian Radiation  
Oncology Research Network



PANACEA

Pfizer ACTREC National Workshop on  
DATA ANALYSIS & CLINICAL RESEARCH

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# WORKSHOP ON CLINICAL RESEARCH AND PROTOCOL DEVELOPMENT



Real World Evidence



Artificial Intelligence



Clinical Trials



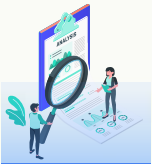
Statistics



Clinical Research



Publications



Study Designs



Data Analysis

**SAVE THE  
DATE**

**VIRTUAL WORKSHOP**

**11<sup>th</sup> - 12<sup>th</sup> & 18<sup>th</sup> - 19<sup>th</sup> August 2023**

**Program Director**

**Dr. Supriya Chopra**

**Program Coordinators**

**Dr. Jayant Goda**

**Dr. Vikram Gota**

**Steering Committee**

**Dr. Sudeep Gupta**

**Dr. S. K. Shrivastava**

**Dr. J. P. Agarwal**

**Dr. Yasushi Nagata**

**Dr. Mayang Permata**

**Dr. Manoj Gupta**

**Dr. Rajesh Vashistha**

**Dr. S. N. Senapati**

**Dr. V. Srinivasan**

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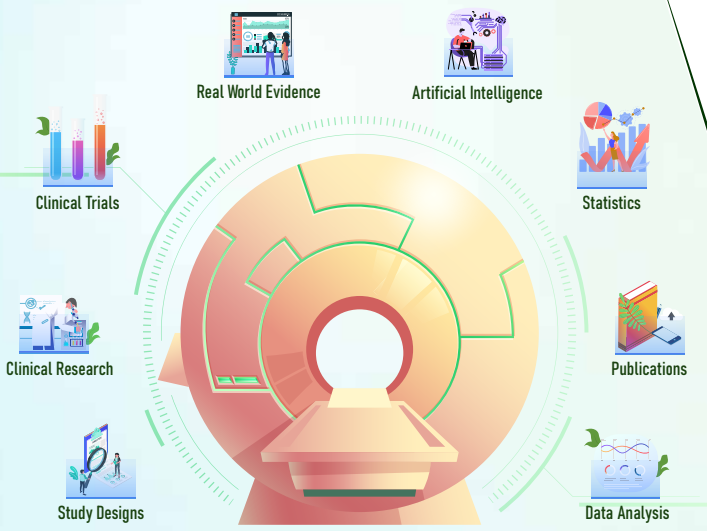
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### Eminent Faculties

#### INTERNATIONAL

Dr. May Abdel Wahab  
Dr. Yasushi Nagata  
Dr. Imjai Chitapanarux  
Dr. Sue Yom  
Dr. Yuta Sekino  
Dr. Mei Ling Yap  
Dr. Gilberto Lopes  
Dr. Tomoaki Tamaki  
Dr. Sajida Naseem

Dr. Asghar H. Asghar  
Dr. Humera Mahmood  
Dr. Mayang Permata  
Dr. Kanyarat Katanyoo  
Dr. Manuel Lopez  
Dr. Ma Than Than Shwe  
Dr. David Tan  
Dr. Warren Bacorro

#### NATIONAL

Dr. Sudeep Gupta  
Dr. Supriya Chopra  
Dr. Bhawna Sirohi  
Dr. Jayant Goda  
Dr. Vikram Gota  
Dr. Sangeeta Desai  
Dr. Indranil Mallik  
Dr. Sarbani Laskar  
Dr. Sadhana Kannan  
Dr. Mahesh Iyer  
Dr. JP Agarwal  
Dr. Shyam Kishore S.  
Dr. Manoj Gupta

Dr. Rajesh Vashistha  
Dr. Senthil Rajappa  
Dr. Surendra Senapati  
Dr. Tejpal Gupta  
Dr. Vedang Murthy  
Dr. V Srinivasan  
Dr. Akash Pawar  
Dr. Madhu Sairam  
Dr. Shwetabh Sinha  
Dr. Bhawana Rai  
Dr. Ajeet Gandhi  
Dr. Anuj Kumar  
Dr. Prachi Mittal

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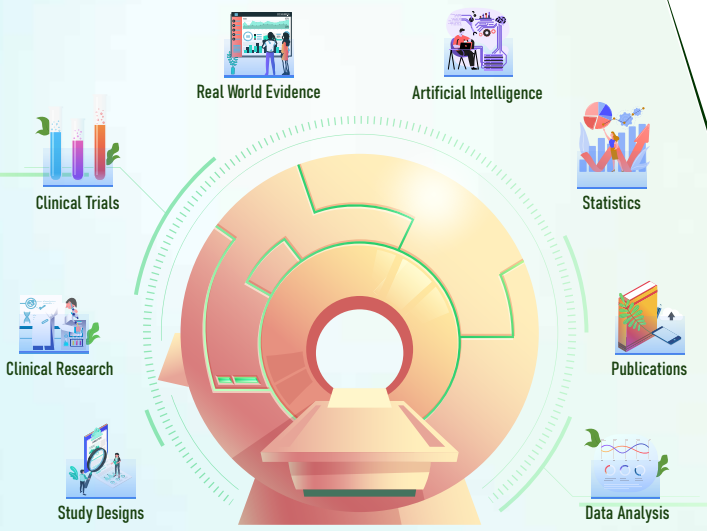
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11<sup>th</sup> - 12<sup>th</sup> & 18<sup>th</sup> - 19<sup>th</sup> August 2023

### Welcome Note

Dear Colleagues,

On behalf of the organizing committee, we are pleased to extend an invitation to all Asian oncologists for the upcoming workshop on clinical research and protocol development.

The workshop will be hosted virtually, allowing attendees from across Asia to participate conveniently. The course is scheduled to take place on two weekends (Friday/Saturday) as a 3-hour per-day module. Please mark 11<sup>th</sup>, 12<sup>th</sup>, 18<sup>th</sup> and 19<sup>th</sup> of August 2023.

This workshop is specifically tailored for oncologists in their early and mid-career levels, providing them with a comprehensive yet practical approach to learn about various aspects of clinical research and protocol development from leading experts in the field.

The workshop is a unique opportunity to develop your research ideas into a full-fledged protocol through engaging lectures and interactive breakout sessions. The lecture sessions will cover an array of topics, such as developing a research question, designing a clinical study, drafting a protocol, comprehending biostatistics, and executing clinical trials.

The workshop coordinators will select the eight best research ideas for in-depth development, and attendees will have the chance to discuss their ideas with leading experts and finalize their protocols.

Upon successful registration, participants will receive an email containing a link to join the workshop, as well as an optional concept note submission link. Whilst submitting a concept note is not mandatory, participants are encouraged to do so, as it will enhance their overall experience during the lectures.

Our goal is to provide a one-of-a-kind opportunity for aspiring oncologists to learn about clinical research and protocol development. We are committed to helping young professionals establish a solid foundation in these essential principles.

We look forward to welcoming you.

Regards,

**Dr. Supriya Chopra**

Research Committee Chair, FARO  
Professor, Radiation Oncology  
ACTREC, Tata Memorial Centre,  
Mumbai

**Dr. Jayant Goda**

Professor, Dept. of  
Radiation Oncology, ACTREC,  
Tata Memorial Centre,  
Mumbai

**Dr. Vikram Gota**

Professor & Officer-in-charge,  
Dept. of Clinical Pharmacology,  
ACTREC,  
Mumbai

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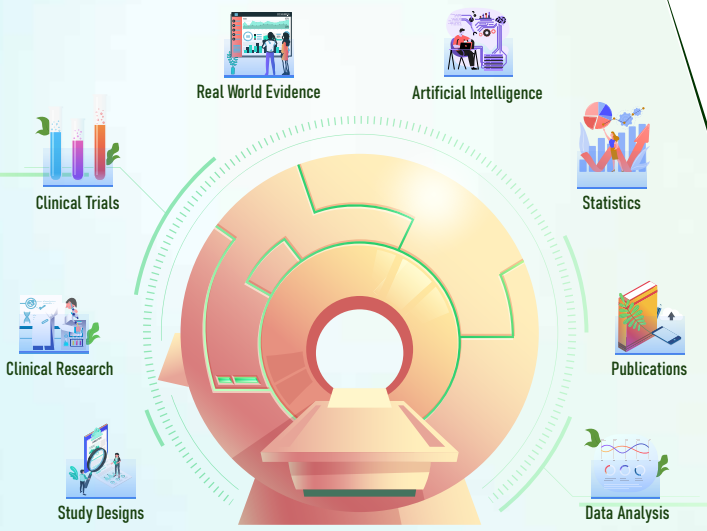
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11<sup>th</sup> - 12<sup>th</sup> & 18<sup>th</sup> - 19<sup>th</sup> August 2023

### Highlights

Workshop for early career oncologists on clinical research and protocol development

Course is divided into two interactive modules

8 Prospective protocols will be selected for complete protocol development

Conveniently scheduled over two weekends for all Asian regions, 3 hours each Friday/Saturday

Eminent national and international faculties

Free Registration

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# WORKSHOP ON CLINICAL RESEARCH AND PROTOCOL DEVELOPMENT

11<sup>th</sup> - 12<sup>th</sup> & 18<sup>th</sup> - 19<sup>th</sup> August 2023

**Scientific Program**

**Day 1 | 11<sup>th</sup> August**

Time	Topic
(IST) 10:30 am - 10:35 am (BKK) 12:00 pm - 12:05 pm (JST) 02:00 pm - 02:05 pm	Opening remarks Speaker: <b>Dr. Yasushi Nagata, Dr. Sudeep Gupta, Dr. Shyam Shrivastava</b>
(IST) 10:35 am - 10:45 am (BKK) 12:05 pm - 12:15 pm (JST) 02:05 pm - 02:15 pm	The Vision of FARO: Research and Leadership development programme Speaker: <b>Dr. Tomoaki Tamaki, Dr. Imjai Chitapanarux</b>
<b>SESSION-1 INTRODUCTION TO CLINICAL RESEARCH AND PROTOCOL DESIGN</b>	
<b>Session Coordinator : Dr. Jayant S Goda</b>	
<b>Chairpersons : Dr. Rajesh Vashistha, Dr. Yasushi Nagata (FARO)</b>	
(IST) 10:50 am - 11:15 am (BKK) 12:20 pm - 12:45 pm (JST) 02:20 pm - 02:45 pm	What is a Big Idea: Introduction to Protocol Writing Speaker: <b>Dr. Supriya Chopra</b>
(IST) 11:20 am - 11:45 am (BKK) 12:50 pm - 01:15 pm (JST) 02:50 pm - 03:15 pm	Framing a research question Hypothesis, Objectives and Aims Speaker: <b>Dr. Mayang Permata</b>
(IST) 11:45 am - 12:00 pm (BKK) 01:15 pm - 01:30 pm (JST) 03:15 am - 03:30 pm	Mini Break
<b>Chairpersons : Dr. J P Agarwal, Dr. Imjai Chitapanarux</b>	
(IST) 12:00 pm - 12:30 pm (BKK) 01:30 pm - 02:00 pm (JST) 03:30 pm - 04:00 pm	Study designs in clinical research Case-control studies & Cross-sectional studies and cohort studies Speaker: <b>Dr. Kanyarat Katanyoo</b>
(IST) 12:30 pm - 13:00 pm (BKK) 02:00 pm - 02:30 pm (JST) 04:00 pm - 04:30 pm	Phase I trial design in radiation oncology or combination drugs Speaker: <b>Dr. Yuta Sekino</b>
(IST) 01:00 pm - 01:15 pm (BKK) 02:30 pm - 02:45 pm (JST) 04:30 pm - 04:45 pm	Q & A <b>All faculty</b>

**Selected concept development proposal will move to breakout sessions.  
End of session for other participants**

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**Scientific Program**

**Day 1 | 11<sup>th</sup> August**

Time	Topic
(IST) 02:00 pm - 04:00 pm	Protocol development
(BKK) 03:30 pm - 05:30 pm	Protocol writing: Background/Rationale, gaps in knowledge, Framing a research question
(JST) 05:30 pm - 07:30 pm	<b>Breakout Session in small groups with designated mentors</b>

**Coordinators for Protocol Development: Dr. Jayant S Goda, Dr. Vikram Gota**

**Faculty Protocol Development/Breakout Rooms :**

**Dr. Indranil Mallik, Dr. Sadhana Kannan, Dr. Mahesh Iyer, Dr. Warren Bacorro, Dr. Ma Than Than Shwe, Dr. Asghar H. Asghar, Dr. Sajida Naseem, Dr. Senthil Rajappa, Dr. Shwetabh Sinha, Dr. Anuj Kumar, Dr. Prachi Mittal, Dr. Akash Pawar, Dr. Madhu Sairam, Dr. Bhawana Rai, Dr. Ajeet Gandhi**

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Scientific Program

Day 2 | 12<sup>th</sup> August

Time

Topic

### SESSION-2 INTRODUCTION TO STUDY DESIGNS

Session Coordinator: Dr. Jayant S Goda

Chairpersons : Dr. V Srinivasan, Dr. Mayang Permata

(IST) 10:45 am - 11:15 am  
(BKK) 12:15 pm - 12:45 pm  
(JST) 02:15 pm - 02:45 pm

Phase-II trial designs: Practical Design  
and Clinical Conduct  
Speaker: **Dr. Vikram Gota**

(IST) 11:20 am - 11:45 am  
(BKK) 12:50 pm - 01:15 pm  
(JST) 02:50 pm - 03:15 pm

Phase-III study designs  
(Superiority, Non-Inferiority and Adaptive Designs)  
Speaker: **Dr. Indranil Mallik**

(IST) 11:45 am - 12:00 pm  
(BKK) 01:15 pm - 01:30 pm  
(JST) 03:15 pm - 03:30 pm

Mini Break

Chairpersons : Dr. Manoj Gupta, Dr. Manuel Lopez

(IST) 12:00 pm - 12:30 pm  
(BKK) 01:30 pm - 02:00 pm  
(JST) 03:30 pm - 04:00 pm

How to write a study protocol  
Speaker: **Dr. Sarbani Laskar**

(IST) 12:30 pm - 13:00 pm  
(BKK) 02:00 pm - 02:30 pm  
(JST) 04:00 pm - 04:30 pm

How to perform a meta-analysis  
Speaker: **Dr. Sadhana Kannan**

(IST) 01:00 pm - 01:15 pm  
(BKK) 02:30 pm - 02:45 pm  
(JST) 04:30 pm - 04:45 pm

Q & A  
**All faculty**

End of Day 2 session.  
Selected participants for concept development  
will move to breakout sessions

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**Scientific Program**

**Day 2 | 12<sup>th</sup> August**

Time	Topic
(IST) 02:00 pm - 04:00 pm	Protocol development
(BKK) 03:30 pm - 05:30 pm	Aims & Objectives, endpoints
(JST) 05:30 pm - 07:30 pm	Methodology: Inclusion exclusion criteria Study procedures
	<b>Breakout session For protocol writing With mentors</b>

**Coordinators for Protocol Development: Dr. Jayant S Goda, Dr. Vikram Gota**

**Faculty Protocol Development/Breakout rooms : Dr. Indranil Mallik,  
Dr. Sadhana Kannan, Dr. Mahesh Iyer, Dr. Warren Bacorro,  
Dr. Ma Than Than Shwe, Dr. Asghar H. Asghar, Dr. Sajida Naseem,  
Dr. Senthil Rajappa, Dr. Shwetabh Sinha, Dr. Anuj Kumar, Dr. Prachi Mittal,  
Dr. Akash Pawar, Dr. Madhu Sairam, Dr. Bhawana Rai, Dr. Ajeet Gandhi**

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Scientific Program

Day 3 | 18<sup>th</sup> August

Time

Topic

## SESSION - 3 STATISTICS IN CLINICAL RESEARCH: IDEAL JOURNEY AND BUMPY ROADS

Session Coordinator: Dr. Vikram Gota

Chairpersons : Dr. Surendra Senapati, Dr. Bhawana Rai

(IST) 10:45 am - 11:15 am  
(BKK) 12:15 pm - 12:45 pm  
(JST) 02:15 pm - 02:45 pm

Real World Data: Design, Interpretation  
and Relevance in Asia  
Speaker: **Dr. Senthil Rajappa**

(IST) 11:15 am - 11:45 am  
(BKK) 12:45 pm - 01:15 pm  
(JST) 02:45 pm - 03:15 pm

Sample size estimation for Phase I-III studies  
Speaker: **Dr. Mahesh Iyer**

(IST) 11:45 am - 12:00 pm  
(BKK) 01:15 pm - 01:30 pm  
(JST) 03:15 pm - 03:30 pm

Mini Break

Chairpersons : Dr. J P Agarwal, Dr. Imjai Chitapananux

(IST) 12:00 pm - 12:30 pm  
(BKK) 01:30 pm - 02:00 pm  
(JST) 03:30 pm - 04:00 pm

Handling Statistical Analysis of Phase I-III trial designs  
Speaker: **Dr. Mahesh Iyer**

(IST) 12:30 pm - 01:00 pm  
(BKK) 02:00 pm - 02:30 pm  
(JST) 04:00 pm - 04:30 pm

Interpreting trials when they unexpectedly halt:  
Examples from the oncology world  
Speaker: **Dr. Sudeep Gupta**

(IST) 01:00 pm - 01:15 pm  
(BKK) 02:30 pm - 02:40 pm  
(JST) 04:30 pm - 04:45 pm

Q & A  
**All faculty**

End of Day 3 session.  
Selected participants for concept development will  
move to breakout sessions

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**Scientific Program**

**Day 3 | 18<sup>th</sup> August**

Time	Topic
(IST) 02:00 pm - 04:00 pm	Protocol development: Mentors
(BKK) 03:30 pm - 05:30 pm	Sample size estimation, writing the statistical analysis plan
(JST) 05:30 pm - 07:30 pm	<b>Breakout session For protocol writing With mentors</b>

**Coordinators for Protocol Development : Dr. Jayant S Goda, Dr. Vikram Gota**

**Faculty Protocol Development/Breakout Rooms : Dr. Indranil Mallik,  
Dr. Sadhana Kannan, Dr. Mahesh Iyer, Dr. Warren Bacorro,  
Dr. Ma Than Than Shwe, Dr. Asghar H. Asghar, Dr. Sajida Naseem,  
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Scientific Program

Day 4 | 19<sup>th</sup> August

Time

Topic

### SESSION - 4 NEXT GENERATION TRIALS IN CLINICAL ONCOLOGY

Session Coordinator: Dr. Supriya Chopra

Chairpersons : Dr. May Abdel Wahab, Dr. Tejpal Gupta

(IST) 10:45 am - 11:15 am  
(BKK) 12:15 pm - 12:45 pm  
(JST) 02:15 pm - 02:45 pm

Treatment Escalation or De-escalation study designs:  
Construct and results interpretation with examples from  
head and neck studies  
Speaker: **Dr. Sue Yom**

(IST) 11:15 am - 11:45 am  
(BKK) 12:45 pm - 01:15 pm  
(JST) 02:45 pm - 03:15 pm

Framing the study questions and protocols  
for access to care research  
Speaker: **Dr. Mei Ling Yap**

(IST) 11:45 am - 12:15 am  
(BKK) 01:15 pm - 01:45 pm  
(JST) 03:15 pm - 03:45 pm

Basket or Umbrella Trials in Oncology  
Speaker: **Dr. Gilberto Lopes**

(IST) 12:15 pm - 12:30 pm  
(BKK) 01:45 pm - 02:00 pm  
(JST) 03:45 pm - 04:00 pm

Mini Break

Chairpersons : Dr. Shyam Shrivastava, Dr. Yasushi Nagata

(IST) 12:30 pm - 01:00 pm  
(BKK) 02:00 pm - 02:30 pm  
(JST) 04:00 pm - 04:30 pm

Developing clinical protocols involving machine learning  
or Artificial Intelligence applications  
Speaker: **Dr. Jayant S Goda**

(IST) 01:00 pm - 01:25 pm  
(BKK) 02:30 pm - 02:55 pm  
(JST) 04:30 pm - 04:45 pm

Shaping Collaborative Research in Asian Region  
Speaker: **Dr. David Tan**

(IST) 01:25 pm - 01:45 pm  
(BKK) 02:55 pm - 03:15 pm  
(JST) 04:55 pm - 05:15 pm

Publishing real world data:  
Insights from Journal of Global Oncology  
Speaker: **Dr. Gilberto Lopes**

(IST) 01:45 pm - 02:30 pm  
(BKK) 03:15 pm - 04:00 pm  
(JST) 05:15 pm - 06:00 pm

Panel Discussion: Potential strategies for developing  
sustainable health research capacity in Asia  
Moderator: **Dr. Bhawana Sirohi**  
Panelists: **Dr. May Abdel Wahab, Dr. Imjai Chitaparanux,  
Dr. J P Agarwal, Dr. Vedang Murthy, Dr. David Tan,  
Dr. Sudeep Gupta, Dr. Humera Mahmood**

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Scientific Program

Day 4 | 19<sup>th</sup> August

Time	Topic
IST) 02:30 pm - 02:50 pm (BKK) 04:00 pm - 04:20 pm (JST) 06:00 pm - 06:20 pm	Building Centralised Biobanks in Asia: Leveraging Bioresource for Collaborative Research Speaker: <b>Dr. Sangeeta Desai</b>
(IST) 02:50 pm - 03:00 pm (BKK) 04:20 pm - 04:30 pm (JST) 06:20 pm - 06:30 pm	Q & A <b>All faculty</b>
(IST) 03:00 pm - 03:15 pm (BKK) 04:30 pm - 04:45 pm (JST) 06:30 pm - 06:45 pm	<b>Valedictory function</b>

## Conference Secretariat & Event Management

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Dr. Rohan Gupta

Email : [rrcg.drrohan@gmail.com](mailto:rrcg.drrohan@gmail.com)

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