

《Event Information》

The 2nd ARISE-PMDA Joint symposium for Asian Clinical Trials

" How to collaborate as one Asia"

Date and Time : July 20, 2023, 13:00 to 18:00 (Japan time)

Event Type : Hybrid meeting

Registration Fee : Free ([Pre-registration is required](#))

National Center for Global Health and Medicine (NCGM) and Pharmaceuticals and Medical Devices Agency (PMDA) will hold the "The 2nd ARISE-PMDA Joint symposium for Asian Clinical Trials "How to collaborate as one Asia" from 13:00 to 18:00 on Thursday, July 20.



Since 2020, NCGM has been supported by the "Project for Establishment of Network of Clinical Research and Clinical Trials in Asia" of the Japan Agency for Medical Research and Development (AMED). Consequently, the NCGM has launched [the ARO Alliance for ASEAN and East Asia \(hereinafter ARISE\)](#) in December 2021, with the aim to promote global clinical trials collaboration in Asia.

To conduct high-quality multi-regional clinical trials that comply with regulations and to accelerate regulatory approval in Asia, sustainable cooperation between academia and regulatory authorities in each country is essential. In the continuity of the efforts to promote regulatory harmonization in Asia, the 2nd joint ARISE-PMDA symposium will be held in Tokyo. This symposium is an opportunity to understand what efforts are needed from Academia, Industry, and Regulatory bodies to accelerate first-patient-in and regulatory approvals in Asia.



Keynotes will be presented by the NCGM, PMDA, and CEPI (The Coalition for Epidemic Preparedness Innovations) on "Latest regulatory strategy in medical research and development. "Following the keynotes presentation, there will be three sessions and a panel discussion at the end. Experts from academia, regulatory authorities from Japan and other Asian countries will share the insights and experiences.

In the first session, "Regulatory Issues surrounding clinical trial in Asia", experts will share about their experiences in dealing with the regulatory authorities.

In the second session, "First-Patient-In (FPI) in clinical trials in Asia", the exchange will be on how to accelerate FPI based on academia and industry experiences, whilst from the regulatory authority efficient process for Investigational New Drug review will be presented.

In the third session, "Utilization of new tools & approaches in clinical trials", speakers will introduce their experience in developing new trials design and the implementation of decentralized clinical trials. An experience from the REMAP-CAP trial that used a novel and innovative trial design will be introduced in this session.

The panel discussion will be held among the invited experts on the theme "How academia, regulators and industry can work together to address obstacles to accelerate FPI and approval in Asia".

The symposium is hoped to be a forum to build continued communication between different stakeholders of clinical trials conduct in Asia particularly between regulatory authorities, sponsors, researchers and sites. Participation to this symposium is free of charge. However, pre-registration is required. We are looking forward to your participation.

The overview of the 2nd ARISE-PMDA Joint symposium for Asian Clinical Trials is as follows.

The 2nd ARISE-PMDA Joint symposium for Asian Clinical Trials "How to collaborate as one Asia"

Date and Time : July 20, 2023, 13:00 to 18:00 (Japan time)

Event Type : Hybrid meeting

Venue: BELLESALLE Jinbocho Annex, Tokyo, JAPAN (*)

2-36-1 Jinbocho, Kanda, Tokyo 101-0051

(Access)

2-minute walk from A2 exit of Jinbocho station (Hanzomon line, Shinjuku line, Mita line)

5-minute walk from No.5 exit of Kudanshita station (Hanzomon line, Tozai line, Shinjyuku line)

8-minute walk from west exit of Suidobashi station (JR line)

(*) Pre-registration is required. Registration will be closed when we reach the maximum or full capacity of the venue.

Language: Simultaneous Interpretation (Japanese and English)

Co-organized : National Center for Global Health and Medicine (NCGM),
Pharmaceuticals and Medical Devices Agency (PMDA)

Sponsors : ARISE Member Institutes,
Japan Agency for Medical Research Department (AMED),
Japan International Cooperation Agency (JICA)

Supporter: Japan Pharmaceutical Manufacturers Association (JPMA)

For more information or registration, please go to the link below.

<https://arise.ncgm.go.jp/en/activities/symposium2023/index.html>

Registration deadline: July 19 2023 at 18:00 in Japan Time

★Contact information for the event

The 2nd ARISE-PMDA Joint symposium for Asian Clinical Trials

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★Contact information for the organizer

ARISE Secretariat

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