

ARISE Asian clinical trial platform NEWSLETTER

New organization: Japan Institute for Health Security



Japan Institute for Health Security

On April 1, 2025, the Japan Institute for Health Security (JIHS) will be established through the merger of the National Center for Global Health and Medicine (NCGM) and the National Institute of Infectious Diseases (NIID). This new expert organization will provide scientific expertise to the Cabinet Agency for Infectious Disease Crisis

Management and Infectious Diseases Control Division, Ministry of Health, Labour and Welfare, with the main following functions:

1. Strengthening the collection and evaluation of data on infections in Japan and overseas (Center of Intelligence);
2. Establishing a platform for the promotion of research and development (Excellence of R&D);
3. Forming the core of the clinical trial network in the region (Chief of clinical trials network);

JIHS will take over NCGM's function of promoting multi-regional clinical research and clinical trials and strengthen its function to be the Chief of the Clinical Trials Network.

Message from Dr. Norihiro Kokudo

President to be, of the new organization Japan Institute for Health Security

We at the NCGM will hold a deep gratitude to our ARISE members and partners for their contributions and support to its history and journey. This spirit of collaboration and continued trust inspires us to succeed together.

From April 2025, our organization will carry a new name: the JIHS, shaped by the legacies of NCGM and the NIID, both renowned institutions for their expertise in infectious diseases. As we embrace this new chapter, the enduring foundation of these two institutions will guide us toward a future defined by excellence and innovation in health security.

One of JIHS's core missions is to establish a core clinical trial network within Japan and ultimately expand its reach to high-quality international clinical

trials. With its network of academic research organizations, ARISE is uniquely positioned to play a crucial role in achieving this goal.

The 3rd ARISE Annual Meeting was successfully organized in November 2024, and it has clearly demonstrated ARISE's dedication to advancing clinical research in the region. Moving forward, JIHS and ARISE will intensify efforts to strengthen collaboration with the current as well as prospective research organizations.

Thank you for your unwavering support.



Editorial

Discover What's News?

This edition highlights key discussions and outcomes from the successful 3rd ARISE Annual Meeting held in Bangkok, Thailand, November 21st-22nd and announces important upcoming event.

Stay tuned for more updates and opportunities to engage with the ARISE network.

3rd ARISE Annual Meeting



The 3rd ARISE Annual Meeting on “Vaccine Trials for Pandemic Preparedness in the ARISE Network”, held in Bangkok on November 21-22, was co-hosted by the Faculty of Medicine Siriraj Hospital, Mahidol University and the NCGM.

All Steering Committee members and their representatives; ARISE members; leaders from the Faculty of Medicine Siriraj Hospital; and guests from the Embassy of Japan in Thailand, the Japan Ministry of Health, Labour and Welfare, the Japan Pharmaceutical and Medical Devices Agency Asia

Office (PMDA), the Japan Agency for Medical Research and Development (AMED) Project Supervisor, the National Cancer Center (NCC) Hospital Asia Office, and several CROs participated in this important activity of the network.

The agenda of the meeting was as follows:

- Steering Committee Meeting
- General Assembly
- Vaccine Workshop
- 5th Symposium and Joint Siriraj-NCGM Symposium



Participants attending the 3rd ARISE Annual Meeting in Bangkok, Thailand. Photo by Siriraj Institute of Clinical Research (SICRES).

Steering Committee Meeting



Steering Committee members gathered for the 3rd ARISE Annual Meeting in Bangkok, Thailand. Photo by SICRES.

The Steering Committee members meet in person once a year to discuss important issues and determine the direction of the network.

Several topics related to improving clinical trials in the region were addressed.

Importantly, the Steering Committee members reached a consensus on the formation of the **“Investigators Group”**.

The Investigators Group will consist of infectious disease experts in the network, working collaboratively

to identify regional research needs and develop research proposals to be implemented by and within the network. It will be announced at the 18th NCGM International Infectious Diseases Forum in February 2025.

In addition, the Steering Committee members recognized the need to expand the network to include other research institutions.

Further actions will be undertaken by the Secretariat to formalize the decisions.

General Assembly Meeting

The General Assembly Meeting took place immediately after the Steering Committee Meeting, beginning with a warm opening address from Prof. Dr. Apichat Asavamongkolkul, followed by remarks from ARISE Chief Representative, Dr.

Hideyo Miyazaki (NCGM) and Assoc. Prof. Dr. Winai Ratanasuwan (SICRES).

Dr. Yasuo Iimura (MHLW, Online), Dr. Yoichi Nakanishi (AMED, Online), and Dr. Jun Kitahara (PMDA) also delivered messages. Representatives

from our 14 ARISE Network member institutions, including Dr. Daisuke Tokita, director of the Department of International Trials at NCGM, shared updates on their clinical trial activities.

The Assembly concluded with an introduction of the ICR Web Training Program from Dr. Mitsumi Terada, representative of the Asian Partnership Office at the NCC Hospital Asia Office.



Dr. Hideyo Miyazaki and Prof. Apichat Asavamongkolkul delivered their speeches at the General Assembly Meeting. Photo by SICRES.



Dr. Daisuke Tokita presented the clinical trial activities of NCGM. Photo by SICRES.

Vaccine Trial Workshop

The workshop was held during the 3rd ARISE Annual Meeting, which focused on a vaccine trial conducted during the Public Health Emergency of International Concern (PHEIC). It aimed to identify actionable strategies and best practices for conducting effective vaccine trials from various countries' perspectives, foster collaboration and information sharing, and further explore how the insight from the trials presented can be applied in practice when conducting vaccine trials at institutions participating in ARISE.

Mr. Naoki Tomotsugu opened the session with an overview of the study's background and major

challenges throughout the trial. Participants were divided into two groups to discuss the specific challenges related to the study design and regulatory aspects of the real-world trial. The discussion also highlighted potential challenges and opportunities for future vaccine trials within the ARISE network.

The workshop enabled active discussions and exchange of ideas from varied perspectives. More importantly, it concluded with a consensus acknowledging the opportunity at hand for joint projects and highlighted the importance of fostering collaboration while promoting knowledge sharing among ARISE network members.



Prof. Kulkanya led the group discussion while Dr. Suvimol took notes. Photo by SICRES.



Assoc. Prof. Winai led the discussion of the other group. Photo by SICRES.

Joint SIRIRAJ-NCGM Symposium 5th NCGM/CCS/DIT Symposium on Clinical Research and Trials

The symposium was held as part of the 3rd ARISE Annual Meeting agenda, co-organized by SICRES and NCGM. It forms part of the capacity building program of the ARISE network with the purpose of sharing information and discussing on how to overcome challenges in infectious diseases trials. The theme for this year focused on vaccine trials: “Challenges and Solutions in Vaccine Trial Implementation: Practical Strategies in Achieving Optimal Outcomes”.

A keynote speech was delivered by Assoc. Prof. Winai, followed by presentations from four speakers and concluded with a panel discussion. Around 200 participants, both onsite and online, attended the

symposium. The presentations outlined the challenges in vaccine trials, including ethical considerations, recruitment challenges, logistic complexities, communication barriers, and public perceptions. It was emphasized that different approaches will be needed to resolve challenges unique to each country. Moreover, to ensure quality, it is important to stay abreast of international standards, such as the recent release of the International Council for Harmonisation-Good Clinical Practice (ICH-GCP) (R3).

The symposium was successfully held and provided a better understanding of the current situation for vaccine trial implementation within the ARISE network.



Prof. Kulkanya presented the topic on “Patients engagement”. Photo by SICRES.



Dr. Sugiura (picture on the right) chaired the panel discussion. Pictured with him were panelists Assoc. Prof. Winai and Prof. Dr. Jarir. The other panelists included Prof. Kulkanya, Prof. Punnee, Dr. Isidro, Dr. Morino, and Dr. Takeshita. Photo by SICRES.

Secretariat Activities

The FERCAP in Nepal



Dr. Sifa introduced the ARISE network at the FERCAP.

Dr. Muchanga Sifa introduced the ARISE’s activities at the 24th Forum of Ethical Review Committees in the Asia and Western Pacific Region (FERCAP) held on November 24-26, 2024, in Kathmandu, Nepal. The theme, “Maximizing

Benefits through Responsible Conduct of Research,” gathered Ethical Committee members and researchers from the region to discuss updates on the safe conduct of clinical research and trials.

FERCAP is a project of the World Health Organization (WHO) Special Training and Research Program in Tropical Diseases (TDR), and it is a regional forum under the umbrella of the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER). Its mission is to improve and standardize the quality of ethical committees (ECs) in the Asia-Pacific region.

Nagasaki University, represented by Professor Kenji Hirayama, Chair of FERCAP, is one of the ARISE members.

The 18th NCGM International Infectious Diseases Forum

February 6, 2025





Theme

**Emerging and Imported Infectious Disease
– New Clinical Research Challenges in the ARISE Network –**

Emerging and imported infectious diseases could potentially trigger the next pandemic, making them a significant concern both in Japan and globally. In April 2025, the National Center for Global Health and Medicine (NCGM) will be restructured as the Japan Institute for Health Security (JIHS). This forum will discuss JIHS's approach to emerging infectious diseases and its utilization of ARISE (ARO Alliance for Southeast and East Asia), an Asian ARO network established by NCGM.

Here we will focus on mpox, dengue fever, and influenza, which have become significant concerns in the ARISE region in recent years. Experts from Japan and other countries will present and discuss trends, research, and treatment strategies for each of these diseases.

Program

Opening Remarks Dr. Norihiro Kokudo (NCGM, Japan)

Co-chairs: Dr. Wataru Sugiura (Center for Clinical Sciences, NCGM, Japan)
Dr. Norio Ohmagari (Disease Control and Prevention Center, NCGM, Japan)

1. JIHS's activities
Lecture 1: Measures Against Emerging Infectious Diseases by JIHS and Expectation for ARISE
Dr. Teiji Takei (Planning and Strategic Bureau, NCGM, Japan)

Announcement : ARISE Investigator's group (NCGM, Japan)

2. Recent Infectious Disease Concerns in Asia
Lecture 2: International Mpox Outbreaks and Trends in MCM Development
Dr. Mugen Ujiie (Disease Control and Prevention Center, NCGM, Japan)

Lecture 3: Update Mpox Epidemiology and Response, Thailand 2024
Dr. Thitipong Yingyong (Division of Epidemiology, Department of Disease Control, Ministry of Public Health, Nonthaburi, Thailand)

Lecture 4: Dengue and Arbovirus Infections in Asia:
Upcoming Challenges and Opportunities in Disease Control
Dr. Moi Meng Ling (Graduate School of Medicine, The University of Tokyo, Japan)

Lecture 5: Epidemiology and the Importance of Early Detection of Dengue in Indonesia: Past, Present and Future Prospect
Dr. Beti Ernawati Dewi (Department of Microbiology, Faculty of Medicine, Indonesia University, Indonesia)

Lecture 6: Development of Next-Generation Influenza Vaccines
Dr. Hideki Hasegawa (Research Center for Influenza and Respiratory Viruses, National Institute of Infectious Disease, Japan)

Panel discussion

Closing

*For attendees participating at the venue, a casual networking reception will be held following the forum.

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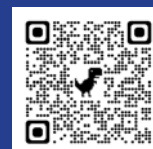
The 18th NCGM International Infectious Diseases Forum (IIDF) will be held on February 6, 2025, from 15:00 to 17:30 (JST) at Bellesalle Nishi-Shinjuku Hall in a hybrid format. A networking session is also scheduled from 17:30 to 18:00 (JST).

Centered on the theme, "Emerging and Imported Infectious Diseases - New Clinical Research Challenges in the ARISE Network," this forum will feature presentations from leading experts on Mpox, Dengue, and Influenza. An introduction to the JIHS will also be part of the program.

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ARISE



DIT

