ARISE NEWSLETTER

Introduction of New Department of International Trials (DIT)

April marked a significant milestone for the Department of International Trials (DIT). As our parent organization, the National Center for Global Health and Medicine transitioned to the Japan Institute for Health Security (JIHS), our department likewise entered a new phase. With the intensified commitment of the Japanese government to improving pandemic preparedness, our role and responsibilities in advancing clinical research and trials on infectious diseases have increased.

This transition has prompted the need for structural adjustments. The department was reorganized to include the Office of Clinical Research Management, led by Dr. Eriko Morino, to meet new expectations and deliver our services with greater efficiency. We now operate through four integrated offices: Project Planning, International Study Management, Project Administration, and Clinical Research Management. This decisive move



supports our vision of a more connected, agile, and collaborative platform for our valued members and partners.

Building on this momentum, we look forward to continuing this new direction together—learning from one another, syncing our efforts, and moving forward with renewed purpose arising in pursuit of a more secure and healthier tomorrow.

ARISE Secretariat

In fiscal year 2025, the ARISE Secretariat includes the following core members. We will continue to do our best to develop and advance international clinical research on infectious diseases, within the ARISE network and beyond!



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Mai Phuong LE MSc Vietnam Liaison Officer ARISE Research Coordinator



Sifa MUCHANGA MD. PhD ARISE Secretariat Coordinator ARISE Research Coordinator



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The 18th NCGM International Infectious Disease Forum

The 18th NCGM (currently, JIHS) International Infectious Disease Forum (IIDF) was held at Bellesalle Nishi-Shinjuku on February 6, 2025, in a hybrid format. This was the first in-person IIDF event in five years, and we had a record-breaking turnout with over 600 participants.

The theme of the forum was "Emerging and Imported Infectious Disease –New Clinical Research Challenges in the ARISE Network", focused on pathogens with potential to cause the next pandemic, an area of growing concern in Japan and globally. After the opening remarks from NCGM President, Dr. Norihiro Kokudo, the forum continued with six lectures facilitated by the Chairs, Dr. Wataru Sugiura (Center for Clinical Sciences) and Dr. Norio Ohmagari (Disease Control and Prevention Center [DCC]).

First, Dr. Teiji Takei (Planning and Strategic Bureau) introduced JIHS activities against emerging infectious diseases and outlined expectations for ARISE. The forum also addressed recent issues related to mpox, dengue fever, and influenza within the ARISE region. It featured presentations on trends, research, and treatment advancements in their respective countries by Dr. Mugen Ujiie (DCC), Dr. Thitipong Yingyong (Ministry of Public Health, Thailand), Dr. Moi Meng Ling (The University of Tokyo), Dr. Beti Ernawati Dewi (University of Indonesia, Indonesia), and Dr. Hideki Hasegawa (National Institute of Infectious Disease [currently, JIHS]). Moreover,

the establishment of the ARISE Investigator's Group, which will focus on an extended-spectrum β -lactamase (ESBL) study among ARISE members, was announced by Dr. Sho Saito (DCC) and Dr. Daisuke Tokita (DIT) during the forum.

The next Forum is planned in early 2026. The team is moving forward with the preparations.





The 18th IIDF Chairs and Speakers

International Health Seminar hosted by the Indonesian Ministry of Health

In February 2025, the Indonesian Ministry of Health invited ARISE to speak at a webinar titled: "Collaboration in Clinical Research: A Step Forward for the Implementation of Asia-Level Multicenter Research", hosted by Sardjito Hospital in Yogyakarta. Dr. Daisuke Tokita and Dr. Sifa Muchanga presented ARISE's initiatives and activities to about 40 Indonesian government hospitals online. Also joining the ARISE Secretariat is Dr. Jun Kitahara, Head of PMDA Asia office, and Mr. Masahiro Sasaki and Ms. Retno Windhiarti from JICA. Last year, the Indonesian Clinical Research Center (INA-CRC) was established to

coordinate clinical trials nationwide, especially in government-run hospitals. It will serve as a hub for overseas collaborators interested in conducting clinical trials in Indonesia. To make Indonesia an appealing destination for clinical trials, INA-CRC has introduced key reforms to the clinical trial registry, the national ethics committee, and the Material Transfer Agreement (MTA) process. With INA-CRC in place, clinical trial implementation in Indonesia is expected to become smoother and more transparent. Together, ARISE and INA-CRC are committed to advancing clinical trial collaboration in Asia.





The ARISE Secretariat, the PMDA Asia office, JICA, with INA-CRC team and Sardjito hospitals

ARISE Introduction Presentation for JPMA

On April 2, 2025, ARISE introductory session for member companies of the Japan Pharmaceutical Manufacturers Association (JPMA) was held in a hybrid format at the Japan Agency for Medical Research and Development (AMED) Headquarters (Chiyoda-ku, Otemachi). Approximately 30 online participants joined the session out of the 69 member companies (as of April 1, 2025).

Dr. Hideyo Miyazaki, Chief Representive of ARISE and Hospital Director of the NCGM, JIHS, gave an opening address highlighting the role of JIHS as a comprehensive science center for infectious diseases since its establishment, and emphasized that ARISE is a critically important initiative for preparedness from peacetime to

emergencies. Following this, Dr. Wataru Sugiura, Director General of the Center for Clinical Sciences, reported on how domestic clinical research/study support activities will be integrated with ARISE.

Dr. Daisuke Tokita, Secretary General of the ARISE and Director of Department of International Trials, introduced the following four core messages to raise awareness of ARISE among JPMA member companies. First, ARISE has been in operation for three years and has strengthened its collaboration with members from ASEAN countries. Second, the presence of liaisons from each country facilitates smooth negotiations. Third, ARISE conducts surveillance studies that provide basic information for clinical research/study/trials.

Fourth, as a national organization, ARISE has established relationships with ministries of health and regulatory authorities in ASEAN countries. During the subsequent discussion, questions were raised regarding how ARISE will collaborate with domestic networks, the role ARISE will play in trial

management, and its track record to date. Each question was addressed, and in-depth discussions were held. This was a valuable opportunity to introduce what we are doing to JPMA member companies. We would like to express our gratitude to AMED for organizing this event.

Official Visits to Vietnam

In early 2025, the ARISE Secretariat conducted two official visits to Vietnam to introduce the newly established organization, Japan Institute for Health Security (JIHS), and explore potential collaboration in infectious disease research and clinical trials with the Vietnamese institutions.

In February 2025, the team, Dr. Daisuke Tokita, Dr. Kathryn Effendi, and Ms. Mai Phuong Le, visited Hanoi Medical University (HMU), and met with Assoc. Prof. Kim Bao Giang, the Vice Rector of HMU. As Vietnam's oldest and most prestigious medical university, HMU expressed strong interest in joining the ARISE network and highlighted its strengths in infectious disease research and training.

In early April 2025, the delegation, Dr. Daisuke Tokita, Mr. Masato Ichikawa, Dr. Sifa Muchanga, and Ms. Mai Phuong Le, visited the University Medical Center at Ho Chi Minh City (UMC), one of the largest hospitals in southern Vietnam, and the Pasteur Institute in Ho Chi Minh City (PI HCM), a key institute in the national preventive medicine system. At UMC, they were warmly welcomed by Assoc. Prof. Nguyen Hoang Dinh, Vice Director, and at PI HCM, Assoc. Prof. Nguyen Vu Trung, Director. Both institutions expressed their interest in future collaboration. The delegation also took a visit to UMC hospital and the University of Medicine and Pharmacy (UMP).



ARISE Secretariat team visited HMU in February 2025



ARISE Secretariat team visited PI HCM in April 2025



ARISE Secretariat team visited UMC

PMDA-NCC-JIHS (ARISE)-JPMA Meeting

On April 17, a joint opinion exchange meeting between JIHS, NCC, PMDA, and JPMA was held in the conference room of the Japan Pharmaceutical Manufacturers Association (JPMA) in Nihonbashi. As a forum for dialogue among industry, government, and academia, participants included members of International Affairs Committee (Asia Committee) of JPMA, members of the Deliverables of Drug Evaluation Committee, researchers from National Cancer Center's ATLAS program, the Director of the PMDA Asia Office, and representatives from ARISE. Each center introduced their activities and discussed the potential for collaboration with pharmaceutical companies. The JPMA highlighted

the importance of addressing unmet medical needs in Asia, particularly by including Asia as a clinical trial region to strengthen Japan's drug development capabilities. They also expressed expectations for cost reduction in clinical study/trials compared to Europe and the United States, especially in ASEAN countries, and the high case accumulation for diseases prevalent in Asia. The discussions and considerations lasted over two hours, but more time was needed. It was confirmed that discussions would continue in the future. As an initial step toward continued collaboration, it was decided to distribute the ARISE newsletter regularly published by DIT, JIHS.

CRM Trial Connect 2025 in Malaysia

CRM Connect 2025, one of the largest clinical research conferences in Southeast Asia, was held on May 8–9, 2025, in Kuala Lumpur, Malaysia. Organized by Clinical Research Malaysia (CRM) under the Malaysian Ministry of Health, an ARISE member, this marked the fourth edition of the event.

With the theme "Accelerate Clinical Trials in Asia", the conference brought together a broad range of stakeholders, including clinical researchers, research institutions, regulatory authorities, sponsors, and CROs. Attracting over 500 participants annually, CRM Connect serves as a key platform for networking and knowledge exchange aimed at advancing clinical trials in Asia and strengthening international collaboration.

The opening ceremony of the conference was graced by the Prime Minister of Malaysia and the Minister of Health, who also serves as Chair of the Board of Directors of CRM. The venue was filled to capacity, and the atmosphere was vibrant as the "Investigator of the Year", "Study Site of the Year", "Sponsor of the Year", and "CRO of the Year" awards were presented. The signing of the MOU



Opening speech by the Prime Minister of Malaysia

with Kyushu University was also celebrated during the ceremony.

After the opening ceremony, the APAC Symposium was carried out. It highlighted key emerging regions for clinical trials in Asia, including the Greater Bay Area—centered on Hong Kong, Shenzhen, and Guangzhou—China's Belt and Road Initiative (BRI), and the launch of the Indonesian Clinical Research Center (INA-CRC). Clinical trial sites in Australia were also introduced. Among these, China's strong and growing presence in the region was particularly



Participants from JIHS, Chiba University, Osaka University, and PMDA

noteworthy.

Following this, a symposium featuring Regional Asian Clinical Trial Association (REACTA) was held. Established in 2013, REACTA is a regional clinical trial network comprising major research institutions from Japan, Korea, Taiwan, and Malaysia. The network aims to strengthen collaboration among AROs in Asia and is primarily led by Chiba University (Japan), Taipei Medical University (Taiwan), Dong-A University (Korea), and CRM (Malaysia). Its mission is to promote international collaborative research in areas that are often challenging for pharmaceutical companies to pursue independently, such as rare diseases and pediatric conditions.

Finally, a symposium was held by ATLAS, an international cancer clinical research network in Asia operated by the National Cancer Center. This marked the second consecutive year that the National Cancer Center has hosted a dedicated session within Connect.

The symposium focused on the importance of building an international clinical trial network in Asia, the expansion of its functions, and the future direction of its development.

Speakers included Dr. Mitsumi Terada from the National Cancer Center, who provided an overview of ATLAS; Dr. Darren Lim, head of the ATLAS Head and Neck Cancer Research Group at the National



Panel Discussion Speakers



ATLAS and JIHS members

Cancer Centre Singapore; Dr. Daisuke Tokita from JIHS, who provided an overview of ARISE.

Mr. Naoki Tomotsugu from JIHS took the stage during the panel discussion. In this discussion, the following three main items were discussed for the future development of the international clinical trial network in the Asian region.

- (1) On strengthening clinical research networks in Asia, it was emphasized that in addition to a robust structure tailored to the region, trust and collaboration built through "face-to-face relationships" have been firmly established among member countries. The network's ability to adapt flexibly to evolving situations was also highlighted as a key strength.
- (2) Regarding collaboration with pharmaceutical companies, the importance of academic partnerships

was underscored, particularly in areas where drug development is challenging for industry alone such as rare diseases and infectious diseases with fluctuating prevalence. The epidemiological study currently being prepared by ARISE was cited as a notable initiative to advance industry-academia collaboration.

(3) In reflecting on challenges and lessons from the COVID-19 pandemic, it was noted that remote monitoring and decentralized clinical trials (DCTs) gained momentum due to the difficulty of conducting on-site visits under travel restrictions. The pandemic also catalyzed international initiatives such as the "100 Days Mission", highlighting the urgency and potential of accelerating global clinical research during health emergencies.

Event Announcement

The 4th ARISE Annual Meeting





SAVE THE DATE: October 16-17, 2025

The 4th ARISE Annual Meeting, co-hosted by Nagasaki University and the Japan Institute for Health Security will take place on October 16-17 at the Nagasaki Stadium City. The meeting will be held in a hybrid format.

It will be the first ARISE Annual Meeting since the Japan Institute for Health Security was formed through the merger of the National Center for Global Health and Medicine and the National Institute for Infectious Diseases.

This year's theme is "Leveraging ARO capacity to strengthen the clinical trials ecosystem in the ARISE".

It was chosen in response to "Global action plan for strengthening clinical trials ecosystem", announced during the 2023 WHO Global Clinical Trials Forum. The Plan proposes several actions to overcome barriers such as poorly designed trials, redundant research efforts, inconsistent and inefficient clinical trial approval processes, and a lack of consistent patient and community engagement.

Several activities will be featured during the event such as the Symposium on Vaccine Research and Development. It is open to the public and will be held on the second day, October 17.

More details will come out soon.

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ARISE





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