

ARiSE&DIT Asian clinical trial platform NEWSLETTER

■ Introducing Our New Newsletter, ARiSE & DIT Newsletter!

Beginning with this volume, the newsletter will cover activities related not only to ARiSE but also to DIT. We hope you find it informative and enjoyable.

Visit of Dr. Norihiro Kokudo Marks the Name Change to JIHS Collaborating Office and Continued Partnership



Group photo of the UPM and JIHS teams in front of the wall mural depicting the building where the NCTTC and JIHS Collaborating Office are located

The renaming of the NCGM Collaborating Office to the JIHS Collaborating Office was marked by a brief gathering on July 21, 2025, at the National Clinical Trial and Translational Center (NCTTC) of the University of the Philippines Manila (UPM), where the office has been housed since its establishment in 2021.

Dr. Norihiro Kokudo, President of the Japan Institute for Health Security (JIHS) and Dr. Marissa Alejandria, Executive Director of the UPM-National Institutes of Health (UPM-NIH), jointly replaced the office signage, symbolizing the transition and continued collaboration between the two institutions.

It was attended by Dr. Lia Palileo-Villanueva, Director of NCTTC; Prof. Edwin Ruamero, Head of the Division of Quality Assurance of NCTTC; Dr.



Dr. Kokudo and Dr. Alejandria are seen holding the office signage and sharing smiles before its official replacement

Karl Evans Henson, Site Primary Investigator for the ABLE study; and their staff. The DIT team, led by its Director, Dr. Daisuke Tokita, was also present to witness the occasion. A group photo was taken to commemorate the event.

An International Multicenter Observational Study on Antimicrobial Susceptibility Study, ABLe Study, to Be Launched in the ARISE Network

During the third ARISE Annual Meeting, the Steering Committee decided to establish investigator groups. These groups bring together infectious disease experts who share an interest in a specific research topic.

The first group, focusing on antimicrobial resistance, has been established. This group has started to plan for a study that will

evaluate bacteremia caused by third-generation cephalosporin-resistant (3GCR) bacteria.

In preparation for implementing the study, the ARISE secretariat at JIHS visited the members' sites to assess the feasibility of the planned study. The discussions focused on the sites' potential for recruitment and their laboratory capacities.

Indonesia

Three institutions from Indonesia expressed their interest and support for the ARISE ESBL Observational Study, or also known as the ABLe study. At the ARISE 3rd Annual Meeting, the ESBL Investigator Group was officially launched. The ABLe study is the first fruit of this Investigator Group. The study is to demonstrate and to model the ARISE platform's readiness for future pandemic preparedness. Two Indonesian ARISE member institutions (the Faculty of Medicine at the University of Indonesia [FMUI] and the Mochtar Riady Institute

for Nanotechnology/Siloam Hospitals Group [MRIN/Siloam]) and one partner institution (the Sulianti Saroso Infectious Diseases Hospital) participated in the study. The ARISE Secretariat and the ABLe core study team visited Indonesia from May 13 to 17, 2025. All of the member institutions and partners welcomed the initiative and are eager to collaborate on the study. During the visit, the ARISE Secretariat also paid a courtesy visit to the Indonesian Clinical Research Center (INA-CRC), where they were greeted by the center's head, Dr. Indri Rooslamati.



1. The ARISE Secretariat and ABLe study PI with Prof. Wawaimuli (FMUI) and potential site PI
2. The ARISE Secretariat and ABLe study PI with Prof. Irawan (MRIN/Siloam) and potential site PI
3. The ARISE Secretariat and ABLe study PI with Dr. Vivi Setiawaty and potential site PI of the Sulianti Saroso Infectious Diseases Hospital
4. A courtesy visit to INA-CRC

Malaysia

ARISE member institutions from Malaysia greatly welcomed the ABLe study. Two sites were engaged for the ABLe study through a facility visit on September 1-2, 2025. The Clinical Research Malaysia (CRM) introduces Sungai Buloh Hospital which is a national hospital and one of the centers for infectious diseases in Malaysia. The second site is the University of Malaya Medical Center (UMMC) which also has the capacity to perform the whole genome sequencing for the study and has previous experience in similar study.



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1. The ARISE Secretariat and ABLe study PI with the Sungai Buloh study team
2. The ARISE Secretariat and ABLe study PI with the potential site PI and study team of the UMMC
3. Dr. Sho Saito, PI of the ABLe study explains the overview of the study to UMMC study team

Philippines

Regional site visits were conducted to engage with ARISE member institutions in the country. From July 21 to 24, 2025, the team visited Corazon Locsin Montelibano Memorial Regional Hospital (CLMMRH, Bacolod), the University of the Philippines Manila (UPM), and West Visayas State University (WVSU, Iloilo). Discussions focused on site feasibility, laboratory capacity, and sample logistics, and proved productive as the research teams on both sides reached a consensus, and sites reaffirmed their willingness and commitment to implement the study. Moreover, our professional camaraderie and collaboration are further strengthened.



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1. The team visited Corazon Locsin Montelibano Memorial Regional Hospital (CLMMRH)
2. The meeting with the University of the Philippines Manila (UPM)
3. The meeting with West Visayas State University (WVSU)

Thailand

On September 4, 2025, the ARISE Secretariat team, accompanied by the study's principal investigator, visited the Faculty of Medicine Siriraj Hospital, Mahidol University. They conducted discussions and a site visit with the local team, including the PI, co-investigators, Siriraj Institute of Clinical Research (SICRES) team, and laboratory staff.



1. Group photo in front of the SICRES
2. The meeting with SICRES team

Vietnam

From July 7 to 11, 2025, the ARISE Secretariat team together with members from the Disease Control and Prevention Center (DCC) visited the ARISE member institutions in Vietnam, including Bach Mai Hospital (BMH), Hanoi Medical University (HMU) in Hanoi and University Medical Center Ho Chi Minh City (UMC) in Ho Chi Minh city. During the visits, the research team and each institution discussed the feasibility questionnaire, explored the advantages as well as identified the challenges in each facility. The research team also conducted laboratory tours to gain deeper understanding of the current situation.



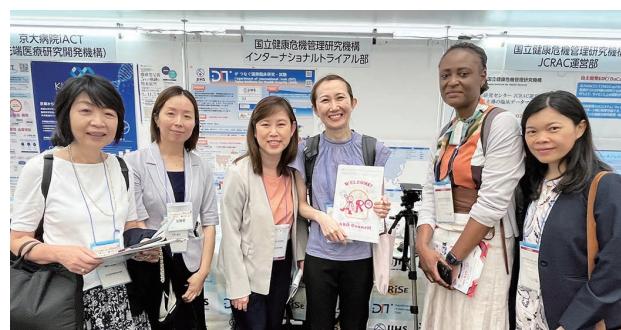
1. The team visited BMH 2. Visit to HMU 3. Visit to UMC

Booth Exhibition and Presentations at the 12th Annual Meeting of the ARO Council

The 12th Annual Meeting of the Academic Research Organization (ARO) Council was held at Chiba University's Inohana Campus in Japan on September 19 and 20, 2025. The ARO Council

was established to build a nationwide academic network, promote collaboration, and contribute to improving public health and the health of the nation through the realization of safer and more effective

medical care. The theme of this year's meeting was "Creating Together – Shaping Our Ideals." The DIT exhibited at a booth and presentations were given by DIT members: Dr. Tsukumi Tondokoro on "Overview of Epidemiological Research on Infectious Diseases in ASEAN Countries -Adenovirus and Enterovirus Infections-: EPIDEA Study Project" and Mr. Naoki Tomotsugu on "Success Factors in the Clinical Trial of the LC16m8 Mpox Vaccine in Colombia."



Attending DIT members in front of the DIT booth

ATLAS-ARISE-PMDA International Symposium 2025: Building a United Asian Clinical Trial Ecosystem



During the opening speech by Dr. Keizo Takemi



Session 3, organized by ARISE, chair and speakers



Session 5 chair and panelists

The "ATLAS-ARISE-PMDA International Symposium 2025" took place on October 3, 2025, in Bangkok, Thailand. Approximately 100 people attended, including representatives from the National Cancer Center, the JIHS, the Pharmaceuticals and Medical Devices Agency, Mahidol University, former Japanese Minister of Health, Labour, and Welfare, Dr. Keizo Takemi, the Embassy of Japan in Thailand, JICA, and other guests.

One of the key sessions was organized by the ARISE Secretariat and focused on accelerating infectious disease clinical trials within the network.

This session featured presentations on topics such as clinical trial digitalization, decentralized clinical trials, artificial intelligence, single institutional review boards, and ICH-E6 (R3). Strengthening Asia's clinical trial capabilities is imperative for preparing for future pandemics.

During the panel discussion, participants expressed their opinions on how to strengthen industry-academia-government collaboration to promote Asia-led clinical development. Support for regulatory harmonization and collaboration with patient organizations are also essential for establishing a robust clinical trial ecosystem in Asia.

Kick-off Meeting at Hai Phong University of Medicine and Pharmacy for the HIPOCAMP Study

The HBV unIversal vs Point Of Care-based Antiviral treatMent to Prevent mother-to child-

transmission (HIPOCAMP) study is a multi-country, cluster-randomized, non-inferiority trial planned

for implementation in four countries: Cameroon, Côte d'Ivoire, Togo, and Vietnam. Its aim is to compare two strategies for starting peripartum antiviral prophylaxis to prevent mother-to-child transmission of the hepatitis B virus (HBV).

JIHS is collaborating with Inserm-ANRS-MIE in France as the study sponsor for the Vietnam site, which is being conducted by Hai Phong University of Medicine and Pharmacy (HPMU). A pilot study to assess feasibility and select sites in Vietnam was completed last year by HPMU and the DIT team. Preparation for launching the main study has continued this year, including work on regulatory approvals and the monitoring plan.

To conduct the project's kick-off meeting, the DIT



DIT-JIHS and HPMU teams during the kick-off meeting

team (Dr. Daisuke Tokita, Dr. Kathryn Effendi, Ms. Mai Phuong Le, and Ms. Noriko Sakaguchi) visited HPMU in early September 2025. They were warmly welcomed by Associate Professor Pham Van Linh, Chairman of the University Council, HPMU and Professor Pham Minh Khue, Principal Investigator of the HIPOCAMP Study. We look forward to continuing the strong collaboration between all project partners.

Visits to the Ministries of Health for the Epidemiological Research on Infectious Diseases in ASEAN Countries -Adenovirus and Enterovirus Infections-

Epidemiological Research on Infectious Diseases in ASEAN Countries -Adenovirus and Enterovirus Infections- (EPIDEA) officially started in May 2025. This five-year research project is being conducted with the support of the Economic Research Institute for ASEAN and East Asia (ERIA), which serves as both the funder and partner. Together with ERIA team, the DIT EPIDEA team (Dr. Daisuke Tokita, Dr. Tsukumi Tondokoro, Dr. Kathryn Effendi, and Ms. Mai Phuong Le) conducted visits to Ministries of Health (MOHs) in the research targeted countries, Indonesia, Malaysia, Philippines, Thailand, and Vietnam, between June and August 2025. The objectives of the visits were to build a research network, to gather country insights, and to identify the country principal investigators (PIs)/experts. The team is currently holding follow-up meetings with MOHs and the identified country PIs/experts to develop the research protocol based on the findings from the visits.



The Ministry of Health, Indonesia



The Ministry of Health, Malaysia



The Department of Health, the Philippines



The Department of Public Health, Thailand



The Ministry of Health, Vietnam

JIHS Supporting a Clinical Study on the Effectiveness of a Japanese-Manufactured Mpox Vaccine in DRC, Funded by the Coalition for Epidemic Preparedness Innovations (CEPI)

The LC16m8 is a live-attenuated vaccine manufactured by KM Biologics. It is primarily licensed for smallpox prevention and has been proven safe and effective in Japan, even for individuals with well-controlled HIV. It is currently being evaluated during a vaccination campaign in the Democratic Republic of the Congo (DRC).

To contribute to the global effort to combat the mpox outbreak, which was declared a Public Health Emergency of International Concern (PHEIC), the Government of Japan donated over three million doses of the LC16m8 vaccine to the Government of the DRC, where the outbreak has heavily affected young people and other populations.

The JIHS is participating as a co-principal investigator in a study consortium that includes the International Vaccine Institute (IVI) as the sponsor and the Institut National pour la Recherche



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1. The consortium members in front of the INRB
2. Representatives from KM Biologics, JIHS, CEPI, and INRB at the opening ceremony

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Biomédicale (INRB) as the co-principal investigator.

The study will evaluate the safety and effectiveness of the LC16m8 vaccine for people aged one year and older (NCT07093489).

To this end, an opening ceremony and courtesy visits to the INRB and the National Institute for Public Health were held in Kinshasa, DRC, from July 14-17, 2025.

Courtesy Visit from ADVANCE-ID Team and Global Antibiotic Research and Development Partnership (GARDP) Japan

On July 28, the Advancing Clinical Evidence in Infectious Diseases (ADVANCE-ID) team, led by its director, Professor David Paterson, paid a courtesy visit to the JIHS.

ADVANCE-ID is a research network in Asia that conducts clinical research with a particular focus on antimicrobial resistance (AMR). The network aims to generate high-quality evidence to improve

the diagnosis and treatment of AMR.

Following introductions to their respective activities, objectives, research interests, and ongoing studies, the ADVANCE-ID and ARISE teams discussed collaboration goals, operational feasibility, and partnership opportunities.

There were a mutual recognition of shared interests and a willingness to collaborate further on the parts of both ARISE and ADVANCE-ID.



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1. Group photo with the ADVANCE-ID team
2. Dr. Wataru Sugiura, Director of CCS, presenting the Token of appreciation to Professor David Paterson

Event Announcement

Luncheon Seminar at the Annual Meeting of Japanese Society for AIDS Research: HIV/AIDS Management in Vietnam – From ARO Network in Asia

This special seminar will be organized by ARISE, initiated by JIHS, and featured Dr. Vo Hai Son, who is an expert in HIV and has in depth understanding about the HIV program in Vietnam.

The lecture will begin with an introduction to ARISE's activities in promoting clinical trials and research on infectious diseases, particularly its collaborative research with Vietnam and research support. Next, Dr. Vo Hai Son, Deputy Director of the Vietnam Administration

of Disease Prevention, the Vietnamese Ministry of Health, will have a presentation on HIV/AIDS program in Vietnam, particularly the implementation of HIV self-testing. He will highlight policy development and practical applications with support from WHO and the Global Fund. He will also share Vietnam's experience in mobilizing local communities to identify new HIV infections and link them to HIV care and treatment services.

The 19th JIHS Global Infectious Diseases Forum

Since 2018, DIT has organized NCGM International Infectious Diseases Forum (IIDF) to share the latest information on infectious diseases. Following the establishment of JIHS through the merger of NCGM and the National Institute of Infectious Diseases, IIDF has been renamed to JIHS Global Infectious Diseases Forum (GIDF).

GIDF will continue to serve as a platform for sharing, discussion and networking among industry, government, and academia on infectious disease and clinical research.

The next GIDF will take place on January 16, 2026 at Nihonbashi Hall in a hybrid format with the theme **“Facing Microorganisms that Cause Cancer—Opening New Horizons.”**

Various research findings on cancer have led to the development of preventive measures, diagnostic methods, and treatments for cancer. The next GIDF will focus on the latest findings on cancer associated with infectious diseases.

GIDF aims to increase interest in developing new preventive measures, diagnostic, and therapeutic drugs, as well as conducting clinical trials overseas for existing products, thereby promoting their implementation. To this end, we share information on the medical situation and challenges overseas, particularly in Southeast Asian countries, with international researchers and domestic pharmaceutical and medical device manufacturers.

More information will be available soon on our website.

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ARISE



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