

ARISE & DIT Asian clinical trial platform NEWSLETTER

The 4th ARISE Annual Meeting Entering the JIHS Era



The 4th ARISE Annual Meeting participants

The Fourth Annual Meeting, held on October 16-17 at Nagasaki University's Technology Innovation Campus and co-hosted by Nagasaki University and JIHS, focused on the theme "Leveraging ARO capacity to strengthen the clinical trials ecosystem in the ARISE." This meeting marked the first since the merger of the National Center for Global Health and Medicine and the National Institute for Infectious Diseases into the Japan Institute for Health Security.

This annual meeting provides an opportunity for the network's Steering Committee (SC) and all other members to gather, evaluate efforts, and

discuss future perspectives.

ARISE members are continuously engaged in improving the network and discussing strategies for the sustainable operation of collaborative research and trials for infectious disease management.

This year's meeting had 251 participants, both online and in person, from ARISE institutions and several partner organizations.

During the two-day gathering, participants immersed themselves in various activities, including the SC meeting, the general assembly, a visit to the BSL4 laboratory, a training workshop, and an international symposium, as described below.

ARISE Steering Committee Meeting

Representatives from all ARISE member institutes and ARISE partner institutions gathered on the first day of the ARISE Annual Meeting. The members shared the updates of the ARISE four

major working groups (WGs): Project Creation WG, Capacity Development WG, Operation WG, and Pandemic WG.

Furthermore, we are proud to share that Dr. Eva

Maria C. Cutiongco-de la Paz (University of the Philippines Manila, Philippines) and Prof. Kulkanya Chokephaibulkit (Siriraj Institute of Clinical Research, Faculty of Medicine Siriraj Hospital, Mahidol University, Thailand) have been recognized for their exceptional contributions and unwavering dedication to ARISE. Their commitment has made a meaningful and lasting impact on ARISE.

In appreciation of their continued support, they



Dr. Eva at the award ceremony



Dr. Kulkanya delivered a heartfelt video message

will remain part of ARISE as honorary members. We extend our heartfelt gratitude for their remarkable service and contributions.

ARISE General Assembly

The ARISE General Assembly was held following the steering committee meeting. After the welcome address by Professor Kenji Hirayama and Professor Naoki Hosogaya of Nagasaki University, co-host of the Fourth Annual Meeting, Dr. Hideyo Miyazaki, Chief Representative of ARISE and Hospital Director of the National Center for Global Health and Medicine gave the opening remarks.

During the opening ceremony, Dr. Norihiro Kokudo, President of the JIHS and General Advisor of the ARISE, emphasized that the JIHS serves as a hub for research and development, including clinical trials, through a robust network. He reassured the members that he will continue to support the network in achieving its objectives.

Dr. Teiji Takei, Director-General of the Bureau of Health Security and Management, Executive Director of Health Security and General Coordination at JIHS, spoke about JIHS's expectations for ARISE. Furthermore, Mr. Gai Jinnai from the Research and Development Policy Division, Health Policy Bureau at the MHLW, Professor Yoichi Nakanishi, ARISE Project Supervisor, and Dr. Mitsumi Terada from National Cancer Center Hospital also expressed their thoughts and support for ARISE.

The members provided updates and discussed the WHO's global action plan for strengthening the clinical trial ecosystem. This plan identifies four key barriers to generating clinical trial evidence for public health. The members then described the

barriers that limit their institutions' ability to create a conducive clinical trials ecosystem and shared their efforts to strengthen it. The result was that all the members shared the same problems to varying degrees, and that common efforts are needed.

Two new ARISE Institutions from Vietnam, Hanoi Medical University (HMU), and University Medical Center Ho Chi Minh City (UMC), were introduced.



1. Welcome address by Prof. Hosogaya 2. Dr. Miyazaki delivering the opening remarks
3. Dr. Kokudo warmly greeting the members and guests
4. Dr. Takei talking JIHS' expectations for ARISE 5 & 6. Dr. Miyazaki/Prof. Hirayama handing the ARISE Membership Plaque to Prof. NGUYEN/Dr. LE

Data Management Workshop: Strengthening Clinical Trial Ecosystem: Translating Insights and Competencies into Capacities

The Data Management Workshop opened the second day of the Annual Meeting. Designed through a shared consensus within the Capacity Development Working Group, the workshop responded to an identified need to strengthen data management competencies across the ARISE network.

The plenary presentations at the start of the workshop set the stage for the breakout sessions that followed.

Mr. Naoki Tomotsugu, Head of Project Planning at the Department of International Trials, presented key concepts in clinical data management, with particular emphasis on data quality.

Mr. Koji Kitajima, Manager of the Office of Clinical Data Management, shared JIHS's experience in building a sustainable clinical data management infrastructure. He introduced the JIHS-developed in-house EDC as a practical example.

Steering Committee members were assigned into two small groups. Dr. Daisuke Tokita, Director of the Department of International Trials, and Dr. Koji Todaka, Director of the Center for Clinical and Translational Research at Kyushu University Hospital, led the group discussions on common data management challenges at their institutions.

Online participants learned basic Case Report Form design through a guided mock case exercise.

The synthesis and reporting session concluded the workshop, drawing attention to persistent gaps in staff expertise, technical infrastructure, training availability, and EDC readiness. Taken together, the workshop demonstrated the value of structured, competency-based, and practice-oriented training, supported by active steering committee involvement in building a robust trial data management ecosystem across the ARISE network.



1. Presentation by Mr. Tomotsugu
2. Presentation by Mr. Kitajima 3. Group 1

Joint Nagasaki University – JIHS Symposium/6th JIHS/CCS/DIT Symposium on Clinical Research and Trials

The JIHS/CCS/DIT Symposium is a key part of ARISE's annual meeting. It focused on innovations, policy trends in vaccines, therapeutics, and diagnostics in Japan and overseas, while highlighting the strategies to strengthen international collaboration for infectious disease control in the region. This year's symposium, co-hosted with

Nagasaki University, is titled "the Joint NU-JIHS Symposium/6th JIHS/CCS/DIT Symposium on Clinical Research and Trials". The sessions, moderated by Prof. Kenji Hirayama and Prof. Naoki Hosogaya of Nagasaki University, brought together leading experts from Japan, Southeast Asia, Singapore, and the UK. Speakers presented



Symposium speakers

on Japan's policy trends in advancing infectious disease R&D, shared regional perspectives on clinical trials and vaccine development in Southeast Asia, and highlighted the importance of international research networks such as ARISE in strengthening global collaboration and evidence generation for infectious diseases.

ABLE Study Central Lab Visits

As part of the ABLe study, the JIHS research team—led by Dr. Daisuke Tokita, Director of the Department of International Trials and ARISE Secretary General, Dr. Sho Saito Principal Investigator, and Dr. Masahiro Suzuki representing the laboratory expert group from Fujita Health University, Japan—together with other team members, conducted visits to central laboratories

in Vietnam, Indonesia, and Malaysia in early January, 2026.

The objective of these visits was to hold in-depth discussions with the central laboratories regarding laboratory capacity and practical experiences on the implementation of whole genome sequencing (WGS) in each country's laboratory setting, as well as to conduct on-site laboratory visits.

ABLE Study Feasibility Visit to Bach Mai Hospital – Central Laboratory for Sequencing in Vietnam – on January 6, 2026

Bach Mai Hospital, one of the largest general hospitals in Vietnam, serves as the central laboratory for the ABLe study.

Assoc. Prof. Dao Xuan Co, Hospital Director, welcomed JIHS delegation and expressed his strong interest in strengthening collaboration with JIHS, particularly in the field of infectious diseases clinical research. The JIHS delegation then visited

the Microbiology Department and had a meeting with the laboratory staff. The discussion focused on Bach Mai Hospital's experience in implementing sequencing, including DNA extraction methods, sequencing platforms and procedures, quality control, and personnel capabilities. With nearly 9,000 outpatient visits per day, Bach Mai Hospital provided practical information on the operation of a

large-scale laboratory. The meeting concluded with mutual agreement on the sequencing plan, SOPs, and other related activities.

After the meeting with the Microbiology Department, the JIHS delegation also visited the Bach Mai Institute of Tropical Medicine and the Intensive Care Unit, where they observed the hospital workload as well as the management of patients with bacterial antimicrobial infections.



Assoc. Prof. Dao Xuan Co welcomed JIHS and Fujita Health University teams

ABLE Study Feasibility Visit to Sulianti Saroso Hospital – Central Laboratory for Sequencing in Indonesia

Three sites in Indonesia will participate in the ABLe study. Sulianti Saroso Infectious Diseases Hospital (IDH) is a government hospital that took the role of a national center for infectious diseases. Sulianti Saroso IDH is a partner member of the ARISE network. In the ABLe study, the hospital will be performing the sequence analysis for all



Group photo with Dr. Vivi and her team

isolates collected in Indonesia. On January 8, the ABLe study team, including JIHS team led by Dr. Daisuke Tokita and Fujita Health University team led by Dr. Masahiro Suzuki did a feasibility visit to the sequencing laboratory and research team led

by Dr. Vivi Setiawaty at Sulianti Saroso IDH. The discussion highlighted the need for shared SOPs for sequencing and opportunities for knowledge transfer WGS analysis by the Fujita Health University team who is responsible for WGS in the ABLe study.

ABLe Study Feasibility Visit to Universiti Malaya – Central Laboratory for Sequencing in Malaysia

In the ABLe study, Malaysia is one of the countries that will be performing their sequence analysis in their own country. Prof. Cindy Teh Shuan Ju's laboratory at Universiti Malaya will take responsibility as the central laboratory for sequencing. The ABLe study team, which consisted of the JIHS team and the Fujita Health University team, visited their facility on



Group photo with Prof. Cindy and her team

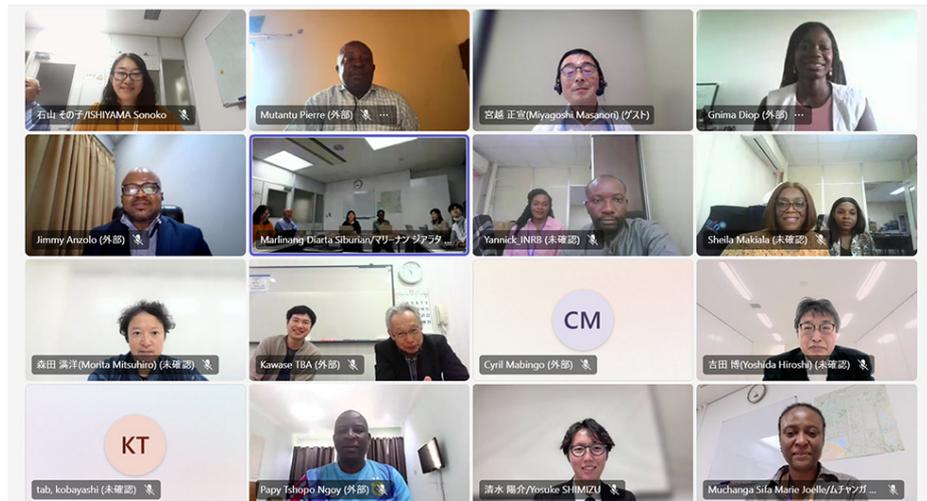
January 14. During the visit, Prof. Cindy introduced the ABLe study team to a private company who provided a sequencing analysis service. The company has been collaborating with Prof. Cindy on

other projects. The company can provide support to perform high-throughput sequencing if needed. Shared sequencing protocol and SOPs will be used for the ABLe study including in Malaysia.

Development of a Point-of-care In-Vitro Diagnostic (POC IVD) Test for Mpox DNA Detection

Japan Institute for Health Security (JIHS) collaborated with NIPRO CORPORATION and Tohoku Bio Array (TBA) to develop a point-of-care in vitro diagnostic (POC IVD) test for mpox. This project is part of JIHS active response to the mpox Public Health Emergency of International Concern (PHEIC), which the WHO announced in August 2024. The project was awarded a funding by the Global Health Innovative Technology (GHIT) Fund on August 21, 2025. The kit

detects mpox DNA and can differentiate between Clades I and II of MPXV in less than an hour without requiring scaled laboratory equipment. The kit is intended for use in limited resource settings such as low- and middle-income countries. An evaluation study will be performed in the Democratic Republic



Iso-PAS project Kick off meeting held online on November 17, 2025

of the Congo (DRC) where mpox is currently endemic. This project is also in collaboration with the Institut National pour la Recherche Biomedicale (INRB), a national research institute in DRC, and PATH, a global development partner. The project began in December 2025 and is ongoing.

ARISE Advancing Ethics Review Preparedness at FERCAP 2025

The 25th FERCAP International Conference took place in Bangkok, Thailand, from November 23 to 26, 2025. With the theme "Ethics and Quality Design," the event attracted around 600 participants from 20 countries across Asia-Pacific, Europe, Africa, and North America.



Nagasaki University hosted session



DIT members at FERCAP

As part of the ARISE 2025 project, Nagasaki University hosted a special session entitled "Strengthening Research Networks: ARISE – Strengthening Ethics and Emergency Response Capabilities" on November 25. Professor Kenji Hirayama served as both Conference Chair and Session Chair. The session focused on strengthening ethics review systems in the ASEAN region and enhancing the capacity of Ethics Committees/ Institutional Review Boards (ECs/IRBs) to respond effectively to emergency research.

Representatives from Japan, Thailand, the Philippines, Indonesia, and Malaysia, including ARISE member institutions, shared their insights based on experiences during the COVID-19 pandemic and the directions they have taken since. They presented on the rapid ethics review

procedures, online systems, and coordination mechanisms introduced during the crisis, along with their current status and development.

Nagasaki University presented findings from a multinational survey of ECs/IRBs in four ASEAN countries, conducted via the FERCAP network, as part of their ARISE 2025 activities. The research noted progress in online review systems, expedited processes, and a shift towards a single IRB model. However, challenges persist, including a lack of experienced reviewers, inconsistencies in research protocol quality, and coordination issues in multi-centre studies.

This session highlighted the importance of ARISE-led regional cooperation for timely and effective ethical reviews in preparation for future public health emergencies and international research.

JIHS and Hai Phong University of Medicine and Pharmacy (HPMU) to Sign Memorandum of Understanding on Joint Clinical Research



MoU signing ceremony

On November 19, 2025, the Japan Institute for Health Security (JIHS) and Hai Phong University of Medicine and Pharmacy (HPMU) in Hai Phong City, Vietnam, signed a five-year Memorandum of

Understanding (MoU) to strengthen collaboration in infectious disease research.

Representing JIHS President Dr. Norihiro Kokudo, Dr. Wataru Sugiura, Director-General of the

Center for Clinical Sciences, attended the signing ceremony along with four other delegates. From HPMU, Rector Assoc. Prof. Nguyen Van Khai and twelve faculty members participated. Covering the five-year period through 2030, the MoU outlines provisions for personnel exchanges, joint meetings and seminars, information sharing, development of research programs, initiation of clinical research projects, and other cooperative activities.

During the event, the two parties discussed the progress of their ongoing joint clinical study on preventing mother-to-child transmission of hepatitis B, as well as potential future collaborations in clinical research and trials. The JIHS delegation also visited University Laboratory, Faculty of Public Health and the HPMU Hospital to observe related laboratories and departments engaged in the ongoing collaborative study.

Launch of the Mpox Vaccine Study in Mbandaka, the Democratic Republic of the Congo (DRC)

Three JIHS researchers attended the launch of the study, "Evaluation of the Effectiveness and Safety of the LC16m8 Mpox Vaccine in Individuals Aged One and Older in the Democratic Republic of Congo".

The launch ceremony was conducted by the Deputy Governor of the Equator Province in DRC and was attended by all the consortium members, including the Institut National de la Recherche Biomédicale,

the Coalition for Epidemic Preparedness, and the International Vaccine Institute.

The deputy governor, provincial health authorities, community health workers, and community representatives all acknowledged the Government of Japan's support in donating the vaccine.

After the ceremony, the consortium members visited sites to understand the current situation in the field.



Consortium meeting in Mbandaka



Consortium members at the Mama Balako site

The 19th JIHS Global Infectious Diseases Forum

The 19th JIHS Global Infectious Diseases Forum (GIDF) was held at Nihonbashi Hall on January 16, 2026, in a hybrid format. As in the previous year, there were many prior registrations and actual participations.

The theme of the forum was "Facing Microorganisms that Cause Cancer—Opening New Horizons," which highlights insights on how bacteria and viruses contribute to cancer development.

Leading experts from Indonesia, Japan, and Taiwan shared the latest findings and therapeutic approaches for oncogenic infectious diseases.

Notably, this was the first ambitious attempt to collaborate with the National Cancer Center Hospital (NCCH), which led to the development of a clinical

study network in the Asia region in the cancer setting, and it was also challenging to demonstrate infectious diseases from a different perspective.

President of JIHS, Dr. Norihiro Kokudo, addressed the opening remarks, emphasizing JIHS's first anniversary, and highlighted JIHS's second function, R&D research network, out of the four functions. Dr. Sifa Muchanga from Department of International Trials in JIHS reported current activities and forward-looking perspectives at ARISE, especially the ongoing study that collects pathogen, and clinical and epidemiological data in drug development systems.

After the two concise reports, there were three distinguished lectures presenting their topic led by



GIDF highlight (Upper right: Dr. Tofan; lower left: Dr. Shibata; lower middle: Prof. Kao)

three chairs, Dr. Wataru Sugiura (Director-General of Center for Clinical Sciences, JIHS), Dr. Takaji Wakita (Vice President, JIHS), and Dr. Kenichi Nakamura (NCCH).

The first lecture was delivered by Dr. Tofan Widya Utami from Cipto Mangunkusumo Hospital, Indonesia, one of our important ARISE counterparts. Her lecture, entitled “Cervical Cancer Prevention Program in Indonesia,” emphasized that cervical cancer remains a major global health burden. Southeast Asia accounts for 11% of global cases and deaths, and Indonesia is one of the most affected countries based on the Age-Standardized Rate. She explained that human papillomavirus (HPV) vaccination coverage under the National Immunization Program has shown good progress. However, screening coverage still needs improvement, particularly in terms of community acceptance.

She concluded that single-dose HPV vaccination and HPV DNA testing using self-sampling are key strategies to expand coverage and strengthen the implementation of the National Action Plan.

The second lecturer was Dr. Tatsuhiro Shibata who is from The University of Tokyo. His recent research has revealed that, unlike previously known bacterial carcinogenesis mechanisms, toxins produced by gut bacteria are directly linked to the development of colorectal cancer. It is known that this toxin-induced onset is more prevalent among young people in Japan compared internationally, but the cause remains unclear and will be further

investigated in ongoing research. Additionally, Dr. Shibata said expectations for ARISE and the Asian network ATLAS in the cancer field, including capable site identification for collaborative research in the basic research areas he is advancing.

The final lecturer was Prof. Jia-Horng Kao who is from National Taiwan University Hospital. He is a superstar physician, researcher, educator, and he presented on the prevention and treatment of hepatocellular carcinoma (HCC) in patients with chronic hepatitis B virus (HBV) infection. Prof. Kao emphasized that HBV-related HCC remains a major yet preventable cause of cancer mortality worldwide, particularly in regions with high HBV endemicity. He highlighted that population-wide HBV vaccination, prevention of mother-to-child transmission, and early detection of chronic HBV infection are the most effective strategies to reduce the incidence of HCC. He concluded that addressing HBV-related HCC requires coordinated action across public health, clinical medicine, and policy, with prevention remaining the most impactful and cost-effective strategy to achieve sustained reductions in global HCC burden.

After three lectures had been concluded, Dr. Hideyo Miyazaki, Hospital Director of the National Center for Global Health and Medicine, JIHS, closed the forum.

The next forum is planned as 20th anniversary sometime in fiscal year 2026. The team is moving forward with the preparations.

ARISE & DIT NEWSLETTER vol.07 Issued in February, 2026

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