

ARISE

Asian clinical trial platform

NEWSLETTER

Message from Editor in Chief and ARISE Secretary General

KOJI WADA, MD, MSc, PhD



The Academic Research Organizations (AROs) Alliance for Southeast and East Asia (ARISE) was launched by the National Center for Global Health and Medicine (NCGM) in 2021, using the grant from the Japan Agency for Medical Research and Development (AMED), to further strengthen international collaboration with Asian countries in the healthcare sector. Its founding vision is to promote efficient and effective collaboration by facilitating clinical trials for infectious diseases among member institutions.

Originally composed by ten member institutions from Indonesia, Japan, the Philippines, Thailand, and Vietnam, the alliance has expanded its network by attracting new academic institutions from Malaysia and Japan. This growth reflects the impact and potential to meet current demand in the healthcare landscape in Asia. Furthermore, ARISE continues to strengthen cooperation with international organizations and clinical trials networks around the world to contribute to a global movement towards more effective clinical research.

In the two years, since it was launched ARISE actively implemented its strategies, achieved remarkable accomplishments that deserve to be shared.

Starting from June 2024, this newsletter will be regularly updating the readers about the Alliance and

its activities.

The first volume will focus on a brief introduction of the Alliance, the ARISE Secretariat and the annual report for the fiscal year 2023 (April 2023- March 2024).

Editorial team

"Welcome to the 1st release of our newsletter! Thank you for your interest and taking the time to read. As a team, we always strive to provide you with the most up-to-date and valuable content that resonates who we are as an organization. And it is with great excitement that we share some of our activities and achievements. Don't miss out on the opportunity to learn, connect, and grow with us."

- Editor in-Chief: Koji Wada, MD, MSc, PhD
- Associate Editor: Muchanga Sifa Marie Joelle, MD., PhD
- Editorial Board: Maria Urbiztondo Umano, MD. PhD, Marlinang Diarta Siburian, MBIomed, Katsumi Ishii, RPh, RMT, MSc, Le Mai Phuong, MSc
- Editorial Assistant : Sonoko Ishiyama



ARISE Secretariat

ARISE operations are maintained by a Secretariat at the National Center for Global Health and Medicine in Tokyo, Japan. The team under the supervision of the Secretary General is composed of following members:



Sifa is an Obstetrician and Gynecologist who holds a PhD in clinical epidemiology. Certified Clinical Research Coordinator. She has more than 5 years' experience at the NCGM as a Project Manager.



Maria is a physician who hold a PhD in Human Pathology. She has completed Clinical Research Coordinator course for trials in Japan. She has more than 5 years' experience at the NCGM as a Project Manager.



Marlinang is a biomedical researcher with 10 years experience on molecular epidemiology on Hep B and liver cancer. She joined DIT since 2018 as Regional Manager and involved in several clinical studies on Covid-19.



Ishii is a registered Pharmacist and Medical Technologist who holds a MSc in international health. He has more than 15 years' experience for Infectious disease control in several countries of Asia.



Mai is a public health researcher. She has over 10 years' experience in infectious diseases, particularly HIV/AIDS. Her research interests focus on health promotion among vulnerable populations. Le presently works as a Vietnam Liaison Officer at NCGM.

Activities during the fiscal year 2023

During the fiscal year 2023, several activities have been done in the network. Activities varied from clinical studies project support to events.

Clinical studies project support

The 2nd Joint International Project on measures against Antimicrobial Resistance (AMR) and Promoting Proper Use of Antibiotics in Vietnam

With the perspective of promoting Public-private-Academia-Partnership; for the second time, the NCGM's Department of International Trials (DIT) provided technical assistance, protocol supervision, and overall project management to Sumitomo Pharma Co.

This joint study evaluated the susceptibility of several antibiotics against 1,263 isolated strains of Gram-negative bacteria collected from 11 Vietnamese institutions: Nguyen Tri Phuong Hospital, Vietnam National Children's Hospital, Viet Duc Hospital, 103 Military Hospital, Cho Ray Hospital, HCMC Medical University Center Hospital, Pediatrics Hospital, Thu Duc Hospital, Gia Dinh Hospital, Thong Nhat Hospital, Trung Vuong Hospital, and Nguyen Tri Phuong Hospital between February 2023 and May 2024.

The results will be used in clinical settings at participating medical facilities, and will be reported to the Ministry of Health for use in future antimicrobial resistance measures in Vietnam.



The project on measures against Antimicrobial Resistance (AMR) closing out

Supporting business plan of Medical Equipment Development for Overseas based on local needs (SMEDO) in Indonesia

Tokyo Government initiated SMEDO project to introduce medical products developed by small-middle



A group photo of SMEDO team: Tokyo Government representative, NCGM team and 10 Japanese medical device company representatives with Siloam Hospitals Group Executives (left) and with University of Indonesia Teaching Hospital (right).

companies in Japan. After a selection process, ten companies were chosen to participate in the project. Bureau of International Health Cooperation (BIHC) and the DIT facilitated the implementation. There were two consecutive visits in February and August to prepare the project. Selected companies introduced their products during the 3-day visit in December at two ARISE member institutions: Siloam Hospitals Lippo Village (SHLV) & Universitas Indonesia Teaching Hospital (RSUI).

Events

The 2nd ARISE-PMDA joint Symposium for Asian Clinical Trials' "How to collaborate as one Asia"

This hybrid symposium held on July 20, 2023 in Tokyo registered 376 participants.

It was a three session symposium that featured presentations on issues and initiatives from the perspectives of pharmaceutical companies, academia, and regulatory authorities which focused on: "Regulatory Issues Surrounding Clinical Trials in Asia," "Using New Tools and Approaches in Clinical Trials," and "First Patient In (FPI) in Asian Clinical Trials".

The discussion was centered on how academia, regulatory authorities, and industry can work together to address barriers and accelerate FPI for approvals in Asia. The panel concluded with the hope that ARISE will continue to bring regulators, academia, and industry to discuss issues related to clinical trials, as well as to promote regulatory harmonization and accelerate regulatory approvals.



The 2nd ARISE-PMDA joint Symposium for Asian Clinical Trials

The 2nd ARISE Annual Meeting

From February 6-7, ARISE members joined physically or online at the 2nd Annual Meeting held in NCGM.

NCGM Executives committee and guests from funding agencies and partner organizations also joined.

During the meeting, the new ARISE committee members from NCGM were introduced: Dr. Haruhito Sugiyama, NCGM's Hospital Director and Chief Representative of the ARISE; Dr. Koji Wada, Director of the DIT and ARISE Secretary General.

Two new member institutions were welcomed, namely, Kyushu University represented by Dr. Koji Todaka and University of Malaya Medical Centre (UMMC) represented by Ms. Zulaikha Syazwani Zulkifly, who attended onsite and Dr. Phan Chai Wei attended online, bringing the network from 12 to 14 members.

During discussions, the members reaffirmed their commitment to continue with the ARISE vision and mission while focusing their attention to infectious disease trials with emphasis on vaccine development for a better preparedness towards a new pandemic.

The freely accessible link to the e-learning course for clinical trial professionals, (<http://kokusairinshouigaku.jp/publicity/index3.html>) developed by the Capacity Development Working Group led by Osaka University was shared.

Guest speakers from the Economic Research Institute for ASEAN and East Asia (ERIA) and the Translational Research Center for Medical Innovation (TRI) gave lectures.

The third annual meeting will be held in Bangkok at the Mahidol University, Siriraj Hospital.



The 2nd ARISE Annual Meeting

The 4th NCGM International Symposium for Clinical research/Trials: "Low- and middle-income countries in the dawning era of clinical trials digitalization"

The hybrid symposium was held on February 7, 2024, with a total of 234 participants.

The program had two sessions and a panel discussion.

In the first session, Prof. Nsengi from DR Congo and Ms. Ordinario from the Philippines talked about the hurdles in implementing digital tools in limited settings. While in the 2nd session, Prof. Todaka from Japan, Prof. Phan from Malaysia, and Prof. Rungroj from Thailand introduced their experience on how digital tools could benefit trial operations particularly for remote trial, subject recruitment and retainment, and outcome measurements. Between sessions, a polling survey was

held for the participants to survey on the digital readiness of their country. The panel discussed about readiness of LMICs for digital transformation, how to overcome the current challenges, and the results of the polling survey.

The use of digital tools was no longer a question of "if" but "when" and "how much". There was high expectation for the use of digital tools from LMICs including ARISE members. Many of the digital tools in trial operations were provided by sponsors and not so much from local institutions. More support from local governments, particularly for guidelines and infrastructure development are needed.



Discussion panel session at the 4th NCGM International Symposium led by Dr. Wataru Sugiura, Director of CCS

ARISE Secretariat activities

Indonesia visit

From mid-February to early March 2024, Ms. Marlinang operated the Indonesia co-office in Jakarta. The objectives of her stay were to introduce Dr. Koji Wada to ARISE members and other collaborating institutes in Indonesia and to further explore future potential collaboration with Indonesia.

She visited two other prominent institutions for introduction and exploring opportunities for future collaboration. First institution was the Clinical Epidemiology and Biostatistics Unit (CEBU), Gadjah Mada University meeting with Prof Dr Jarir At Thobari and his team who is an expert in clinical research especially vaccine trials. The second visit was to the Faculty of Medicine, Hasanuddin University (Unhas), meeting with Prof Dr Haerani Rasyid and her team. Unhas is a renown academic institution especially in the field of infectious diseases.



Top left: at Faculty of Medicine, University of Indonesia

Top right: at Moctar Riady Institute for Nanotechnology, Indonesia

Bottom left: at Gadjah Mada University, Indonesia

Bottom right: at Medical Faculty of Medicine, Hasanuddin University, Indonesia

University of the Philippines Manila (UPM)

Dr. Koji Wada and Dr. Maria Ruriko Umano visited the University of the Philippines Manila (UPM) in March 2024. The purpose of the visit was to gain a better understanding of the clinical trial environment at ARISE member institutions. They also paid a courtesy call to key official leaders of the UPM and the Philippine General Hospital.

NCGM's reorientation of its vision of conducting clinical trials on infectious diseases and finding prospective sites and collaborators was another aim of this three-day trip. The visit included tours of the Research Institute for Tropical Medicine and San Lazaro Hospital. Both facilities are known for their expertise in infectious diseases.

On these engagements, discussions and meetings were held, focused on potential collaborations and future opportunities. Additionally, the research institutes provided an overview of their ongoing activities. Overall, the visit was a resounding success and laid the foundation for stronger academic collaboration between the two institutions, paving the way for joint projects and initiatives.



Group photo (L to R) : Prof. Ed Ruamero, Dr. Benjamin Sablan Jr., Dr. Eva Cutiongco- dela Paz, Dr. Gerardo Legaspi, Dr. Koji Wada, Dr. Maria Ruriko Umano, Dr. Maria Rejane Umano



Dr. Koji Wada and UPM Manila Chancellor, Dr. Michael Tee

Mahidol University, Siriraj Hospital and Thailand Collaborating Office

From 27 February to 2 March 2024, Dr. Wataru Sugiura, Dr. Koji Wada, Mr. Masato Ichikawa, Mr. Naoki Tomotsugu and Dr. Muchanga Sifa accompanied with the delegation from the AMED, and the Ministry of Health Labor and Welfare (MHLW) visited the Mahidol University, Siriraj hospital to discuss about the organization of the 3rd ARISE Annual Meeting and future clinical trials collaboration. Participants concluded that the meeting will be held in Bangkok and Siriraj Hospital will host the meeting on November 21-22, 2024.

The team also visited the Asian Partnerships office of the National Cancer Center Hospital. It is worth to strengthen the collaboration between the two national centers for efficient implementation of trials in the Asian region.

At the Ramathibodi Hospital, a monitoring visit was conducted for the Virtual Reality (VR) study which is a study for treating Major Depressive Disorders using virtual therapy. (Study registration: UMIN000052903)



In front of the Faculty of Medicine Siriraj Hospital, Mahidol University



In the NCGM Thailand Collaborating Office



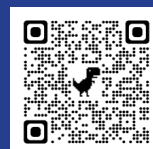
Meeting with SICRES management staff office



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