



13th, January, 2022
National Center for Global Health and Medicine
Center for Clinical Sciences
Department of International Trial

The Japan-led International Network for Clinical Researches and Clinical Trials in Asia "ARO Alliance for ASEAN & East Asia (ARISE)" was established to enhance multicenter international clinical research and trials in the Asian region.

Main Point

The Center for Clinical Sciences (CCS), National Center for Global Health and Medicine (NCGM) has established ARISE, an international collaborative clinical research and network, to lay the foundation for the promotion of multi-center global clinical research and trials in Asia.

1. Overview

On December 9, 2021, National Center for Global Health and Medicine (NCGM) launched the "ASEAN & East Asia International Clinical Research Alliance, ARO Alliance for ASEAN & East Asia (hereinafter ARISE)" to lay the foundation for clinical research and clinical trial implementation in Asia. ARISE is a network of core clinical research facilities in Asia based on the cooperative relationships, NCGM has established it in Asia to realize rapid and low-cost drug and medical device development. The Center for Clinical Sciences, NCGM the Clinical Research Center began this effort with support from the Japan Agency for Medical Research and Development (AMED) (1).

2. Background

Currently, it is difficult to say that Asian countries have sufficient access to pharmaceuticals and medical devices, including products using innovative technologies. Therefore, it is becoming increasingly important to contribute to health promotion in Asian countries by improving access to medicines and medical devices in Asian countries.

Since its establishment in 2016, the Department of International Trial (DIT) of the Clinical Research Center (CCS) of NCGM has been working with the Disease Control and Prevention Center (DCC), Research Institute, and other relevant departments to promote various international collaborative clinical research and trials. We have implemented "Joint international research



project on measures against antimicrobial drug resistance (AMR) and proper use of antimicrobial agents in Vietnam" and "Clinical Performance Studies of In-Vitro Malaria Diagnostics and Medical Devices in Thailand and Japan" in cooperation with medical device companies.

In addition, in 2020, we launched the AMED subsidized project, "Clinical research and clinical trial platform formation to promote international research cooperation between Japan and Asian countries in the field of infectious diseases." This project promotes the establishment of international joint research bases and infrastructure in Asian countries, as well as international joint clinical research and trials in emerging and re-emerging infectious diseases such as COVID-19, malaria and tuberculosis.

3. ARiSE (Arise) Overview

ARiSE, together with Thailand, the Philippines, Indonesia, Vietnam and other countries that are actively promoting clinical research and development in the Asian region under the leadership of Japan, will build a network of international joint clinical research and trials, aiming to develop research and development in the Asian region through physician-led and corporate clinical trials for pharmaceutical approval applications. We also aim to promote health and reduce diseases and disabilities. In addition, we will strive to achieve the following missions through efficient and effective collaboration with member organizations and stakeholders.

- (1) to promote the integrity, safety, ethics, and quality of investigator-initiated clinical studies;
- (2) to contribute to developing innovative medical products to address unmet health needs and diseases of public health significance in the region;
- (3) to contribute to improving the resources and capacity of clinical study sites in the region;
- (4) to accelerate clinical studies and improves timelines and processes for authorization;
- (5) to promote Public-Academic-Private-Partnerships (PAPPs) in the region; and
- (6) to bridge the gap between sciences and policy for health.

ARiSE was headed by NCGM President Norihiro KOKUDO, and its secretariat office was established within the Center for Clinical Science (Director: Wataru SUGIURA), Department of International Trial (Director: Tatsuo IYAMA) (Figure 1). At present, 10 organizations in 5 countries are members (Figure 2), and the number of member countries and organizations is expected to expand gradually.

Figure 1. ARISE Organizational Structure

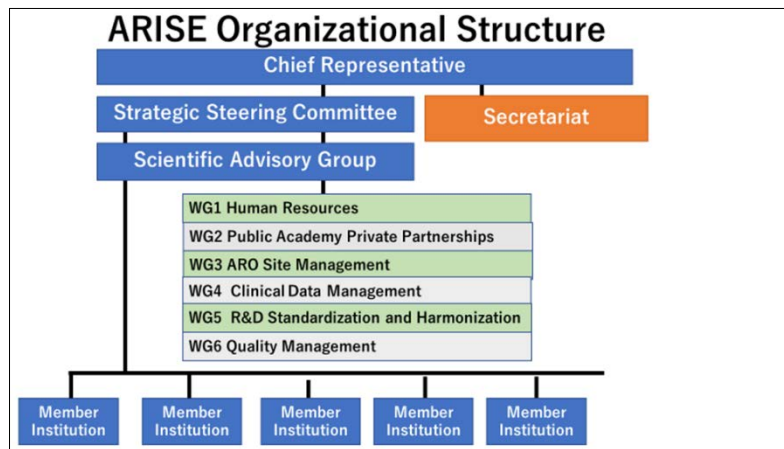


Figure 2. ARISE member Organizations

The Kingdom of Thailand	Faculty of Medicine, Siriraj Hospital, Mahidol University (NCGM collaborative office opened in January, 2021)
The Republic of Indonesia	University of Indonesia (NCGM collaborative office will be open during FY2022)
	Mochtar Riady Institute for Nanotechnology
The Republic of the Philippines	The University of the Philippines Manila (collaborative office opened in January, 2021)
	Corazon Locsin Montelibano Memorial Regional Hospital
	Manila Doctors Hospital
Socialist Republic of Vietnam	Bach Mai Hospital (NCGM collaborative office opened)
Japan	National Center for Global Health and Medicine (NCGM)
	Osaka University
	Nagasaki University
	International University of Health and Welfare (IUHW)

4. Specific Activities

Currently, we are conducting the following activities with ARISE member organizations.

ARISE plans to further increase the number of international joint clinical studies to carry out the activities of each working group.

- ① Development of clinical research infrastructure in ARISE member institutions
- On-site research support through the establishment of an NCGM collaboration office (Thailand, Philippines, Indonesia, Vietnam)

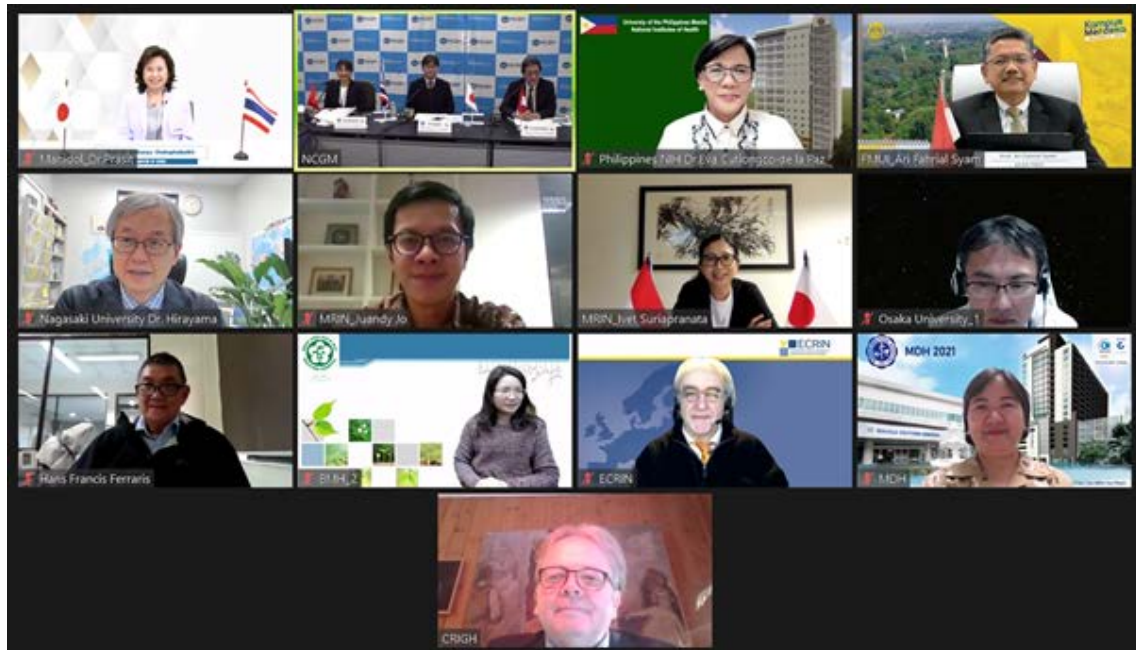


- Support for the establishment and strengthening of clinical research centers within NIH in the Philippines
 - On-line and onsite training to strengthen the capacity of clinical research staff (Indonesia, Thailand, Philippines, Vietnam, Democratic Republic of Congo)
 - Introduction of standard competencies for clinical research and testing personnel/Survey of actual competencies (Indonesia, Thailand, Philippines, Vietnam, Democratic Republic of Congo)
 - Introduction of EDC, ePRO, eConsent and CTMS, and development of Standard Operating Procedures (SOP) for efficient global trials
- ② International joint clinical researches conducted with ARISE member organizations and member countries
- An international study to evaluate the efficacy and safety of antiviral drugs in patients with COVID-19 (Thailand, Philippines, etc.)
 - Drug susceptibility testing of clinical isolates (Vietnam)
 - Clinical performance tests of malaria drugs and medical devices (Thailand, Japan)
 - COVID-19 in-vitro diagnostics and medical device clinical performance tests (Vietnam, Indonesia, Philippines)
- ③ ARISE Research Network Cross-Sectional Working Group (WG) Activities (planned)
- WG1: Human Resources (HR)
 - WG2: Public-Academic-Private-Partnerships (PAPPs)
 - WG3: ARO site management
 - WG4: Clinical Data Management
 - WG5: R & D Standardization and Harmonization
 - WG6: Quality Management
- ④ Holding of various symposiums and workshops (planned)

4. Holding a Kick-Off Meeting

On December 9, the ARISE Kick-off Meeting was held online, with approximately 70 participants from medical institutions in Asia and around the world. At the meeting, presentations were given on the introduction of the 10 member organizations and the concept and governance of ARISE. In addition, representatives from the Clinical Research Initiative for Global Health (CRIGH), the European Clinical Research Infrastructure Network (ECRIN) in Europe, and the MRCT Center of Brigham and Women's Hospital and Harvard (MRCT Center) in the United States presented

their experiences on international collaborative clinical research networks in Europe, the United States, and the world. We also discussed future activities and international cooperation.



ARISE Kick-Off Meeting on December 9, 2021

5. Future Outlook

International cooperation is essential not only in the field of infectious disease pandemics but also in clinical research in the field of rare diseases. As an ARO (2) in the global health field, ARISE promotes collaboration with major organizations in Europe and the United States, in addition to building alliances in Asia, standardizing operations, and developing human resources, with a view to pursuing efficiency and quality control in peacetime, and responding quickly in emergencies. ARISE will continue to work with stakeholders in Japan and overseas to contribute to improving global health through research and development and the generation of evidence.

★Contact information

(ARISE)

National Center for International Medical Research (NCGM)

Clinical Research Center International Trial Department ARISE Secretariat

TEL: 03-3202-7181 (main line), Extension: 2408 * 9: 00 - 17: 00 (weekdays only)

Email: arise@hosp.ncgm.go.jp

ARISE Web site https://ccs.ncgm.go.jp/050/en/capacity_building/arise.html



★References and related Links

(1)

Funding Source: Japan Agency for Medical Research and Development (AMED)

Program Name: Clinical Research and Clinical Trials Promotion Project and Network
Development Project in Asia.

Project Name: Clinical research and clinical trial platform formation to promote international
research cooperation between Japan and Asian countries in the field of infectious diseases

(Project Number 201k020100j0001)

Principle Investigator: Tatsuo IYAMA, National Center for Global Health and Medicine

(2)

ARO stands for Academic Research Organization. Academic clinical research institute. An organization that supports clinical and non-clinical research, including drug development, by utilizing the functions of universities, etc., that have research institutes, medical institutions, etc.