

## Boosting multiregional clinical trials (MRCT) in Asia through the establishment of the Japan-led network for clinical research, the ARO alliance for ASEAN & East Asia (ARISE)

Miwa Sonoda\*, Maria Ruriko Umano Urbiztondo, Marlinang Diarta Siburian, Nattha Kerdsakundee, Sifa Marie Joelle Muchanga, Tatsuo Iiyama

Department of International Trials, National Center for Global Health and Medicine, Tokyo, Japan.

**Abstract:** There is an increasing demand for clinical research, and this demand has particularly increased during the novel coronavirus infection (COVID-19) pandemic. In the light of these events, fostering international cooperation has become essential. The ARO Alliance for ASEAN & East Asia (ARISE) is a Japan-led international network for clinical research in Asia that was established to encourage and facilitate multiregional clinical trials. The Department of International Trials of the National Center for Global Health and Medicine (NCGM) launched ARISE in December 2021 to pursue efficacious, high-quality clinical research and ensure rapid responses to health emergencies, with the timely provision of new medicinal products to patients in Asia.

**Keywords:** clinical research, clinical trial, global health, Asia

To respond to rapidly growing demands for clinical research at the local level, it is important to build robust research infrastructure in low- and middle-income countries. The 2014–2015 Ebola outbreak in West Africa revealed the lack of infrastructure, expertise, and regulations in the face of an urgent need for clinical trials at the local level during public health crises (1). The number and complexity of clinical trials have increased significantly in recent years. According to ClinicalTrials.gov, a registry of clinical studies conducted worldwide in 220 countries, the number of registered clinical studies is rising from 325,773 in 2019–2020 to 362,505 in 2020–2021 (2). The complexity of clinical trials has also increased, particularly since the novel coronavirus infection (COVID-19) pandemic. Consequently, the demand for clinical research professionals exceeds availability, and global efforts to increase the clinical research workforce are underway (3).

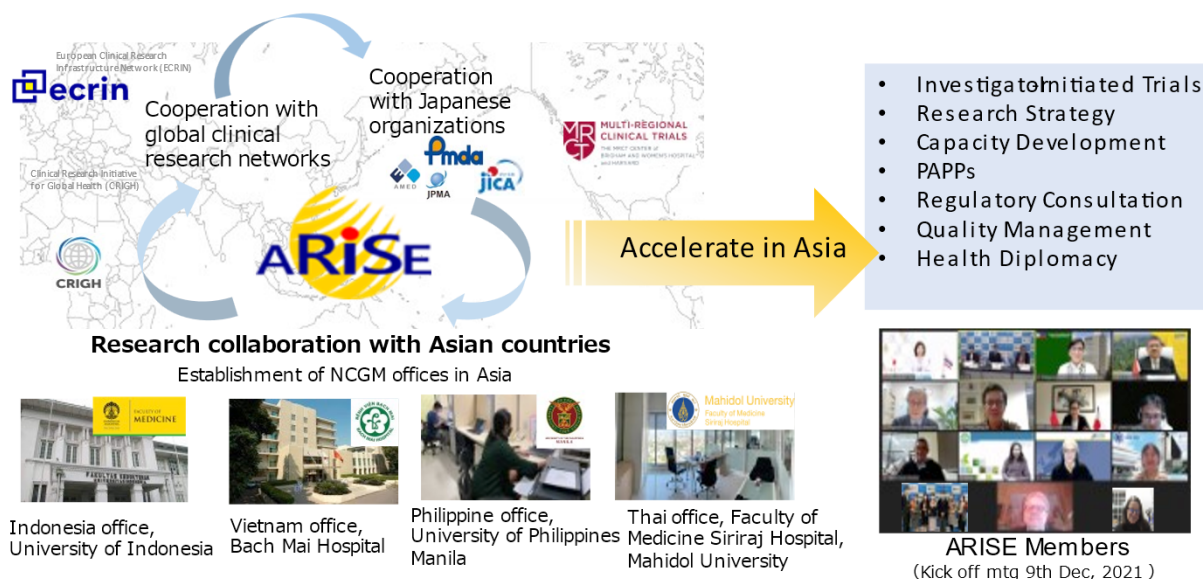
International cooperation in clinical research is essential for addressing common global health issues and enabling the provision of evidence-based solutions to patients and health professionals in a timely manner. In the face of the COVID-19 pandemic, the need for global cooperation in clinical research to overcome unprecedented health challenges has been reaffirmed. However, multinational research is complex due to differences in regulatory and ethical requirements, medical systems, health priorities, and cultures between countries. These barriers affect the scope of research

and reduce its potential impact on healthcare industries, health economies, and societies.

To tackle this problem, the Asian Health and Welfare Initiative (AHWIN), created in 2019 by the Japanese government, has promoted establishing a clinical research network to improve the infrastructure and development capacity of clinical research in Asia (4). Undertaking these missions as one of the national centers for Advanced and Specialized Medical Research under Japan's Ministry of Health, Labour, and Welfare, the National Center for Global Health and Medicine (NCGM) launched the ARO Alliance for ASEAN & East Asia (ARISE) in December 2021. ARISE is a network of major academic research organizations (AROs) that promotes and facilitates multiregional clinical trials (MRCTs) in Asia. ARO denotes "an academic and non-profit institution that performs one or more functions in the conduct of clinical trials" (5). The NCGM established this ARO network with the support of the Japan Agency for Medical Research and Development (AMED) to enable the rapid and low-cost development of pharmaceuticals and medical devices. ARISE is headed by the President of the NCGM, and its secretariat office is within the Department of International Trials of the Center for Clinical Sciences. There are currently ten member AROs from Indonesia, Japan, the Philippines, Thailand, and Vietnam, and membership is expected to grow in the future.

On December 9, 2021, the ARISE kick-off meeting

## ARO Alliance for ASEAN & East Asia (ARISE)



**Figure 1. ARISE's strategic framework for partnership and collaborative relationships to accelerate clinical research in Asia.**

was held online, with approximately 70 participants from both Asian and international medical institutions. During the meeting, the concept of ARISE (Figure 1) was elucidated and members introduced their organizations. Representatives from the Clinical Research Initiative for Global Health (CRIGH), European Clinical Research Infrastructure Network (ECRIN), MRCT Center of Brigham and Women's Hospital, and Harvard (MRCT Center) shared their experiences of international collaborative clinical research networks in Europe, the USA, and the world.

As an Asian clinical research network responsible for global health, ARISE aims to promote health and reduce illness and disability by creating a network of Asian AROs. Through the efficient and effective collaboration of member organizations and stakeholders, it strives to achieve the following objectives: *i*) Promote the integrity, safety, ethics, and quality of clinical research; *ii*) Contribute to the development of innovative medical products that address unmet health needs and significant diseases in Asia; *iii*) Improve the resources and capacity of Asian clinical study sites; *iv*) Accelerate clinical research and authorization processes; *v*) Promote public-academic-private-partnerships in Asia; *vi*) Bridge the gap between scientific research and health policies.

Since its inception, ARISE members have conducted several activities to develop clinical research capacity, including introducing core competencies for clinical research professionals and training in member countries. We also have undertaken international studies to evaluate the safety and efficacy of antiviral drugs for COVID-19 treatment and drug susceptibility measurement of gram-negative bacteria. In the future, we plan to increase the

number of global clinical research further and conduct thematic working groups to address specific needs and common issues relevant to clinical studies.

To advance clinical research activities, member organizations will share their experiences and resources and work closely with the governments and regulatory authorities of the concerned countries. We will also ensure value to commercial and academic partners through sustainable and expeditious research development. Finally, we will advance regional collaborations with the instigation of international medical research cooperation, which will enable us to deliver valuable medical products to people in need.

**Funding:** The ARISE network is funded by the Japan Agency for Medical Research and Development (AMED 201k020100j0001).

**Conflicts of Interest:** The authors have no conflicts of interest to disclose.

### References

1. National Academies of Science, Engineering and Medicine (NASEM), 2017. Integrating Clinical Research into Epidemic Response: The Ebola Experience. The National Academies Press. <https://www.ncbi.nlm.nih.gov/books/NBK441679/> (accessed April 28, 2022).
2. ClinicalTrials.gov. Trends, Charts, and Maps. <https://clinicaltrials.gov/ct2/resources/trends#RegisteredStudiesOverTime> (accessed April 28, 2022).
3. Sonstein SA, Jones CT. Joint task force for clinical trial competency and clinical research professional workforce development. *Front Pharmacol.* 2018; 9:1148.

4. Takemi K. Lecture No. 6 Asia health and wellbeing initiative (AHWIN) and cancer. *Jpn J Clin Oncol.* 2021; 51:i24-i27.
5. Reist CJ, Rorick TL, Berdan LG, Lopes RD. Chapter 3. The Role of Academic Research Organizations in Clinical Research. In: Lopes RD, Harrington RA. eds. *Understanding Clinical Research.* McGraw Hill/Medica, New York, USA, 2013.

May 17, 2022.

Released online in J-STAGE as advance publication May 23, 2022.

*\*Address correspondence to:*

Miwa Sonoda, Department of International Trials, Center for Clinical Sciences, National Center for Global Health and Medicine, 1-21-1 Toyama Shinjyuku-ku, Tokyo 162-8655, Japan.

E-mail: [misonoda@hosp.ncgm.go.jp](mailto:misonoda@hosp.ncgm.go.jp)

----

Received February 24, 2022; Revised May 3, 2022; Accepted