

The Academic Research Organization Alliance for Southeast and East Asia (ARISE) in the new era: An international trials network towards pandemic preparedness

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Abstract: The Academic Research Organizations (ARO) Alliance for Southeast and East Asia (ARISE), established in 2021, is a network of academic research organizations in Southeast and East Asia. Its founding vision was focused on conducting effective, high-quality clinical research and providing timely access to new medicinal products during health crises. Through its focused efforts, ARISE has fostered regional cooperation and contributed to implementing clinical trials of medical products in its network. In response to global health challenges, the Government of Japan is establishing a new organization, the Japan Institute for Health Security, with functions encompassing infectious disease control and pandemic preparedness. As ARISE continues to fulfill its mission of addressing emerging infectious diseases, the ongoing changes in its founding organization will significantly impact its operations. With this article, we aim to highlight ARISE's achievements in its first two years and to explain how its strategy has been adapted to the new organizational structure and evolving global health landscape. ARISE strives to strengthen its network collaboration and further enhance the ability of member organizations to respond rapidly and effectively to future health emergencies.

Keywords: pandemic preparedness, infectious diseases, clinical trials, ARO, ARISE

Introduction

The Academic Research Organizations (AROs) Alliance for Southeast and East Asia (ARISE) is a network of AROs in Southeast and East Asian countries. It is an initiative of the Japanese National Center for Global Health and Medicine (NCGM), founded upon the Asia Health and Wellbeing Initiative in 2021. ARISE's founding vision and mission were primarily focused on the performance of effective, high-quality clinical research and the provision of timely access to new medicines for Asian patients during health crises (1-3). To fulfill ARISE's function and operations in pursuit of its original mission, the Department of International Trials under the Center for Clinical Sciences at the NCGM serves as ARISE's secretariat (1,4).

ARISE's core mission aligns with a global imperative, the "100 Days Mission", launched to enable the development and deployment of new diagnostics, therapeutics, and vaccines within 100 days of a pandemic. This shared goal underscores the importance of timely access to new medical products during emerging

health crises. The lessons learned from the COVID-19 pandemic have led Asian countries to recognize the major challenges in managing such outbreaks and the important role of vaccine development during a pandemic. To fulfill the 100 Days Mission, Southeast Asian countries have identified that strengthening regional collaboration ties and clinical research networks will facilitate knowledge sharing and research collaboration (1,5). ARISE's role is pivotal in this context and can contribute significantly to identifying and mitigating emerging diseases in the region.

As ARISE continues to fulfill its mission to address emerging diseases, ongoing changes in the structure of its founding organization, the NCGM, will substantially impact its operations. These changes reflect the Japanese Government's efforts to prepare for future pandemics and to foster collaborations with other countries in the region. In 2022, Prime Minister Fumio Kishida took a significant step toward bolstering Japan's preparedness for future infectious disease crises by establishing a specialized, world-class science center (6). In response to the Prime Minister's Declaration, in 2023, the Minister

of Health, Labour, and Welfare launched "T-Vision", which is the strategic framework of the new organization centered on health security (7). Under this initiative, a new organization, the Japan Institute for Health Security (JIHS), will be formed in April 2025 by merging two national centers specializing in infectious disease treatment and research: the NCGM and the National Institute of Infectious Diseases. The founding of the JIHS will be a notable milestone in Japan's response to public health emergencies. It will perform three critical functions: *i*) strengthening the collection and evaluation of data on infections in Japan and overseas; *ii*) establishing a platform for the promotion of research and development; and *iii*) forming the core of the clinical trial network in the region (7). This article aims to highlight ARISE's achievements from 2021 to 2023 and explain how ARISE is adapting its strategy within the new organizational framework.

ARISE achievements – The first two years of its journey

In its first two years, from 2021 to 2023, ARISE actively implemented its strategies, achieved key milestones, and reinforced its network. Through focused efforts, it has promoted regional cooperation, contributed to implementing clinical trials for medicines and medical devices, and fostered a collaborative and supportive environment for clinical research. These achievements demonstrate ARISE's effectiveness in advancing its mission and contributing to the strengthening of regional collaboration in the field of clinical research.

Establishment and fostering of a regional network of AROs

Since its establishment in 2021, with the participation of 10 institutions, ARISE has grown to 14 member organizations (Figure 1) and established collaborative offices in four countries to further enhance its regional presence and deepen its engagement with member organizations. ARISE also continued to strengthen cooperation with international organizations and networks, such as the Clinical Research Initiative for Global Health, and the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital, and Harvard, and to engage with important organizations in Japan. This growth reflects its impact and potential of meeting the current demand in the healthcare landscape in Asia, as well as its contribution to the global movement towards more effective clinical research.

Promoting clinical research activities in the region

ARISE has affirmed its important role as an academic research-support platform, an initiative that is paving a way for improving access to medicines and medical



Figure 1. ARISE network map and member organizations in 2024. Japan: ① National Center for Global Health and Medicine. ② Nagasaki University. ③ Kyushu University. ④ International University of Health and Welfare. ⑤ Osaka University; Indonesia: ⑥ Faculty of Medicine, University of Indonesia, ⑦ Mochtar Riady Institute for Nanotechnology; Malaysia: ⑧ Clinical Research Malaysia. ⑨ University of Malaya Medical Center; Thailand: ⑩ Faculty of Medicine, Siriraj Hospital, Mahidol University; The Philippines: ⑪ Corazon Locsin Montelibano Memorial Regional Hospital. ⑫ University of the Philippines Manila. ⑬ West Visayas State University; Vietnam: ⑭ Bach Mai Hospital.

devices in the region. Through strong collaborations with member organizations from Indonesia, Japan, Malaysia, the Philippines, Thailand, and Vietnam. ARISE has facilitated various forms of clinical research activities with a strong focus on addressing infectious diseases (8). Even during the COVID-19 pandemic, ARISE demonstrated its ability to facilitate research collaboration between its members in the network and Japanese pharmaceutical companies, which contributed to the development of medicine and medical devices, essential components of medical countermeasures to outbreaks (9-12).

Enhancing clinical research capacity

At its inception, ARISE served as a central network to connect and enhance collaboration between its members and other organizations while emphasizing capacity building within the network. Several training sessions for clinical research professionals were implemented based on international standards, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), and local regulatory requirements. The training consisted of a mixed model, the "Evolving Partnership Training", which reached more than 2,000 clinical research professionals in the region (11). Moreover, ARISE member organizations joined the global project to translate the Joint Task Force Core Competency framework into the various languages of these clinical trial professionals, making it accessible to a larger number of professionals (13).

ARISE facilitates communication between its members and regional health regulatory authorities by

providing a space in which they can interact directly. A joint symposium with the Japanese Pharmaceuticals and Medical Devices Agency, a regulatory authority for pharmaceuticals and medical devices, provided member organizations with the knowledge needed to address the regulatory challenges of conducting clinical trials in the region. The symposium also highlighted the importance of regulatory harmonization and adherence to Good Clinical Practice Guidelines to promote high-quality clinical research and ensure early access to medicines for Asian populations (9,10).

ARISE in the evolving era: A rising alliance for pandemic preparedness

Previous outbreaks, such as the SARS and Ebola outbreaks and the recent COVID-19 pandemic, showcased the severity of economic, social, and healthcare burdens posed by emerging infectious diseases (14). Moreover, globalization exacerbates the spread of diseases, rendering preparedness for future pandemics more increasingly crucial, especially as the timing and severity of the next pandemic remain unknown. To effectively address these challenges, ARISE has recognized its crucial role under the new organization, the JIHS, and its responsibility to make the collaboration among its members more cohesive. Therefore, ARISE will continue fulfilling its mission while upgrading its various functions to contribute significantly to pandemic preparedness in the region.

With the strong collaboration among its member organizations in Asia, ARISE provides a platform to promote research and development in the region, with a primary focus on the development of therapeutics, medicines, and vaccines for infectious diseases. ARISE fosters an environment that encourages innovative research and collaboration to address the health challenges in the field of infectious diseases. Moreover, as the core role player in clinical research on infectious diseases in the region, ARISE will continue to play an important role in coordinating and enhancing its network to improve the efficiency and effectiveness of clinical research.

The ARISE strategic plan for 2024-2025 prioritizes the abovementioned JIHS functions and focuses on the following: *i*) strengthening the clinical trial network in the field of infectious diseases, particularly with partners in Asian countries; *ii*) promoting cooperation in clinical trials; *iii*) enhancing emergency response capabilities; *iv*) improving operational efficiency for clinical trials; and *v*) enhancing capacity building for human resources among member organizations. To achieve these goals, ARISE aims to facilitate joint research projects on emerging infectious diseases, vaccine development, and therapeutic interventions. Additionally, it will organize symposiums and seminars and provide technical support for researchers and healthcare professionals to

enhance their skills and expertise in clinical research. Furthermore, ARISE will be committed to strengthening its partnerships with governments, academic institutions, and industry stakeholders to ensure that its efforts align with the broader goals of the regional and global health agendas.

Targeting both the opportunities and challenges posed by the new structure of its founding organization is necessary in order to fulfill these expectations. As they share the same vision and mission, ARISE will seek more support from its founding organization, in the form of invaluable guidance, infrastructure, or financial assistance. Additionally, being part of a larger organization may enhance ARISE's visibility and influence, leading to greater recognition and support for its activities. Thus, ARISE will look to strengthen its network and expand its collaboration with other organizations to make a bigger impact.

Despite its opportunities, ARISE has identified potential obstacles to achieving its mission. Differences have been observed among the member organizations in terms of the regulatory approval process and clinical research capabilities. These barriers can lead to difficulties in involving all members in a unified platform. To overcome these challenges, ARISE aims to develop workable approaches and create relevant strategies to adapt to the wide range of capabilities and specific needs of each member.

By implementing a multifaceted strategy, ARISE aims to develop an epidemic-ready platform for clinical trial operations with AROs and to promote clinical trials for the development of diagnostics, treatments, and vaccines for infectious diseases in Asia. These efforts will enhance its ability to immediately respond to future pandemics within the region and mitigate the threat of emerging infectious diseases.

Conclusion

ARISE has demonstrated its pivotal role in advancing clinical research and promoting the development of medicines and medical devices in Asia. Committed to adapting its strategies to align with the emerging priorities of the soon-to-be-established JIHS, ARISE recognizes its position as an impactful network for pandemic preparedness. Through continued innovation and collaboration, ARISE strives for a future in Asia in which everyone is protected from health emergencies and has equal access to vaccines, new medicines, and treatment methods.

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