



ARO Alliance for ASEAN & East Asia (ARISE)

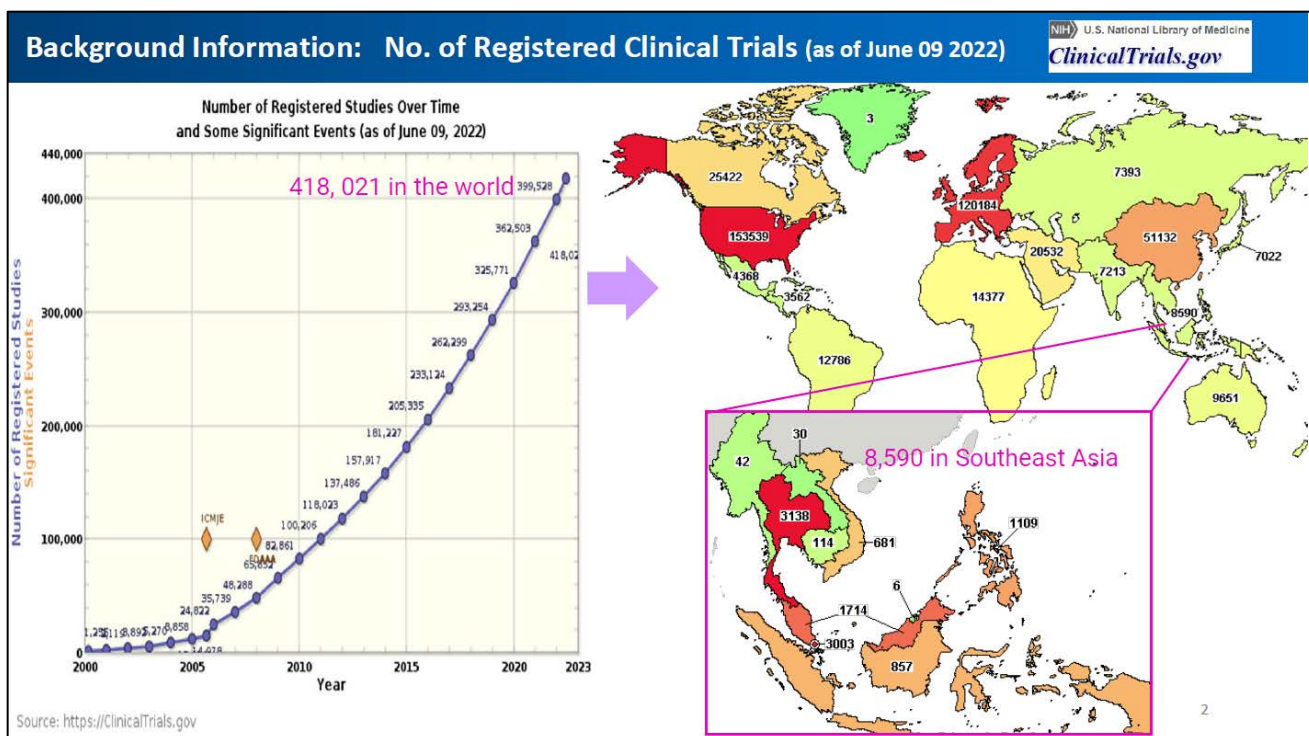
A global ARO network to leverage academic clinical trials in Asia

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I am Sonoda speaking. Thank you very much for this opportunity. The title of my presentation is "A global ARO network to leverage academic clinical trials in Asia." So, with the initiative of NCGM, this ARO Alliance for ASEAN and East Asia or ARISE was established. So, let me introduce that to you.



So, this is the background information. NIH ClinicalTrials.gov has the registration of the clinical trials. Throughout the world, currently, there are more than 400,000 registered. If you look at the breakdown throughout the world, this is the number. In Japan, around 7,000, and in Southeast Asian countries

8,590. That accounts for 1% of the total. So, the number of clinical trials conducted in Southeast Asian countries is quite limited. Especially for the drug development necessary for Southeast Asian countries, clinical trials in Asia are quite important. And they know that to proceed with that we have decided to establish ARISE.

Launching of ARISE

~Kick off meeting (9th Dec, 2021) ~




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Nikkei Biotechnology & Business (13 Jan)



ANTARA NEWS.COM(Dec 31)

Indonesia, Japan ink MoU on solutions for global health problems


"We are not only building the foundation for ARISE by conducting the beneficial discussions but also all the institutions here can open the opportunity to collaborate for further elaborative projects."

Depok (ANTARA) - The University of Indonesia (UI) and Japan's National Center for Global Health and Medicine (NCGM) signed a memorandum of understanding (MoU) on solutions for global health problems.

This ARISE kickoff event took place in December last year, and this article was covered by about 16 news media in Japan. As you see here, in the Asian area, the multinational clinical trial foundation is the purpose of this establishment of the ARISE, and that was how the article was covered.

ARISE Members & Partners

Large Network in Asia & world



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Country	Member Organization	NCGM Co-office
Japan	National Center for Global Health and Medicine	
	Nagasaki University	
	Osaka University	
	International University of Health and Welfare	
Indonesia	University of Indonesia	○
	Mochtar Riady Institute	
Thailand	Faculty of Medicine Siriraj Hospital, Mahidol University	○
Philippines	University of the Philippines Manila	○
	Manila Doctors Hospital	
	Corazon Locsin Montelibano Memorial Regional Hospital	
Vietnam	National Bach Mai Hospital	○
Expected member country... Malaysia, India, Taiwan, Korea, Singapore, Myanmar, Cambodia, Laos and so on		

Partner global clinical networks & organizations

- ◆ Economic Research Institute for ASEAN and East Asia (ERIA)
- ◆ Harvard MRCT Center (Harvard Multi Regional Clinical Trials Center)
- ◆ Clinical Research Initiative for Global Health (CRIGH)
- ◆ Global Research Collaboration for Infectious Disease Preparedness (GloPIDR-R)
- ◆ European Clinical Research Infrastructure Network (ECRIN)
- ◆ Global Antibiotic Research & Development Partnership (GARDP)

Expected partners...

- The European & Developing Countries Clinical Trials partnership (EDCTP)
- Singapore Clinical Research Institute (SCRI)
- Korea National Enterprise for Clinical Trial (KoNECT)

These are the members. More specifically, this is the ARISE members and partners. In Japan, the

National Center for Global Health and Medicine, Nagasaki University, Osaka University, and International University of Health and Welfare member; in Indonesia, the members are the University of Indonesia and Mochtar Riady Institute; and in Thailand, the Faculty of Medicine Siriraj Hospital, Mahidol University. These are members. In the Philippines, the University of the Philippines Manila and Manila Doctors Hospital and also the Corazon Locsin Montelibano Memorial Regional Hospital; and in Vietnam, National Bach Mai Hospital are the members. What's in pink, are NCGM collaborator research residing in these facilities and they would like to expand this to other Asian countries – Malaysia, India, Taiwan, Korea, Singapore, and Myanmar. Those are the countries that we are expecting to expand further.

And not only the medical institutes but the Global Clinical Trial Network and Organizations are also our partners. For Examples, the ERIA, Harvard MRCT Center, and also the world's largest clinical research network - Clinical Research Initiative for Global Health, CRIGH. And also GloPiDR is the funding network for infectious diseases. Those are also partners for us. And also GARDP (Global Antibiotic Research and Development Partnership). Well, yesterday with us NCGM, we agreed on an MOU for the expectation of collaborative activities. The number of institutions as a partner might be considered to be a bit limited. However, these institutions – are those conducting clinical trials most actively in each country. So, each has access to other research institutes for each country. And as you know as well, we have a closer collaboration with the research institutions having a wider scope of the research and research partnership in Japan as well. So, we can reinforce and expand our collaboration further. That's why we put this as a large alliance network.

AROSE Alliance for ASEAN & East Asia (ARISE)

ARISE Chief Representative: NCGM

ARISE Secretariat: DTI, NCGM

Cooperation with global clinical research networks: ecrin, CRIGH

Cooperation with Japanese organizations: fmda, JPMA

Cooperation with Japanese organizations: MRCT (Multi-Regional Clinical Trials)

Promote in Asia

Today's main topic

1. Clinical Study Support
2. Medical product Development
3. Capacity Development
4. Regulatory Support
5. PAPPs
6. Health Policy

Research collaboration with Asian countries
Establishment of NCGM offices in Asia

Indonesia office, University of Indonesia

Vietnam office, Bach Mai Hospital

Philippine office, University of Philippines Manila

Thai office, Faculty of Medicine Siriraj Hospital, Mahidol University


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This is the overall picture of ARISE. So, organizations in Japan and research organizations in Asia and as NCGM, we have the office in these organizations and institutions, and also global


organizations that we collaborate.


And as NCGM, the ARISE chief representative, ARISE Secretary – those are what we are serving for ARISE as NCGM. Through this collaboration, mission-wise activities are being conducted.


ARISE's MISSION


- 1 Clinical Study Support** 

Promotes the integrity, safety, ethics, and quality of investigator-initiated and industry initiated clinical studies.
- 2 Medical Product Development** 


Contributes to developing innovative medical products to address unmet health needs and diseases of public health significance in the region.
- 3 Capacity Development** 

Contributes to improving the resources and capacity of clinical study sites in the region.
- 4 Regulatory Support** 

Accelerates clinical studies and improves timelines and processes for authorization.
- 5 PAPPs** 

Promotes Public-Academic-Private-Partnerships (PAPPs) in the region.
- 6 Health Policy** 

Bridges the gap between sciences and policy for health.

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So, today I would like to talk mainly about these ARISE activities.

In ARISE, there are six missions and each has a label, as you see. So, the first one is the Support of Clinical trials, and second – Is medical Product Development, the third – is Capacity Development, the fourth – Is regulatory Support, the fifth – Public-Academic-Private-Partnerships, and the sixth is Health Policy Contribution. That's our mission.

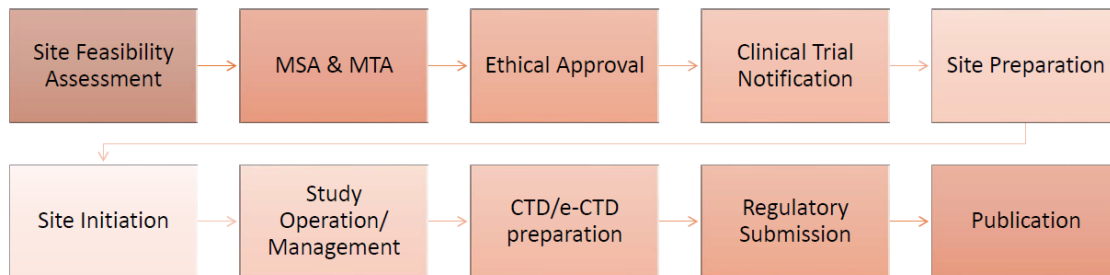
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Clinical Study Support

2

Medical Product Development**Ongoing study in ARISE member countries**

- International study for the evaluation of safety and efficacy of antiviral for covid-19 treatment (Thai, Philippines etc.)
- Drug susceptibility measurement of gram-negative bacteria (Vietnam)
- New diagnostic kit for Malaria in Thailand
- Performance study for SARS-CoV-2 IVD tests (Vietnam, Indonesia etc.)

ARISE supports overall study management for industry & investigator initiated study

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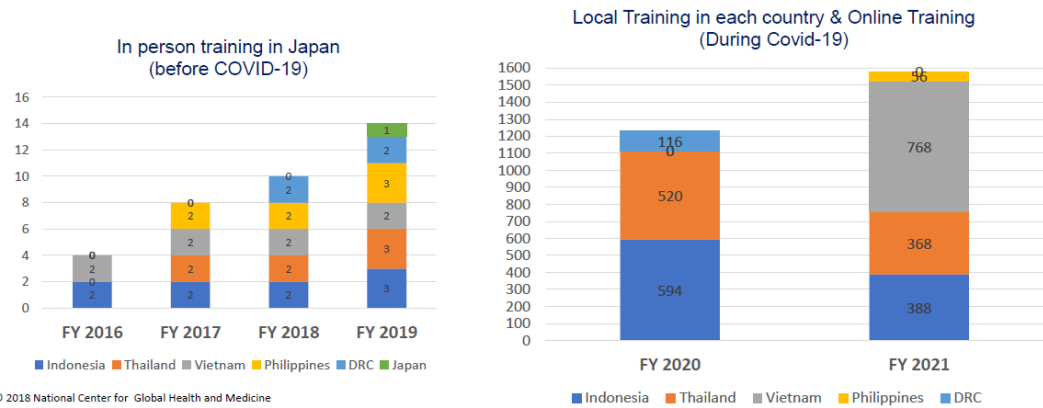
So, first mission that is the Clinical Study Support and the second – Medical Product Development, those prioritize activities for us and our recognition. So, with our ARISE members, we have been conducting these clinical trials already, for example, the development of the COVID-19 treatment. And just like Dr. Kanazawa explained that is about the surveillance in Vietnam for infection and the new diagnostic kit for malaria and also COVID IVD tests.

So, with the companies and academia, we would like to cooperate so that we can increase the number of studies. With that in our mind, each party has been making an effort. So, industry-initiated or investigator-initiated studies are available and those are needed to be managed. For each study, there are different steps and each step requires support. So, for example, the very first one is site assessment to the very end which is regulatory submission and also publication. So, for these steps and for each item, as ARISE, we would like to collaborate with each country, especially with the CROs and also research institutes, and the government as well, so that we can fulfill further the level of activities.



- Onsite & Online training for clinical research professionals
- Dissemination of Competency Standard for clinical research professionals
- Strengthening of Clinical Research Center of NIH in the Philippines
- Introduction of EDC, ePRO, eConsent, and CTMS, and SOP creation for efficient global testing

NCGM-supported Clinical research training: participants in ARISE countries (N=2,999)



The third one – is Capacity Development. For example, onsite and online training has been provided, and also dissemination of Competency Standard or Strengthening of Clinical Research Center of NIH in the Philippines, and also the introduction of EDC, ePRO, and such. You see the graphs here that are NCGM-supported clinical research training. All the participants for this about six years in total around 3000 and you see the breakdowns of participants from each country. GCP certificate is one day to be gained. And GCP certificate if that is gained, then they will proceed to their mid-class training. And afterward, they can go to advanced-class for online training, so that they can improve their capability further. That's what we have been doing in Asian, as well as African countries.

3

Capacity Development of Philippines-NIH

University of Philippines; National Institute of Health, National Clinical Trial & Translation Center (NCTTC)



- Enhance the Organizational Capacity (CRC→NCTTC)
- Research Equipment
- Create SOPs
- Conduct trainings for Philippines researchers
- EDC & Data management
- Data Safety Monitoring Committee



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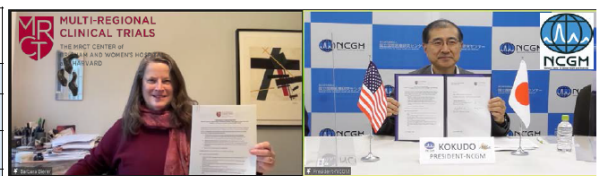
This is the Philippines NIH of the University of Philippines, for this has been providing the support. The building construction is almost in the final phase. As you see, this NIH building is such a beautiful building. The function here has been expanding. Originally, its name was clinical research center, but it has started to be set as the National Clinical Trial and Translation Center. The organization becomes bigger. Research equipment installation, creation of SOPs, supporting training in the country, outside of the country, EDC data management, data safety monitoring committee – those are what we have been supporting. So, there is a team to support the Philippines and we are very proud of being involved in these activities.

3

Capacity Development

Translation of Competency Documents & Survey for the Clinical Research Professionals

	Competency assessment survey (N=1,019)	Competency Translation
ARISE/ NCGM (2021-) 	Thai	Thai
	Indonesia	Indonesia
	Vietnam	Vietnamese
	The Philippines	(English)
	DRC	(French)
CRIGH Project 2 (2016-) • Global Survey was done by Harvard MRCT Center (2016, 2020)	Japanese	
	French	
	Portuguese	
	Italian	
	Spanish	
	German	
	Russian	
Korean		



JTF Core Competency Framework for Clinical Research Professionals



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<https://mrctcenter.org/clinical-trial-competency/>

As a part of capacity development, we have this. That's about the competency. Harvard University

and Brigham and Women's University and multiregional clinical trials. With this MRCT Center, the core competency was developed.

So, they are working for the dissemination of this in the world and this has been promoted by CRIGH and we are translating this into the Asian and African languages and for the capability or for further understanding of that at each region, we have been conducting survey.

4 **Regulatory Support**

5 **PAPPs**

ARiSE NCGM PMDA AWED JPMA

Basic Info Program Representatives of ARiSE and PMDA Register English 日本語

ARISE - PMDA

Joint symposium for Asian Clinical Trial

"How to promote clinical trials in Asia to enable early patient access for pharmaceutical products"

Date and Time: July 12, 2022, 15:00 to 18:00 (Japan time) **Online workshop (Zoom)**

Registration : Pre-registration is required

Language : Simultaneous Interpretation (Japanese and English)

Registration is currently open @ https://event-info.jp/NCGM/event/arise_symposium/

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The fourth and fifth mission is Regulatory Support and PAPPs or Public-Academic-Private-Partnerships. Currently, the number that we have done is quite limited. But there is one event related to this. On July 12th, we are going to do the joint symposium together with PMDA. Each country's academia and regulatory people participating. So, GCP-related discussions and also the development of COVID-19 drugs are going to be the topic of the discussion, so that we can promote this PAPP. We are still in the process of registration. So, if you are interested, please visit this site.

1. Health policy research by Health Labour Sciences Research Grant (厚生労働行政推進調査事業)

➡ Developing Policy recommendation to Japanese Government

Study Title: Study on systems for clinical research in response to infectious disease pandemics
& research on future systems development in Japan (21HA 2018)

PI: Tatsuo Iiyama

2. GlopID-R: Clinical Trial Networks and Funders Working Group



➡ Developing Policy recommendation to international research funders

Objective: To identify and incorporate lessons learnt from the pandemic into improved preparedness plans.



At the end, lastly, but not leastly, let me touch upon health policy. So, NCGM established Asian Network as a national mission. So, in Asian countries relevant authority become also the member. So, our activities and challenges are necessary to be reflected into the policy, so that there will be improvement. That is one of the policy or mission that we have as well. For example, this one - Health Policy Research by Health Labor Sciences Research Grant, in COVID or the emerging infectious diseases, the pandemics, how the clinical trials are conducted, how we can develop the products as early as possible. Those are part of the issues discussed and researched.

Of course, ultimately, towards the Japanese authority or the government, we would like to raise this kind of proposal and the other one is GlopID-R. This is the Clinical Trial Networks and Funders Working Group. So, this working group has been acting, for example, for the global collaboration for pandemics like COVID to conduct clinical trials. We are having discussions, we will make a proposal for funders or funding organizations in various countries.

Summary

Strength

ARISE can

- Work with partners **on the foundation of mutual trust** that NCGM has been building in Asia over the years.
- Cooperate with excellent national research institutes → **Smooth communication with Ministries and Regulatory Authorities** in each country.
- **Work with leading researchers** in Asia and from around the world
- Access to **a large numbers of domestic and overseas research institutes** through each member's network

Challenges

- **ARISE needs more to collaborate with companies.**
- To sustain activities with a sustainable fund.

皆様のご連絡お待ちしております
ARISE 事務局一同



The ARISE network is funded by the Japan Agency for Medical Research and Development (AMED 201k020100j0001) (AMED 221k0201006j0001)



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This is the last slide, a summary slide from me. Here are the strengths and challenges of ARISE. NCGM has established the collaborative approach in Asian countries and that's the foundation of ARISE. There is a trust relationship there for the activities and mainly excellent national research institutes are cooperators, so through that, each ministry and regulatory authorities, there is always smooth communication and we are working with leading researchers in Asia and also from around the world. We can have access to a large number of domestic and overseas research institutes through each member's network. But there are challenges. We have such a strong cooperation with academia and also the government side, but we need more to collaborate with the companies or industries. So, if you are interested, please contact us. And also the foundation of these activities are supported by the AMED fund. But supporting this activity sustainably or continuously is another thing we need to think about.

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)

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<https://doi.org/10.35772/ghm.2022.01007>

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

Our activities are covered by our research letter in this way. So if you are interested in, please refer to it. Thank you very much.