

The Collaborative Efforts of the National Center for Global Health and Medicine (NCGM) to improve Clinical Trial Capacity in Asia



Daisuke TOKITA, MD, PhD

Director,

Department of Clinical Research Promotion,

Center for Clinical Sciences,

National Center for Global Health and Medicine

Highlights

- **Merging of the National Center for Global Health and Medicine (NCGM) and the National Institute of Infectious Diseases (NIID)**
 - to integrate information analysis and research on infectious diseases, human resource development, international cooperation, and provision of optimum medical care
- **ARISE (ARO Alliance for Southeast and East Asia)** efforts to promote and enhance international clinical trials

Central organizations for clinical and basic research on infectious diseases



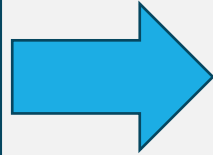
National Center for Global Health and Medicine

- Consists of two hospitals, a research institute, a College of Nursing, and a Center for Clinical Sciences.
- The center hospital has a total of 719 beds
- Three centers dedicated for Infectious Diseases
 - Disease Control and Prevention Center (DCC)
 - AIDS Clinical Center (ACC)
 - The Research Center for Hepatitis and Immunology



National Institute of Infectious Diseases

- Purpose
 - conducts leading, original, and comprehensive research on infectious diseases to clarify and support the scientific basis for national healthcare administration.
- Functions
 - Research services
 - Reference work on infectious diseases
 - Surveillance of infectious diseases
 - National certification and inspection services
 - International cooperation-related services
 - Training services
 - Outreach activities, etc.



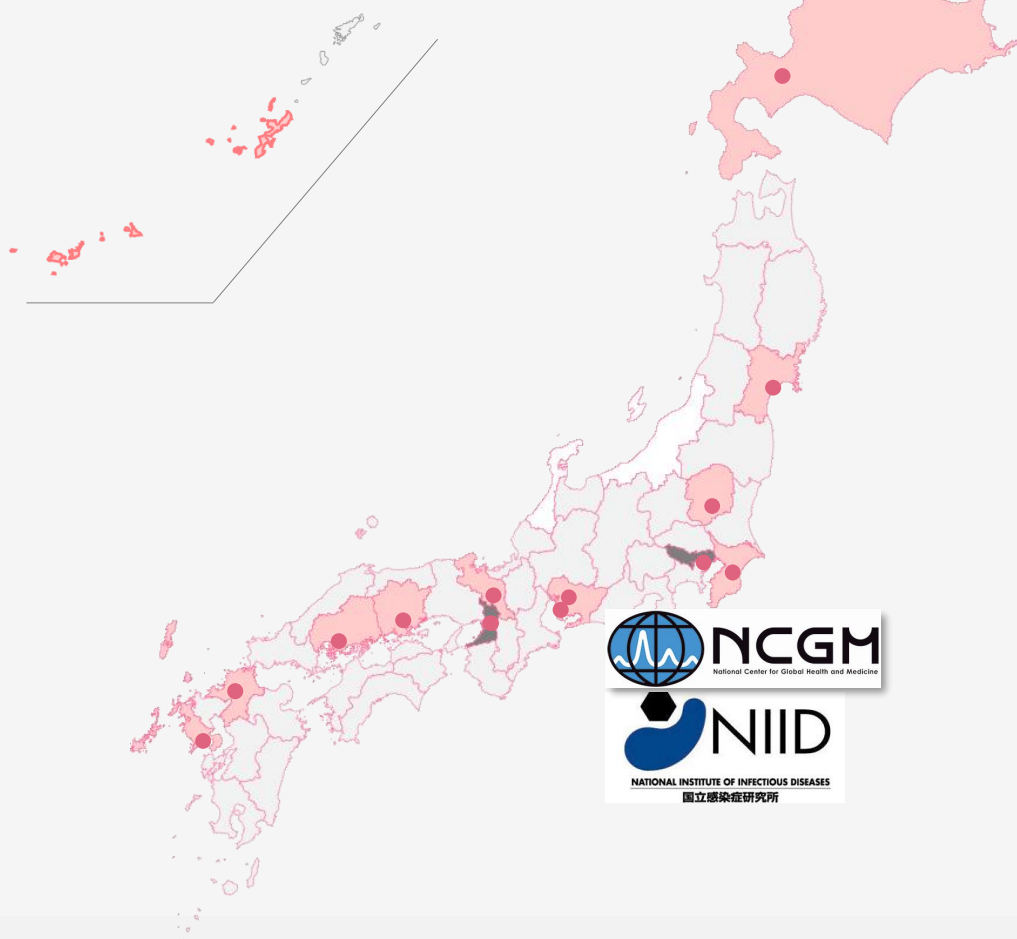
Japan Institute for Health Security (JIHS)

Three pillars of JIHS:

- Enhancement of collection and evaluation of the status of infection in Japan and overseas
- Foundation to promote research and development
- Core of clinical trial network

Clinical Research Network for Infectious diseases in Japan

Objective Respond rapidly to emerging and reemerging infectious diseases through collection of patient information, identification of pathogens, and establishment of a clinical trial system for drugs



Clinical Research Network for Infectious Diseases is being established.

- Secretariat functions for one-stop solution
- Consolidation of profiles of facilities
- Central IRB
- Preparation of Master protocols
- Preparation of Common ICF Template
- Preparation of SOPs
- DCT (Decentralized Clinical Trial)

About our activities outside of Japan

Objective To foster and facilitate international clinical trial collaborations on infectious diseases for both academia and industry

Global collaboration for clinical research and trials

- Mpox vaccine (LC16m8) study in:
 - South America
 - Africa



Platform for clinical research and trials in ASIA

- Thailand
- Malaysia
- Philippines
- Vietnam
- Indonesia





ARO Alliance for Southeast and East Asia (ARISE)

ARISE, established in 2021, is a network of academic research organizations (AROs) in Southeast and East Asian countries. One of its objectives is to ensure the quality of international clinical trials.

ARISE network:
14 institutions from 6 countries.
3 collaborating offices



★ **NCGM Co-office**
location





Collaborative activities with Thailand



2018-



- 2018-2022 Clinical performance study of IVD for malaria
- 2019.03 First visit to Siriraj Hospital



NCGM is working with **Siriraj Hospital, Faculty of Medicine, Mahidol University, Thailand.**

2020-



- 2020 **MOU** was signed
- 2021 Establishment of the **Thailand Collaborative Office**
- 2021- Clinical trial on the use of Virtual Reality therapy in depression
- 2021 **ARISE** was launched



2023-



- 2024.11, The 3rd **ARISE Annual Meeting** will be held at **Mahidol University**



< Strengthening the function of collaborative office >

Representative:

Mr. Naoki Tomotsugu, DIT Executive Manager and Head of Collaborative Office (concurrent appointments)



Goals of ARISE

NCGM, in collaboration with other ARISE member institutions, aims to achieve the following goals for conducting clinical trials of drugs, vaccines, and diagnostics for infectious Diseases in the Asian region

Ensure and maintain the integrity, safety, ethics and quality of Investigator-initiated clinical trials

Collaborate with industries to participate and conduct clinical trials

Ensure the capacity of resources for clinical trial implementation



ARISE Strategies

NCGM makes continuous efforts to promote the implementation of trials for infectious diseases with high quality in the countries of ARISE member institutions by:

Facilitating the conduct of clinical trials of drugs, vaccines and diagnostics for infectious diseases to improve preparedness for public health emergencies

Assigning a liaison officer capable of fostering good relationship and effectively coordinating with key opinion leaders of respective member institutions

Conducting discussions with national and international stakeholders responsible for clinical trials in the event of a pandemic

Clinical Study Projects

IICS: Investigator initiated clinical study
CISC: Company initiated clinical study

Regulatory survey,
Market search,
Site feasibility,
R&D strategy

Pre-consulting

Study design,
Protocol drafting,
Document creation

IRB, Contract,
System development

Monitoring,
Analysis, CSR

Marketing
strategy

Regulatory
approval

2019

2020

2021

2022

2023

Gene test for Malaria (2 trials)

IICS, project management 350/350

IICS, project management 350/350

Gene test for asymptomatic Malaria (2 trials)

IICS, project management 3,315/3,300

IICS, project management 3,315/3,300

Treatment drug for Malaria

Protocol development support

VR digital therapy for depression

IICS, project management ,FPI 20/100

AMR Surveillance (1) Project management 1,262/1,280

IVD for COVID-19

IICS, project management 205/150

AMR Surveillance (2)

CIT, Project management 1,266/1,300

epidemiological study for Neonatal sepsis

CICS, Site identification

Development for ozone disinfectant

CICS Project management, under FDA review

IVD for COVID-19 (4 trials)

IICS, project management 150/150

IICS, project management 150/150

IICS, project management 150/150

IICS, project management 76/75

IVD for COVID-19

IICS, project management 180/175

MPOX vaccine

IICS, project management, FPI 556/9,000

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Summary

- **The ARISE platform is instrumental in delivering high-quality and impactful international clinical trials.**
- **Advice from PMDA Bangkok Office and other regulatory authorities is essential for the proper conduct and seamless collaboration in international investigator-initiated clinical trials.**
- **The establishment of JIHS, which will integrate infectious disease information, marks an important first step towards a more coordinated response for future pandemics.**

We would be very grateful for your cooperation
in clinical trials with you in Asia!
THANK YOU

Contact Us:
ARISE SECRETARIAT OFFICE
Department of International Trials (DIT)
Center for Clinical Sciences
National Center for Global Health and Medicine

1-21-1, Toyama, Shinjuku, Tokyo 162-8655 JAPAN

Tel : +81-3-6228-0445

e-mail: arise@hosp.ncgm.go.jp

 dit-info@hosp.ncgm.go.jp



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