



**24th FERCAP International CONFERENCE**

**Kathmandu, Nepal**

**24-27 November, 2024**

**The Academic Research Organization Alliance for  
Southeast and East Asia (ARISE) – A Regional  
Collaborative Network for Infectious Diseases  
Research and Development.**

**Muchanga Sifa Marie Joelle, MD, PhD**

Department of International Trials

Center for Clinical Sciences

National Center for Global Health and Medicine

Tokyo, Japan





## MUCHANGA SIFA MARIE JOELLE, MD, PHD

### **Current position**

Senior Research Fellow

ARISE Research Coordinator

Department of International Trials, Center for Clinical Sciences,

National Center for Global Health and Medicine, Japan

Sifa is an Obstetrician, Gynecologist, clinical epidemiologist, and Trialist.

She oversees clinical research coordination in the ARISE international network and the design of international training courses for clinical trial professionals.

She has more than 10 years of experience in epidemiological and clinical studies, and her research are published in international peer-reviewed journals.

She is also a researcher of the Japan Environmental and Children Study “JECS”, the ongoing Japanese birth cohort study that scrutinizes the effect of environmental factors on children’s development.



## **DISCLAIMER**

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1.  
The Japan Institute for Health Security

2.  
Academic Research Organization (ARO) Alliance  
for Southeast and East Asia (ARISE) for pandemic  
preparedness

3.  
ARISE Activities

1.



**JIHS**

**Japan Institute for Health Security**

## The Japan Institute for Health Security (JIHS)

- Enhancement of collection and evaluation of the status of infection in Japan and overseas
- Foundation for research promotion and development
- Core of clinical trial networks



### National Center for Global Health and Medicine

- Two Hospitals, a Research Institute, a College of Nursing, and a Center for Clinical Sciences.
- Three specialized centers for Infectious Diseases
  - Diseases Control and Prevention Center (DCC)
  - AIDS Clinical Center (ACC)
  - The Research Center for Hepatitis and Immunology

### National Institute of Infectious Diseases

- Conducts basic research on infectious diseases research and services to support health policy

#### Functions

- Surveillance of infectious diseases
- National certification and inspection services
- International cooperation-related services
- Training services, etc



2.

**Academic Research Organization (ARO) Alliance  
for Southeast and East Asia (ARiSE) for pandemic  
preparedness**



# Center for Clinical Sciences (CCS)



To deliver and ensure quality international clinical trials.

Since 2021

- ❖ 14 members from 6 countries
- ❖ 4 collaborating offices



### Japan

- ① National Center for Global Health and Medicine
- ② Nagasaki University
- ③ Kyushu University
- ④ International University of Health and Welfare

### 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

### Asian Collaborating offices



Indonesia@FMUI



Viet Nam@BMH



The Philippines@UPM



Thailand@FMSH-MU



# A Comprehensive International Multi-layered Clinical Research Network

## Global Partners



- Capacity building
- Global Clinical Trial network
- Funding agency
- Pandemic preparedness

## CT Stakeholders



- Government
- Regulatory authority
- International cooperation agency
- Pharmacy/Medical device manufacturer associations

## AROs from Southeast & East Asia



# ARiSE

Promoting international infectious diseases trials in Asia with global stakeholders

## Agencies



## Goals of ARISE



- 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

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### Governance

ARISE is funded by the Japan Agency for Medical Research and Development (AMED)



## ARISE Strategies

- ❑ Facilitating the conduct of clinical trials for infectious Diseases
- ❑ Ensuring the capacity of resources for clinical trial implementation
- ❑ Conducting discussions with national and international stakeholders responsible for clinical trials in the event of a pandemic
- ❑ Assigning a liaison officer capable of fostering good relationships and effectively coordinating with key opinion leaders of respective member institutions



### **3. ARISE Activities**

# ARiSE Activities

- ARiSE Member's Regular Meeting
- Capacity Development
- Clinical Research Project development
- Clinical study consultation
- International Infectious Diseases Forum (IIDF)

## Study consultation



## IIDF

**第16回 NCGM 国際感染症フォーラム**  
The 16th NCGM International Infectious Diseases Forum

**Date & Time**  
Sept 29, 2023 (Fri)  
15:00-17:45 (Japan Time)

**Presentation Format**  
Online (ZOOM)

**Language**  
English and Japanese  
(Simultaneous Interpretation)

**Entry Fee**  
Free

**Register Here**

**Theme**  
Update on AMR - Trends and Countermeasures for Antimicrobial-resistant Bacterial Infections, and New Antibiotics

**Program**  
15:00-15:07 Opening Address  
Dr. Norihito KUMEDA (President, National Center for Global Health and Medicine (NCGM))  
15:07-17:37 Symposium  
**Chairpersons:**  
• Dr. Yutaka SUGIURA (Director, Center of Global Science, NCGM)  
• Dr. Norio OHMAGARI (Director, Disease Control and Prevention Center (DC), NCGM)

**Part 1: Current Status and Issues of Antimicrobial-resistant Bacterial Infections**  
15:07-15:17 Initiatives of AMR Clinical Reference Center in Japan  
Dr. Nobuaki MATSUNAGA (AMR Clinical Reference Center, NCGM)  
15:17-15:27 **Current Situation & Challenges of Antimicrobial Resistant Bacteria in Indonesia**  
Dr. Agus Karamawan, SpMR, Ph.D. (General, University of Indonesia, Indonesia, Chair of the Antimicrobial Resistance Control Committee, Indonesia)  
15:17-15:37 **Current Situation & Challenges of Antimicrobial Resistant Bacteria in Vietnam**  
Dr. Vu Quoc Dat (General, Hanoi Medical University, Vietnam)

**Part 2: Clinical Testing, Countermeasures, Antibacterial Therapy and Antidotes**  
16:07-16:27 **Issues in Antimicrobial Susceptibility Test and Appropriate Test Methods**  
Mr. Masahiko SHIBATA (NCGM Clinical Reference Center, NCGM)  
16:27-16:57 **AMR Pathogen Surveillance and Antimicrobial Resistant Bacterial Bank in Japan**  
Dr. Mayumi SUGAI (Director, Antimicrobial Resistance Research Center, National Institute of Infectious Diseases)

**Antimicrobial Therapy: Now and the Future**  
Dr. Sabur DOI (Professor, Aichi Medical University)  
17:27-17:37 **Plenary Address**  
Dr. Norio OHMAGARI (Director, Disease Control and Prevention Center (DC), NCGM)

17:37-17:40 Arrangement of Next Forum  
**Secretariat of NCGM Infectious Diseases Forum**  
17:40-17:45 Closing Address  
Dr. Norihito KUMEDA (President, National Center for Global Health and Medicine)

**Secretariat of NCGM Infectious Diseases Forum**  
Department of International Trials, Center for Clinical Sciences, National Center for Global Health and Medicine  
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# Clinical Study Projects

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

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



## Gene test for Malaria (2 trials)



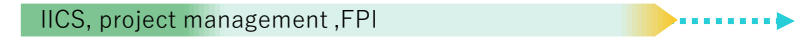
## Gene test for asymptomatic Malaria (2 trials)



## Treatment drug for Malaria



## VR digital therapy for depression



## AMR Surveillance (1)



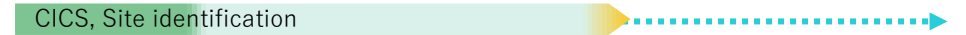
## IVD for COVID-19



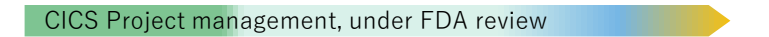
## AMR Surveillance (2)



## epidemiological study for Neonatal sepsis



## Development for ozone disinfectant



## IVD for COVID-19 (4 trials)



## IVD for COVID-19



## MPOX vaccine



Thailand



Vietnam



Philippines



Indonesia

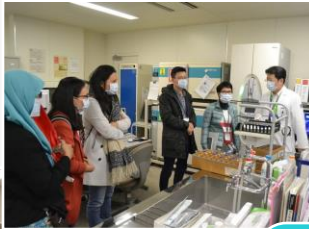


Colombia

# Comprehensive Capacity Building



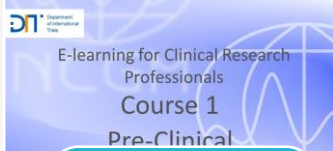
Local Training



MRCT Training



International Symposium



E-Learning





# Competency Framework Translations

## JTF Core Competency Framework for Clinical Research Professionals

The Joint Task Force for Clinical Trial Competency (JTF) is an international team of investigators, educators and clinical research professionals that has developed a framework that defines the knowledge, skills, and attitudes necessary for conducting safe, ethical, and high-quality clinical research.

Collaborators:



日本語, French, Thai, Bahasa Indonesia, Vietnamese

# Seed-Need Matching



321 registered organizations for Public-Private-Academic Partnership

## International Infectious Diseases Forum (IIDF)

IIDF promotes international development through public-private-academia collaboration. Experts provide the latest information and exchange opinions among relevant parties such as companies and medical and research institutions.

東京都 現地ニーズを踏まえた海外向け医療機器開発支援 SMEDO

Japanese English

現地ニーズを踏まえた  
海外向け医療機器開発支援

(Supporting business plan of Medical Equipment Development for Overseas based on local needs)

SMEDO

第18回 NCGM 国際感染症フォーラム  
The 18th NCGM International Infectious Diseases Forum

Theme: Updates on AMR - Trends and Countermeasures for Antimicrobial-resistant Bacterial Infections, and New Antibiotics

Program

15:00-15:07 Opening Address  
Dr. Norihiko KAWAIEDO, Director, National Center for Global Health and Medicine (NCGM)

15:07-17:37 Symposium

Chairpersons  
• Dr. Hiroaki SUGIURA, Director, Center of Global Diseases, NCGM  
• Dr. Norio OHMAGARI, Director, Disease Control and Prevention Center (DCPC), NCGM

Part 1: Current Status and Issues of Antimicrobial-resistant Bacterial Infections

15:09-15:27  
Institute of AMR Clinical Reference Center in Japan  
Dr. Nobuaki MATSUMURA, NCGM Clinical Reference Center, NCGM

15:27-15:47  
Current Situation & Challenges of Antimicrobial Resistant Bacteria in Indonesia  
Dr. Ann Karaningsari, SpMSc, PhD, Universitas Indonesia, Indonesia, Chair of the Antimicrobial Resistance Control Committee, Indonesia

15:49-16:07  
Current Situation & Challenges of Antimicrobial Resistant Bacteria in Vietnam  
Dr. Vu Quoc Dat, University of Medicine and Pharmacy, Vietnam

Part 2: Clinical Testing, Countermeasures, Antibacterial Therapy and Antibiotics

16:07-16:27  
Issues in Antimicrobial Susceptibility Test and Appropriate Test Methods  
Mr. Tetsuyuki SHIBASAKI, IDSSP (IDSS/ALU-0273)

16:27-16:57  
AMR Pathogen Surveillance and Antimicrobial Resistant Bacterial Bank in Japan  
Dr. Motoyuki SEGAI, Division of Antimicrobial Infection Research Center, National Institute of Infectious Diseases

16:57-17:27  
Antimicrobial Therapy: Now and the Future  
Dr. Takashi DOI, Professor, Fukuoka University, Fukuoka, Japan

17:27-17:37 Plenary Address  
Dr. Norio OHMAGARI, Director, Disease Control and Prevention Center (DCPC), NCGM

17:37-17:40 Announcement of Next Forum  
Secretary of NCGM International Infectious Diseases Forum

17:40-17:48 Closing Address  
Dr. Haruhiko SUGIYAMA, Director, Center Strategy, NCGM

Secretariat of NCGM Infectious Diseases Forum  
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Entry Fee Free

Register Here

東京都 TOKYO METROPOLITAN GOVERNMENT

National Center for Global Health and Medicine, Japan Bureau of International Health Cooperation

Department of International Trials



Center for Clinical Sciences  
NCGM National Center for Global Health and Medicine

Department of International Trials

GLOBAL CLINICAL STUDY CONSULTATION





## Objectives

- Discuss vaccine trial implementation
- Share updates on clinical trial activities in the Clinical Trials Network
- Discuss plans for Clinical Trials Network functions
- Share other topics of mutual interest

## Participants

- ARISE members (Steering Committee and other members)
- Guests: Ministry of Health, Labor and Welfare, AMED, Embassy of Japan in Thailand, NCC, PMDA
- Guests from SIRIRAJ (Mahidol Trop Med, National Vaccine Institute, Thai FDA, etc.)

## PROGRAM OUTLINES

- Steering Committee and General Assembly
- Vaccine Trial Workshop "Mpox Vaccine Trial: Scenario-Based Case Study Analysis"
- NCGM-SICRES Joint 5th Clinical Research Symposium: "Challenges and Solutions in Vaccine Trial Conduct: Practical Strategies to Achieve Optimal Results"



# THANK YOU

Contact Us:  
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