

ARISE Asian clinical trial platform NEWSLETTER

New Director of the Department of International Trials, NCGM

Continuing the Vision and Commitment

Daisuke Tokita

Dr Daisuke Tokita is a urologist by training, completed his medical degree at Hiroshima University and earned his PhD in Transplantation from the University of Pittsburgh. He has a strong background in clinical research with over ten years of R&D experience in both academia and pharmaceutical industry.



It is with great enthusiasm that I take on the role of Director of the Department of International Trials and Secretary General for ARISE, beginning by acknowledging the progress made by my predecessor and the entire team.

My main goal is to build on the strong partnerships and research initiatives within the department and ARISE network, which fosters knowledge-sharing and capacity building. As we grow, I will seek new international engagement opportunities while preserving the collaborative spirit that has brought us this far. The network's

focus on research collaboration aims to deliver evidence-based solutions that address the specific health challenges of ARISE member countries and Japan, particularly in combatting infectious diseases.

I am eager to leading this talented team as we continue to foster partnerships, embrace new opportunities, and expand our reach. Guided by the vision of our department and with utmost dedication, let us advance together as we embark into the promising next chapter that lies ahead.

Thank you for your ongoing support and cooperation.

Editorial

■ What's New? Fresh Updates from our Network

Within the ARISE network, collaboration is fundamental to our operations. This volume highlights our ongoing interactions with members of ARISE and our collective activities with partners from the academic and industrial sectors. We present the outcomes that have resulted from these collaborations.

Don't miss the 3rd ARISE Annual Meeting at Siriraj University Hospital, Thailand on November 21-22.

Important Announcements

- **November 21-22, 2024** The 3rd ARISE Annual Meeting at Siriraj University Hospital, Thailand
- **April 2025** Introducing JIHS: NCGM and NIID to Merge

Working Group Updates

Operation Working Group in Malaysia

The Operations Working Group (WG) looked into the prospect of implementing Decentralized Clinical Trials (DCT) as a future pandemic response strategy, collaborating with Kyushu University, known for its DCT simulation for infectious diseases in Japan.

Last October 2 to 5, Dr. Koji Todaka, Director of Kyushu University's Center for Clinical and Translational Research with Mr. Naoki Tomotsugu, Ms. Mieko Hamana, and Ms. Marlinang Siburian visited Clinical Research Malaysia (CRM) in Kuala Lumpur as Malaysia is the only Asian country with formal DCT guidance. They learned from CRM that a phase IIB DCT pilot study on inflammatory

bowel disease (IBD) was conducted using the Local Care Model (LCM), a system designed by Malaysia to effectively integrate the involvement of tertiary hospitals and health clinics. The study incorporated DCT elements by making specific changes to the protocol and the SOP.

Discussions with one of the main sites, the primary investigators, and the University of Malaya Medical Center (UMMC) underscored the DCT challenges and benefits, along with its potential application in other ASEAN countries. The WG plans to conduct future DCT simulations in collaboration with Malaysia and Kyushu University, leveraging the lessons learned.



Group photo with Dr. Akhmal Yusof, CEO of Clinical Research Malaysia CEO and his team



Group photo with Dr. Yeoh Wei Sien, Head of Clinical Investigation Center (CIC), University of Malaya Medical Center and his staff

Capacity Development Working Group in the Philippines

On September 24 to 27, the University of the Philippines Manila held its 1st Annual Clinical Trials and Translational Science Meeting themed, "Enhancing Capacities and Collaborations towards Patient-centered Trials." The National Clinical Trials and Translation Center under its Director, Dr. Benjamin Sablan Jr. organized the event with the

support from AMED and NCGM.

The first two days focused on clinical trial training modules, developed from prior JTF Competency assessment by NCGM. The third day featured integrating patient preferences into trial designs and vaccine trial presentations. Dr. Wataru Sugiura, Director of NCGM's Center for Clinical Sciences, provided updates on HIV/AIDS, and Mr. Yasuhiko Shinmura of KMBio introduced the mpox vaccine. The event concluded with a forum on strategies and opportunities for patient-centered trials

NCGM representatives, Dr. Sifa Muchanga, Mr. Katsumi Ishii, and Dr. Maria Ruriko Umamo joined professionals from academia, government, private industry, and contract research organizations in discussions on inclusivity and effective clinical trial approaches for infectious diseases, fostering deeper understanding and valuable connections among participants.



Organizers and participants pose for a group photo after the successful completion of day two of the event

Secretariat Recent Activities

On the Ground: Visit to ARISE member institutions in the Philippines

ARISE Secretariat members, Dr. Sifa Muchanga and Dr. Maria Ruriko Umamo, visited West Visayas State University (WVSU) on September 30 and Corazon Locsin Montelibano Memorial Regional Hospital (CLMMRH) on October 1.

In meetings with Dr. Joselito Villaruz, President of WVSU, and Dr. Julius Drilon, Medical Chief of CLMMRH, and their respective teams, challenges and efforts to overcome them were discussed. WVSU, experienced in Phase II and III clinical trials with international collaborators, currently has 13 active trials, with infectious diseases ranking third among treated conditions. At CLMMRH, about 70% of admissions are infectious diseases, and a new Clinical Trial Unit has been established.

The visits included facility tours that provided clear insight into their infrastructure and clinical operations. Both institutions reaffirmed their

strong support and commitment to advancing clinical research and collaboration.



Above: Group photo with WVSU president and staff
Below: Group photo with CLMMRH Chief and staff

Key Events and Accomplishments

The 17th NCGM International Infectious Diseases Forum

The 17th NCGM International Infectious Diseases Forum (NCGM-IIDF) was successfully held on September 5, 2024, continuing its tradition since 2018. This year's theme was **"The Forefront of Diagnosis & Treatment of Viral Hepatitis, and Future Prospect"** which drew significant interest due to the widespread hepatitis B virus (HBV) infections, particularly in Africa and Asia. The forum set a record with 710 registered participants.

Notable speakers included Dr. Takako Inoue (Graduate School of Medical Sciences, Nagoya City University), Dr. Masaya Sugiyama (Department of Viral Pathogenesis and Controls, Research Institute, NCGM), Dr. Yasuhito Tanaka (Department of Gastroenterology and Hepatology, Kumamoto University), Dr. Mei-Hsuan Lee (Institute of Clinical Medicine, National Yang Ming Chiao Tung University, Taiwan), and Dr. Pisit Tangkijvanich (Center of Excellence in Hepatitis and Liver Cancer, Chulalongkorn University, Thailand).



Image of panelists captured during an engaging discussion led by Dr. Wataru Sugiura and Dr. Tatsuya Kanto (NCGM).

Most international attendees joined from the Philippines, Indonesia and Africa. Feedback was overwhelmingly positive, with 63% rating the content as excellent. NCGM aims to continue hosting engaging forums that emphasize the importance of international collaboration in infectious disease research.

PMDA International Symposium and Launch of Branch office in Bangkok, Thailand

The **PMDA International Symposium**, held on August 29, 2024, in Bangkok, marked the launch of PMDA's first overseas office in Asia. The event focused on strengthening regional pharmaceutical regulation and collaboration. HE Keizo Takemi, former Minister of Health, Labor and Welfare, opened the meeting, emphasizing Japan's efforts in Universal Health Coverage and the need for regional collaboration to address the aging population, future pandemics, and regulatory harmonization.

Hospital Director, Dr. Hideyo Miyazaki discussed collaboration with the PMDA Asia Office, introducing NCGM's '3G initiative' for biobanking and genomic medicine and ARISE's COVID-19 and malaria trials since 2021. He also highlighted the upcoming merger of NCGM and the National Institute of Infectious Diseases to form the Japan Institute for Health Security (JIHS), aiming to advance drug development with Asian regulators.

Dr. Daisuke Tokita, Director of the Department of International Trials (DIT), presented on the need to



Commemorative photo of guests and speakers at the symposium

enhance Asia's clinical trial capacity through JIHS and ARISE for pandemic preparedness. Mr. Naoki Tomotsugu, Executive Manager of DIT, stressed the importance of Asia-focused clinical trials, genetic considerations, rapid study startups, and reliable data quality for global approval.

Dr. Sifa Muchanga Introduced ARISE activities at Singapore Workshop

Dr. Sifa Muchanga represented ARISE at the **"Collaborative Initiative Research Workshop: Data Empowerment for Infectious Diseases clinical research: Perspectives from Japan and Singapore"** on October 7 to 9, 2024. The three-day workshop took place at the Lee Kong Chian School of Medicine, Nanyang Technological University, in Novena, Singapore. During the event, delegates from Japan and Singapore explored ways to optimize the use of existing health data for predicting future pandemics and improving regional preparedness. Dr. Sifa Muchanga presented ARISE ongoing activities, emphasizing the importance of

collaboration among network members to enhance research capabilities across the region.



Participants gathered outside the venue for a group photo

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DIT

