

**Day 2: 15:20 – 15:35**

**ARISE Initiatives to Implement “The Core Competency Framework for Clinical Research Professionals” in Asia and Africa**



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**Short CV**

Ms. Sonoda has a long career as a global health research manager and program officer for international cooperation. Prior to serving her current position in ARISE/NCGM from 2021, she had engaged in several global health research programs at the Japan Agency for Medical Research and Development (AMED) from 2016 to 2021.

Ms. Sonoda also served for several Japan International Cooperation Agency (JICA) health-related ODA programs in Vietnam, Lao P.D.R, Myanmar, and the Philippines, as a technical advisor in the Maternal and Child Health Care and HIV/AIDS fields from 2006 to 2016. In addition, she also worked on economic partnership projects with Asian countries at the Ministry of Health, Labor, and Welfare Japan from 2013 to 2014.

Ms. Sonoda earned her Master's degree in Public Health at Johns Hopkins University (JHU), and obtained graduate certificates in Clinical Trial and Global Health at JHU. She is a Ph.D. candidate from the KEIO University School of Medicine.

**Abstract**

With the increase and complexity of clinical research, the demand for clinical research professionals is increasing worldwide. Although the quality of clinical research depends on the human resources involved, it has been pointed out that it does not meet international standards due to the lack of training opportunities, especially in low- and middle-income countries.

Through ARISE (ARO Alliance for ASEAN & East Asia), competencies of clinical research professionals will be implemented in five countries: Indonesia, Thailand, Vietnam, the Philippines, and the Democratic Republic of Congo.

In collaboration with AROs, which play a central role in clinical research in each country, we translated into local languages the “The Core Competency Framework for Clinical Research Professionals” developed in 2016 by the Harvard MRCT Center and other organizations. Furthermore, a competency self-assessment questionnaire using this framework was prepared in 5 languages and we conducted online surveyed in 5 countries (March-June 2022).

A new competency framework in Indonesian, Thai, Vietnamese and French translations was completed and made known to research institutions, government agencies and regulators in each country. A total of 1,017 people responded to the self-assessment survey, revealing that some attributes influenced self-perceived competency levels. Working groups were also formed during these collaborative processes, which led to collaboration with the MRCT centers and the Clinical Research Initiative for Global Health (CRIGH).

Implementing international competency standards at the national level to promote high-quality international collaborative clinical research in accordance with ICH-GCP will be useful in eliminating the critical gap (perception gap) among stakeholders.