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Pharmaceuticals and Medical Devices Agency

National Cancer Center Japan and Pharmaceuticals and Medical Devices Agency Endorsed as a joint Center of Excellence by APEC

April 27, 2021

National Cancer Center Japan

Pharmaceuticals and Medical Devices Agency

The National Cancer Center Japan (NCC, President: Hitoshi NAKAGAMA, Tokyo) and the Pharmaceuticals and Medical Devices Agency (PMDA, Chief Executive: Yasuhiro FUJIWARA, Tokyo) have been endorsed on April 6th 2021 as a joint Center of Excellence (CoE) for Regulatory Science in the Priority Work Area (PWA) of Multi-Regional Clinical Trials & Good Clinical Practice Inspection by the Asia Pacific Economic Cooperation Life Science Innovation Forum Regulatory Harmonization Steering Committee (APEC LSIF RHSC).

APEC LSIF RHSC aims to promote regulatory convergence, capacity building and cooperation in regulations on drug and medical device within the APEC region. As part of this, APEC LSIF RHSC endorses academia, regulatory authorities and educational organizations with authoritative knowledge in various fields as the CoE, and supports them to host training programs for regulatory authorities in the region.

NCC and PMDA concluded a comprehensive collaborative agreement for regulatory science research activities in 2016, and were endorsed as a joint CoE by co-sponsoring “PMDA-ATC with National Cancer Center MRCT Webinar 2021” in January 2021.

Collaboration between PMDA with successful achievements as a CoE, and NCC, provides training for both regulatory authorities and academia, allowing new drug application reviewers and clinical investigators to deepen mutual understanding of their respective specialties, further activating global clinical trials within APEC region. NCC is recognized as the second academic CoE host institution in Japan, following Kobe University, a CoE for PWA of Biotherapeutic Products.

National Cancer Center Hospital of NCC (Director: Kazuaki SHIMADA) was certified as the Global Clinical Trial Core Center of Global Clinical Trial Development Project in 2016 by Japan Agency for Medical Research and Development (AMED), and has been enhancing its support function for international collaborative clinical trials. By forming the Asian Oncology Early Phase 1 Consortium (ASIA ONE) in Asian regions (Japan, Korea, Taiwan, Hong Kong, and Singapore) and conducting a number of international academic clinical trials, including GCP compliance international investigator-initiated clinical trials for new drug application in Japan, Korea, Taiwan and Singapore, NCC has been accumulating expertise in international clinical trials and

disseminating them through symposiums in and outside Japan.

PMDA established “Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)” in April, 2016 to provide training to regulators in Asia. PMDA-ATC was endorsed as a CoE for PWA of MRCT-GCP Inspection and Pharmacovigilance in February 2017 and for a PWA of Medical Device in June 2020.

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[REFERENCE] About APEC LSIF Regulatory Harmonization Steering Committee (APEC LSIF RHSC)

APEC LSIF RHSC is one of regional economic integration frameworks by APEC composed of 21 economies in the Asia-Pacific area, and an organization established to promote regulatory harmonization of drug and medical device within the area. The committee is co-chaired by Japan and the United States, with participation of regulators, industries from APEC economies.

APEC LSIF RHSC identifies 7 areas of regulatory harmonization activities as Priority Work Areas (PWAs) and its leading economy as the Champion Economy, promoting regulatory harmonization through high-quality training programs hosted by certified regulatory agencies and academia in the region with the authoritative knowledge as Centers of Excellence (CoEs).

Japan is the Champion Economy in 3 Priority Work Areas (PWAs), “Multi-Regional Clinical Trials & Good Clinical Practice Inspection”, “Good Registration Management” and “Medical Devices”. PMDA, Kobe University and NCC are formal CoEs in Japan (See below Table).

Table：List of RHSC PWA, Champion Economy, and CoE/pilot CoE (as of 27 April 2021)

Priority Work Areas (PWAs)	**Champion Economy**	**CoE/pilot-CoE**
Multi-Regional Clinical Trials & Good Clinical Practice Inspection	Japan, Thailand	・Pharmaceuticals and Medical Devices Agency (PMDA) with National Cancer Center Japan (NCC), Japan ・Peking University (PKU), China ・Duke-NUS Medical School, Singapore ・The MRCT Center of Brigham and Women's Hospital and Harvard (MRCT Center), The United States ・Korea National Enterprise for Clinical Trials (KoNECT), Korea
Pharmacovigilance	Republic of Korea	・Pharmaceuticals and Medical Devices Agency (PMDA), Japan ・Korea Institute of Drug Safety and Risk Management (KIDS), Korea ・Peking University (PKU), China
Biotherapeutic Products	Republic of Korea	・Northeastern University (NEU), The United States ・Kobe University, Japan ・Duke-NUS Medical School, Singapore*
Advanced Therapy Products	Singapore	・Northeastern University (NEU), The United States ・Duke-NUS Medical School, Singapore ・United States Pharmacopeia (USP), The United States*
Good Registration Management	Chinese Taipei, Japan	・TFDA with Regulatory Affairs Professionals Society (RAPS) Taiwan Chapter, Chinese Taipei ・Food and Drug Administration, Thailand (Thai FDA)
Global Supply Chain Integrity	The United States	・United States Pharmacopeia (USP), The United States ・The University of Tennessee Health Science Center (UTHSC), The United States ・Taylor’s University, Malaysia
Medical Devices	Japan, the United States, and Republic of Korea	・National Institute of Medical Device Safety Information (NIDS), Korea ・University of Southern California (USC), The United States ・Pharmaceuticals and Medical Devices Agency (PMDA), Japan ・Sichuan University (SCU), China ・Taiwan Food and Drug Administration (TFDA), Chinese Taipei ・Soonchunhyang University (SCH), Korea ・Northeastern University (NEU), The United States* ・Duke-NUS Medical School, Singapore*

*CoE at the pilot stage.