Notice of Webinar on " Safety Cornerstone of Vaccine Clinical Trials: Building Vaccine Vigilance Systems and Meeting Regulatory Standards "

Dear Colleagues in the Vaccine R&D Field,

Vaccine vigilance is a crucial pillar in safeguarding public health throughout the vaccine life cycle. To delve into the establishment of vaccine vigilance systems and regulatory standards in clinical trials, Council for the Promotion of International Vaccine Cooperation (CPIVC) is pleased to announce the upcoming webinar titled " Safety Cornerstone of Vaccine Clinical Trials: Building Vaccine Vigilance Systems and Meeting Regulatory Standards " on April 8, 2025, from 15:00 to 16:30 (Beijing Time).

This online event will feature presentations by distinguished pharmacovigilance experts from around the globe and provide a platform for industry peers to engage in discussions. Together, we aim to fortify the safety framework of vaccine clinical trials and ensure public health protection. Your participation would be highly valued.

For details on the agenda, speakers, and moderators, please refer to the attachments.

Contact Person: Ms. Yang Dan

Tel: 18210332798

Email: yangd@vandh.org

Annex: 1. Conference Agenda

2. Introduction of Speakers and Moderator

CAV CPIVC

March 17, 2025

Annex 1

Conference Agenda

Organizer: CPIVC

Time: April 8, 2025 (15:00-16:30, Beijing time)

Format: Webinar (ZOOM)

Conference registration link:

https://us06web.zoom.us/webinar/register/WN_WpzenrZtTdi5870g-H7uVg

Date/Time	Topic	Speaker
15:00-15:05	• Welcome and warm up • Introduce attendees, speakers and agenda	Tharinee Sakhakorn (P95)
15:05-16:05	Topic 1: Establishment and development of PV system in Vaccine field (30 minutes) Topic 2: Regulatory requirements of PV in vaccine clinical trials (30 minutes)	Xiaoyao Mo (PVing) Marc Ceuppens (P95)
16:05-16:20	Online interview	Yuanyuan (CPIVC, interviewer)/Xiaoyao Mo (PVing, interviewee)
16:20-16:25	Q&A	Tharinee Sakhakorn (P95)
16:25-16:30	Summary	Yuan Yuan (CPIVC)

Notes:

1. Click on the above ZOOM link to register. Please provide your organization's name, your full name, and any other requested details. This helps the conference administrator verify your identity and grant access.

2. Feel free to submit questions in advance to the host, who will relay selected ones to the speakers for feedback. We'll also reserve time during the discussion session for live Q&A with the attendees.

3. Simultaneous interpretation will be available. Please download the ZOOM software beforehand.

Annex 2

Introduction of the speakers and Moderator

Ms. Xiaoyao Mo

Xiaoyao Mo and her team provides PV technical services to biopharma industries, regulatory agencies, HCPs and their customers. She has total 25 years of pharmacovigilance working experience including 18 years of biopharma experiences in J&J/Pfizer/Merck/AZ China medical and global RnD. Since 2017, Xiaoyao founded PVing®, lead team to provide PV consulting and PV system quality audit to MAHs, sponsors and their vendors. She and her team continued to research and develop safety database and PV data analysis tools. They have solutions in signal detection used in real world data and different data sets. She accepted excellent leadership training from Harvard Business School. Prior to industry, she was a respiratory physician in Beijing Xuan Wu hospital, China.

Xiaoyao plays a leadership role for internal and external partnerships in PV enterprise. From 2022, she was assistant chief editor for Chinese Journal of Medicinal Guide. She is Pharmacovigilance committee member of China Society for Drug Regulation since 2023, is ACC member of DIA China from 2020-2024, and a volunteer for DIA since 2010. She leads China Industry Pharmacovigilance (PV) working stream in RDPAC from 2004 to 2014. She was invited by CFDA as ICH expertise, Multidisciplinary group, China CFDA ICH Study Group from 2009-2012. She reviewed Chinese version of clinical safety related ICH guidelines in 2006-2007. She was core teaching faculty of CCDRS postgraduate education program, collaborated among Peking university, University of Basel, Switzerland and University of California at San Francisco in 2008-2013 and key PV program for Training center of NMPA.

Mr. Marc Ceuppens

Marc Ceuppens, MD, graduated as a medical doctor in 1991. He is an experienced vaccine and drug safety physician with a proven track record in various pharmaceutical companies for more than 25 years, including Janssen Pharmaceutica, Bristol-Myers Squibb and GlaxoSmithKline Vaccines. He most recently held the position of Therapeutic Area Safety Head for Vaccines, Infectious Diseases and Global Public Health products at Janssen, supporting multiple new product license applications and a variety of product safety, risk management and quality management activities. He joined P95 in June 2023 as PV advisor.

Ms. Tharinee Sakhakorn

Tharinee Sakhakorn is currently a Regional Director of South-East Asia at P95. She brings over 20 years of global experience in clinical operations, with expertise in team leadership, organizational transformation, project management, training, and quality and risk management. She has held key roles in vaccine development at GSK, Takeda, and Clover Biopharmaceuticals, contributing to the advancement of HPV, COVID-19, dengue, and norovirus vaccines.

With extensive international experience across Emerging Markets, Asia Pacific, and Europe, Tharinee has previously been based in Belgium and Switzerland.

Ms. Yuan Yuan

Yuan Yuan, Secretary-General of CPIVC, has been working at PATH since January 2007, serving as Project Assistant, Project Administrator, Project Manager and Alliance Manager. She is currently the Country Representative in China, responsible for PATH's commercial and business development in China. During the 18 years of working in the vaccine field, she participated in WHO precertification of JE vaccine, rotavirus vaccine development, pneumonia conjugate vaccine development and training, OPV overseas clinical practice, Sabin IPV D antigen international standard development, HPV vaccine precertification and other projects. Familiar with vaccine life cycle production, quality, clinical, drug administration, pharmacovigilance, biosafety and other aspects. Prior to joining PATH, she was a project manager at Integrity Metals in Singapore and worked in Indonesia.