DIA-NIFDS-ICH Workshop on Pharmacovigilance

Best Practice in Pharmacovigilance

September 6th, 2019 | Grand Hilton Seoul | Seodaemun-gu, Seoul

ICH was established in 1990 and has since facilitated professionals from the three global regions (EU Japan and USA) to formulate appropriate practice guidelines. The rationale behind its formation was the growing understanding within scientific communities that the goals of pharmacovigilance services would be better met if there existed a greater degree of uniformity regarding testing and safety regulations across the different regions.

As an essential part of patient safety, pharmacovigilance is of worldwide interest and should expand its scope and focus on new emerging issues. The change in pharmacovigilance paradigm is a global trend and Korea has excellent infrastructure and in the near future the paradigm of pharmacovigilance will shift in Korea.

Objective

The objective of this Workshop is to provide a common platform for regulatory authorities, academia, investigators, service providers and the Biopharmaceutical industry, to deliberate upon and understand PV Regulatory requirements the most recent updates, impacting the Drug Safety spectrum. Providing case studies in the workshop, which helps participants how to apply the guidelines to their system and practices.

Key Topics

- DSURs and PBRER writing: Aspects of Benefit – Risk Assessment
- Signal Detection Method and evaluation from Regulatory Perspective
- Signal detection methodology in real practices - Industry Experience
- Recent changes in PMS and utilization of RWD/RWE in Japan PMS
- Use of RWD/RWE in PV/PMS area
- CCSI & CCDS development in real practice
- Introduction to elabeling

Advisory Committee

Kyung Won See
Director General NIFDS
MFDS

Chul Kim
Senior Vice President
Samsung Bioepis

Seung Jae Baek
Executive Director -
Clinical Science & PV
Hanmi Pharm. Co. Ltd.

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Registration Opening Soon
or
Please contact us at
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for assistance

Committee Members

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Hwayoung Lee
Team Lead,
APAC International
Labeling Group
Pfizer Pharmaceuticals

AGENDA | Day 1 | September 6, 2019

8:00–9:00	**Registration**
9:00–9:10	**Welcome** **Youngshin Lee** SVP / MD DIA Korea ASEAN INDIA
9:10–9:20	**Opening Remarks** **SangHee Kim** Chief Executive Officer Protech Pharmaservices Corporation (PPC) Korea
9:20-9:30	**Congratulatory Speech** **Kyung Won Seo** Director General NIFDS MFDS
9:30-10:30	**DSURs and PBRER Writing: Aspects of Benefit – Risk Assessment** **Dawn Ren** Head of Therapeutic Area Specialty Medicine, Benefit Risk management Pharmacovigilance, Bayer
10:30-11:30	**Signal Detection Method and Evaluation from Regulatory Perspective** **Gerald Dal Pan** Director of the Office of Surveillance and Epidemiology Center for Drug Evaluation and Research U.S. Food & Drug Administration (USFDA)
11:30-12:30	**Signal Detection Methodology in Real Practices** Industry Speaker Invited
12:30-13:30	Lunch
13:30-14:30	**Recent Changes in PMS and Utilization of RWD/RWE in Japan PMS** **Shuya Yoshida** Office of Medical Information & Epidemiology PMDA
14:30-15:30	**Use of RWD/RWE in PV/PMS Area** **Prof. Euna Han** Associate Professor. College of Pharmacy Yonsei University, Incheon South Korea. **Prof. Manabu Akazawa** Professor, Public Health and Epidemiology Meiji Pharmaceutical University
15:30-16:00	Coffee Break
16:00-17:30	**CCSI & CCDS Development in Real Practice** • RSI (Reference Safety Information) Use in Clinical trials / develop the CCDS • To include 'Expectedness assessment' • Introduction of e-labelling **Rie Matsui** Director International Labeling Asia, Regulatory Affairs Pfizer
17:30–17:45	**Closing Remarks** **Min-Jung Lim** Chief Executive Officer MediSafe