DIA

MINISTRY OF FOOD AND DRUG SAFETY
National Institute
of Food and Drug Safety Evalution

DIA-NIFDS Workshop on Pharmacovigilance

Best Practice in Pharmacovigilance with ICH E2 and RWD

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

ICH Recognised Training Programme

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

- Aspects of Effective Safety Reporting and Risk Benefit Assessment with ICH E2-DSURs and PBRER
- Signal Detection Method and Evaluation from Regulatory Perspective
- Signal Detection Methodology in Real World Practice with E2E
- Recent Changes in PMS and Utilization of RWD/RWE in Japan PMS
- Use of RWD/RWE in PV/PMS Area - the ICH Way Forward
- Application of CCDS and CCSI in Real World with ICH E2C(R1)

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.

JunJeong Choi
Yonsei University

Moin Don
President & CEO
PVCON Consulting

Program Committee

Chair
SangHee Kim
Chief Executive Officer
Protech Pharmaservices
Corporation (PPC) Korea

Co-Chair
Min-Jung Lim
Chief Executive Officer
MediSafe

Committee Members

Yongseok Ko
Deputy Director NIFDS
Ministry of Food and Drug
Safety (MFDS)

EunAh Paek
Head of Medical
Operation Group
Boryung Pharmaceutical
Company

SuWon Kim
Pharmacovigilance
Manager
Donga-A ST

HyeYoung Kim
Medical Information
& Pharmacovigilance
Manager
Chong Kun Dang Pharm

Mijeong Kim
Pharmacovigilance
Director
C&R Research

SoYeon Park
Senior Drug Safety
Manager
Celgene

Hwayoung Lee
Team Lead
APAC International
Labeling Group
Pfizer Pharmaceuticals

AGENDA | September 6, 2019

8:00–9:00	**Registration**
9:00–9:05	**Welcome**
	Youngshin Lee SVP / MD DIA Korea ASEAN INDIA
9:05–9:10	**Opening Remarks**
	SangHee Kim Chief Executive Officer Protech Pharmaservices Corporation (PPC) Korea
9:10-9:15	**Congratulatory Speech**
	Kyung Won Seo Director General NIFDS MFDS
9:15-10:15	**Aspects of Effective Safety Reporting and Risk Benefit Assessment with ICH E2- DSURs and PBRER**
	Dawn Ren Head of Therapeutic Area Specialty Medicine, Benefit Risk management Pharmacovigilance, Bayer
10:15-10:30	Coffee Break
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)
11:30-13:00	**Signal Detection Methodology in Real World Practice with E2E**
	Yasufumi Kuroda Associate Director Pharmacovigilance Department Daiichi Sankyo Co., Ltd **Hannah Jeon** Cluster Head APAC Roche
13:00-14:00	Lunch

Registrations Open
Please contact us at **Korea@DIAGlobal.org** for assistance

AGENDA | September 6, 2019

14:00-15:00	**Recent Changes in PMS and Utilization of RWD/RWE in Japan PMS** **Shuya Yoshida** Office of Medical Information & Epidemiology PMDA
15:00-16:00	**Use of RWD/RWE in PV/PMS Area - the ICH Way Forward** **Prof. Euna Han** Associate Professor. College of Pharmacy Yonsei University, Incheon South Korea. **Prof. Manabu Akazawa** Professor, Public Health and Epidemiology Meiji Pharmaceutical University
16:00-16:30	Coffee Break
16:30-17:30	**Application of CCDS and CCSI in Real World with ICH E2C(R1)** • 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