DIA-NIFDS Pharmacovigilance Workshop:
Diversification in the Practical Application of Pharmacovigilance

November 18th, 2020
Virtual Meeting

DIA-NIFDS Pharmacovigilance Workshop is the premier resource to hear the global standards in pharmacovigilance and drug safety and how they are implemented in real practice. In this year's program, biopharmaceutical and regulatory agency experts will engage with the audience on topics such as safety information updates, MedDRA Labelling Grouping (MLG) initiative, practical approaches in active safety surveillance, and safety management of cell and gene therapy products.

Objective

This Workshop aims to provide a common platform for regulatory authorities, academia, investigators, service providers and the Biopharmaceutical industry, to deliberate upon and understand the most recent updates impacting the Drug Safety spectrum.

At the completion of this workshop, the participant should be able to:

- Explain the process and timing for development and updates of target labeling/DCDS/CCDS and local labels
- Describe how MedDRA is used in label development
- Evaluate safety data/signals and incorporate them into labeling based on spontaneous reports, publication, interventional/non-interventional studies
- Explain the requirements for presenting safety data in labeling
- Evaluate the effectiveness of labeling as a risk minimization measure
- Understand the regulators expectations for risk management plan and post-approval safety studies.
- Explain how safety studies are planned, especially using RWE such as EHR, health insurance data, and other patient data.
- Discuss "lessons learned" from current uses of RWE, and how these can be applied for other future applications of RWE
- Describe the recent MFDS safety management strategy on regenerative medicine and cell & gene therapy products
- Explain what should be considered for a long-term follow-up study of cell & gene therapy products

Key Topics Covered

- Effective presentation of safety data on labeling
- MedDRA and Product Labeling
- Practical approach in active surveillance
- Implementation of RMP in Korea and future plans
- Safety insight in advanced cell and gene therapy products
- Safety management of Regenerative medicine and Cell & Gene Therapy Products

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Who should attend?

Professionals with intermediate to advanced knowledge of, and experience in, clinical safety and who are involved in:

- Drug Safety/Pharmacovigilance
- Risk Management, including Risk Evaluation and Mitigation Strategies (REMS)
- Benefit-Risk Assessment and Communication
- Medical Product Safety Assessment
- Regulatory Affairs
- Clinical Research
- Pharmacoepidemiology
- Post-Market Studies and Real World Evidence Generation
- Medical Communications
- Health Outcomes

The Workshop is also designed for professionals who work for:

- Industry: Pharmaceuticals, Biologics, Combination Products, Devices
- Clinical Research Organizations, Contract Service Organizations
- Academic Research Centers
- Regulatory Agencies
- Government Research Programs

Agenda

	Topics	Chair / Speaker
	Opening	
9:10-9:20	**Opening Remarks** • DIA • National Institute of Food and Drug Safety Evaluation(NIFDS)	Hajime Saijo, DIA Japan
Session 1	**Effective Presentation of Safety Data on Labeling**	**Chair** Rie Matsui, Pfizer HyangWon Min, Janssen
9:20-9:50	**Development and Update of Safety Labeling - 1** • Reference Safety Information in IB • Process and timing for development and updates of target labeling/DCDS/CCDS and national labels	Mark Collins, CSL Behring
9:50-10:20	**Development and Update of Safety Labeling - 2** • Presenting safety data in labeling • How to use MedDRA for labeling	Leander Fontaine, Pharmiceutics LLC
10:20-10:30	**Break**	
10:30-11:00	**Evaluation of Safety Information for Labelling** • Evaluation of safety data/signals and incorporation of them intolabeling based on spontaneous reports, publication, interventional/non-interventional studies	E. Stewart Geary, Eisai
11:00-11:30	**Near-Synonymous MedDRA® Terms in Medical Product Labeling**	William W. Gregory, Pfizer Ilona Große-Michaelis, Bayer AG
11:30-12:00	**Labeling as Risk Communication** • Updates on electronic labeling initiative • Labeling as Risk Mitigation	Rie Matsui, Pfizer Philip Arena, Pfizer
12:00-13:00	**Lunch**	

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Session 2	**Practical Approach in Active Surveillance**	**Chair** Euna Han, Yonsei University
13:00-13:20	**Implementation of RMP in Korea and Future Plan**	Seong Eun Moon, MFDS
13:20-13:35	**Registry with an Orphan Drug**	YeoKyeong Kim, HANDOK
13:35-13:50	**Research Using Health Claims Database: Sponsor Perspectives**	Yoo Jung Park, Pfizer
13:50-14:05	**Research Using Health Insurance Data and WHO-UMC Vigibase**	Ju-Young Shin, SungKyunKwan University
14:05-14:20	**EMR Driven Big DATA – What happens in Korea**	Insan Jo, EvidNet
14:20-14:50	**Current procedure of developing post-marketing study plan in Japan** • Experience in using RWD/RWE • How to calculate a sample size for a PMS (instead of 3000 cases/600 cases)	Ayano Kobayashi, PMDA
14:50-15:20	**EU Experience Sharing - PASS** • When is a PASS imposed? • How to decide the design of a PASS? • What are the popular types of studies for PASS? (Registry, database study, double-blind study, etc.) • Example of PASS	Jan Petracek, International Society of Pharmacovigilance
15:20-15:40	**Break**	
Session 3	**Safety Insight in Advanced Regenerative Medicine and Cell & Gene Therapy Products**	**Chair** Se Eun Kim, NIFDS SoYeon Park, Celgene/BMS
15:40-15:55	**Long Term Follow Up after Administration of Advanced Biopharmaceuticals - Regulatory Perspective** • New regulation on Regenerative Medicine and Cell & Gene Therapy Products	Yeonhae Han, MFDS
15:55-16:10	**Long-term Follow-up of Advanced Biopharmaceutical Products**	SoYoung Lee, NIFDS
16:10-16:30	**Global Guidelines for Long-term Follow-up Studies of Cell and Gene Therapy Products**	Mireille Muller, Novartis
16:30-16:50	**Consideration for Long-term Follow-up Studies of Cell and Gene Therapy Products**	YeunKum Lee, KIDS
16:50-17:10	**Case Sharing of Long-term Follow-up Studies**	Daniel Stiehl, Novartis
	Closing	

REGISTRATION FORM

DIA-NIFDS Pharmacovigilance Workshop: Diversification in the Practical Application of Pharmacovigilance
Event #83420 | November 18th, 2020 | Virtual Meeting | Korea

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CANCELLATION POLICY: ON OR BEFORE OCTOBER 17, 2020

- Cancellations must be in writing and received on or before October 17, 2020. Registrants who do not cancel in writing by that date and do not attend the event will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations.
- DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.
- UPON CANCELLATION, the administrative fee that will be withheld from refund amount is 25% of the delegate fee

FULL MEETING CANCELLATION

- Post 17 October 2020 the full registration fee will be forfeited, and no refunds will be made. All refunds will be issued in the currency of the original payment

Registration Fee (KRW)

Early Bird Rates (on or before 16th October)	
Industry - Member	90,000
Industry - Non Member	100,000
Government	50,000
Academia	70,000
Standard Rates (after 16th October)	
Industry Member	130,000
Industry Non Member	150,000
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