



15 September 2020

International Pharmacovigilance Day Virtual

A Global Pharmacovigilance Network: Opportunities and Challenges

9:30 - 9:35 **Welcome from LS Academy Staff**

9:35 - 9:40 **Welcome from the Scientific Board**

9.40-10.55 **Round Table chaired by Jabeen Ahmad**

Effective PV System Development

Jabeen Ahmad - Associate Group Director, PV Process Strategy at Roche

EFPIA LATAM initiative

Santiago Schiaffino - Regional PV Head EM LATAM at Boehringer-Ingelheim

Inspection & Audit programs

Rebecca Webb - Director of Pharmacovigilance Quality Assurance at AbbVie

10:55 - 11:10 **Coffee Break**

11:10 - 11:35 **The e-label: case studies on doing a great e-label**

Rüdiger Faust – Head Telematics & Digital Solutions at Grünenthal GmbH

11:35 - 12:00 **Real life experience on an acute treatment, a chronic treatment and a clinical trial setting:
How can we incorporate the patients' voice & perspectives into the pharmacovigilance
system in order to bring safety to patient?**

Sandrine Lavallé – EUPATI Luxembourg representative

Mitchell Silva – CEO at Esperity

12:00 - 12:25 **Pharmacovigilance in clinical trials, first in-human safety monitoring guideline**

Mircea Ciuca – Global Therapeutic Area Head (Immunology & Neurology/Transplant) in Clinical Safety
and PV dept. at CSL Behring

12:25 - 12:30 **Morning conclusion**

12:30 - 14:00 **Lunch Break**

14:00 - 14:10 **Afternoon start**

14:10 - 15:00 **Digital Health Session**

An industry approach on handling safety information received via digital health apps

Birgitte Scharling – *Pharmacovigilance Policy Expert* at Novo Nordisk

Digital Health: data management, AI and new information sources

Nikolai Constantin Brun – *Director of Division, Medical Evaluation & Biostatistics, CMO* at Danish Medicines Agency

15:00 - 15:25 **Opportunities arising from WEB-RADR for digitisation of vigilance activities**

Phil Tregunno – *Vigilance, Intelligence and Research Group Manager* at MHRA

15:25 - 15:40 **Coffee Break**

15:40 -16:05 **PRAC insights and strategy to measure impact of pharmacovigilance**

Doris Stenver – *Independent Pharmacovigilance Adviser, Founder of Unique Advice*

16:05 - 16:30 **The future of the drug safety professional**

Pilar Carrero – *QPPV Office Vice President* at Novo Nordisk A/S

16:30 - 16:55 **Medical Devices: new combination products in the pipeline and a new legislation**

Jan Bart Hak – *Head Medical Device Team* at ProPharma Group

16:55 - 17:00 **Conclusions**