

# Explore New Strategies to Maintain a Global Pharmacovigilance System this June at SMI's 5th Drug Safety conference

LONDON, UNITED KINGDOM, March 20, 2018 /EINPresswire.com/ -- SMI's 5th Drug Safety [conference](#) will take place on the 11th - June 2018, in London, UK. Hear from Astellas,

Mundipharma Research and Lygature as they will be exploring the 'Improvements on Signal Detection', on day 2. Benefit from Astellas, Mundipharma Research and Lygature on Day 2 to explore Eudravigilance in Practice

Bert P. van Leeuwen, Deputy Qualified Person for Pharmacovigilance, Astellas will be examining: 'Signal Detection and Management 2018 in the EU: First experiences with Eudravigilance.'

Summary of presentation:

- Informing the EMA and national competent authorities of validated signals
- A review of our experiences so far
- Developing and finalising a process for Eudravigilance

Heike Benecke, Director of Vigilance Risk Management, Mundipharma Research will be exploring: 'ICSR Download from Eudravigilance in practice: First Experiences and Hurdles with Generic Products.'

Summary of presentation:

- Hurdles in the management of E2BR3 cases in E2BR2 environment
- First experiences using Eudravigilance download functionalities
- Management of Eudravigilance cases in global environment
- Effect of Eudravigilance cases in safety data base on MAH signalling activities and processes: effects of "conservative" case download

Kevin Klein, Project Manager, Lygature will be discussing: 'Is more always better? Non-value added reports from patient support programmes as an example of the 'precautionary reporting bias'.'



SMi Presents the 5th Annual Conference:  
**Drug Safety 2018**  
Holiday Inn Kensington Forum  
London, UK  
11th - 12th  
JUNE  
SMi [www.drugsafetyconference.co.uk](http://www.drugsafetyconference.co.uk)  
Drug Safety 2018

## Summary of presentation:

- A large number of nonvalue-added reports have been accumulating in ADR databases that can potentially impede safety signal detection
- The extensive patient contact by MAHs in such patient support programs was identified as an important source of such nonvalue-added reports
- These reports could be regarded as precautionary reports by MAHs to meet regulatory requirement
- In this presentation, they demonstrate the suppressing effect of such precautionary reports on statistical signal detection methods

Download the complete brochure online for all sessions and speaker line-up:

[www.drugsafetyconference.co.uk/ein](http://www.drugsafetyconference.co.uk/ein)

For those looking to attend there are currently [early-bird](#) rates available up to £400, for a limited time only!

Further information is available at: [www.drugsafetyconference.co.uk/ein](http://www.drugsafetyconference.co.uk/ein)

SMi presents the 5th conference on:

Drug Safety 2018

Date: 11th – 12th June 2018

Workshops: 13th June 2018

Location: Holiday Inn Kensington Forum, London UK

Website: [www.drugsafetyconference.co.uk/ein](http://www.drugsafetyconference.co.uk/ein)

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