



# EMA Signal Management Information Day

Event # 17597  
27 October 2017  
European Medicines Agency, London, United Kingdom

## PROGRAMME COMMITTEE

### Sabine Straus

Head of Pharmacovigilance, Medicines Evaluation Board (MEB)  
The Netherlands, PRAC member

### Sabine Brosch

Principal Scientific Administrator, Pharmacovigilance and Epidemiology, EMA, EU

### Georgy Genov

Head of Signal and Incident Management and Acting Head of Pharmacovigilance and Epidemiology Department, EMA, EU

### Rodrigo Postigo

Signal and Incident Management Service  
EMA, EU

## FACULTY

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Data Scientist  
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### Irina Caplanusi

Signal Management Lead, Pharmacovigilance Department  
EMA, EU

### Julie Durand

Signal Management Lead, Pharmacovigilance Department  
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### Nick Halsey

Scientific Administrator, Data Collection and Management  
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### Martin Huber

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### Nils Lilienthal

Pharmacovigilance assessor (Drug safety) BfArM, Germany

### David Lewis

Global Head of Pharmacovigilance,  
Novartis Pharma AG, Switzerland

### Valerie Simmons

EU QPPV, Global Patient Safety  
Eli Lilly, UK

### Romana Slovakova

Scientific Administrator  
EMA, EU

### Kiernan Trevett

Senior Pharmacovigilance Inspector  
MHRA, United Kingdom

### Alison Turney

Surveillance Business Process Advisor, Global Patient Safety  
Eli Lilly, USA

### Margaret Walters

Director & Deputy EU QPPV  
MSD, United Kingdom

### Cosimo Zaccaria

Signal Management Lead, Pharmacovigilance Department  
EMA, EU

## OVERVIEW

This Information Day will provide an update of the key elements related to the signal detection and management activities in the EU essential to the overall surveillance and risk management process of a medicinal product. We will explore the final guidance provided upon finalisation of the Good Vigilance Practice Module IX on Signal Management where the different aspects of the EU pharmacovigilance legislation on the topic will be covered. We will also drill down to the EudraVigilance access by Marketing Authorisation Holders and the tools and training provided by the EMA to support the stakeholders. The approaches and perspectives from the different stakeholders involved in the signal management process will be also explored and discussed.

## KEY TOPICS

- Good Pharmacovigilance Practice Module IX on Signal Management
- Communication of signals to the Regulatory Authorities
- Marketing Authorisation Holders access to EudraVigilance
- Tools to support Signal Detection and Validation in EudraVigilance
- Stakeholders' involvement in Signal Detection and Management
- Training opportunities

## TARGET AUDIENCE

- Qualified Persons Responsible for Pharmacovigilance (QPPVs)
- Professions involved in Signal Detection and Management
- Individuals involved in Clinical Development, Information Management, Safety Databases
- PV Information Technology Professionals

## DETAILS OF THE INFORMATION DAY

Location: European Medicines Agency  
30 Churchill Place  
Canary Wharf, London E14 5EU, United Kingdom

Capacity: The event is limited to 146 participants



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



## AGENDA

### 08:00 REGISTRATION

### 08:45 WELCOME NOTE

Georgy Genov, EMA

### 09:00 SESSION 1

#### THE NEW EUDRAVIGILANCE SYSTEM AND IMPLICATIONS FOR SIGNAL MANAGEMENT IN THE EU NETWORK

Session Chairs: Georgy Genov, EMA, and Rodrigo Postigo, EMA

This session will provide an overview of the impact in the EU Signal Management procedure following the go-live of the new EudraVigilance system and the full implementation of the EudraVigilance access policy (Revision 3) in November 2017. The different aspects for implementation of the updated Good Pharmacovigilance Practice Module IX and the submission of validated signals to regulatory authorities will be developed. The role of the PRAC and the expectations following the monitoring of the EudraVigilance data by Marketing Authorisation Holders (MAHs) will be also discussed.

#### Go-live of the new EudraVigilance system: What will happen in November 2017

Sabine Brosch, EMA

#### GVP IX Module on Signal Management: Highlights of Revision 1 and practical implementation

Julie Durand, EMA

#### PRAC expectations on the Signal Management procedure following the go-live of the new EudraVigilance system

Sabine Straus, MEB, PRAC member

#### Q&A/Panel Discussion

Discussants: Margaret Walters, MSD, Nils Lilienthal, BfArM, Valerie Simmons, Eli Lilly, and Irina Caplanusi, EMA

### 10:30 COFFEE BREAK

### 11:00 SESSION 2

#### EUDRAVIGILANCE ACCESS BY MAHs – TOOLS FOR SIGNAL DETECTION AND VALIDATION

Session Chairs: Sabine Straus, MEB, and Sabine Brosch, EMA

This session will provide an overview of the EudraVigilance access and data provided to MAHs via the EudraVigilance Data Analysis System (EVDAS) together with the tools and statistical method to support signal detection and validation. The provision of level 2b access through EudraVigilance WEB trader (EVWEB) which includes the case narratives will also be demonstrated.

#### The MAH Pharmacovigilance queries dashboard: Principles of the EVDAS access for MAHs and EVDAS reports

Gianmario Candore, EMA, and Rodrigo Postigo, EMA

#### Level 2b access: How to retrieve the case narratives (live demonstration) in EVWEB

Nick Halsey, EMA

#### The electronic Reaction Monitoring Report (eRMR): Tool for signal detection in EudraVigilance

Cosimo Zaccaria, EMA

#### Q&A/Panel Discussion

Discussants: Margaret Walters, MSD, Nils Lilienthal, BfArM, Valerie Simmons, Eli Lilly, and Romana Slovakova, EMA

### 12:30 SANDWICH LUNCH

### 13:30 SESSION 3

#### SIGNAL DETECTION AND MANAGEMENT BY MARKETING AUTHORISATION HOLDERS

Session Chairs: Georgy Genov, EMA, and Sabine Straus, MEB

This session will cover the MAHs perspectives and approaches taken in order to comply with their pharmacovigilance obligations, following the release of the EudraVigilance data. The key changes and modifications of the internal process to incorporate EudraVigilance monitoring will be highlighted. Furthermore, the steps within the signal management process in relation to the key aspects considered during a pharmacovigilance inspection will be explored.

#### Pharmaceutical industry perspective on the EU Signal Management process: Key changes in the process

David Lewis, Novartis

#### Signal Management by MAHs: Steps to incorporate the EudraVigilance data into safety surveillance

Alison Turney, Eli Lilly

#### EU Signal Management process and Pharmacovigilance Inspections: Good practices in the MAHs signal management process

Kiernan Trevett, MHRA

#### Q&A/Panel Discussion

Discussants: Margaret Walters, MSD, Valerie Simmons, Eli Lilly, and Nils Lilienthal, BfArM

### 15:00 COFFEE BREAK

### 15:30 SESSION 4

#### EUDRAVIGILANCE DATA FOR SAFETY MONITORING OF MEDICINAL PRODUCTS

Session Chairs: Georgy Genov, EMA, and Sabine Straus, MEB

This session will provide with the perspective and experience of a National Competent Authority with the monitoring of the EudraVigilance data and the role of Lead Member State for the signal management procedure in the EU. The session will also explore the opportunities the EudraVigilance provides together with the optimal use of the data for an effective functioning of the EU regulatory network. The future challenges approaches and research in light of the SMART - Work Stream Methods – Roadmap will be also presented.

#### Use of EudraVigilance data by National Competent Authorities: The role of the Lead Member States in the EU Signal Management process

Martin Huber, BfArM

#### Opportunities with the release of EudraVigilance data: Optimal use of the data for signal management and training support

Rodrigo Postigo, EMA

#### SMART - Work Stream Methods: Roadmap and new perspectives in signal detection

Gianmario Candore, EMA

#### Q&A/Panel Discussion

Discussants: Margaret Walters, MSD, Nils Lilienthal, BfArM, Valerie Simmons, Eli Lilly, and Cosimo Zaccaria, EMA

### 17:00 END OF INFORMATION DAY

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

# REGISTRATION FORM

ID #17597

Signal Management Information Day

27 October 2017 | European Medicines Agency, London, United Kingdom

SEND YOUR COMPLETED REGISTRATION FORM TO DIA EUROPE, MIDDLE EAST & AFRICA CONTACT CENTRE TEAM,  
E-mail: EMEA@DIAGlobal.org Fax: +41 61 225 51 52 For more information please call +41 61 225 51 51

## Registration fees\*

	Fees
Industry	500.00 EUR <input type="checkbox"/>
Government/Academia/Charitable/Non-Profit (full time)	250.00 EUR <input type="checkbox"/>

\*Registration fee includes: refreshments, sandwich lunch and delegate material  
Payment is due 30 days after registration and must be paid in full by commencement of the event.

## HOTEL INFORMATION

Participants are kindly requested to make their own hotel reservation.

## ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

Prof  Dr  Ms  Mr

Last Name	<input type="text"/>
First Name	<input type="text"/>
Company	<input type="text"/>
Job Title	<input type="text"/>
Address	<input type="text"/>
	<input type="text"/>
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City	<input type="text"/>
Country	<input type="text"/>
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Email*	<input type="text"/>

\*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

## PAYMENT METHODS

**Credit cards:** Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

Please charge my  VISA  MC  AMEX

Card N°

Exp. Date  /

Cardholder's Name

**Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Event ID #17597 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA EMEA.**

By signing below, I confirm that I agree with DIA EMEA Terms and Conditions of booking. These are available from the office or on <http://www.diaglobal.org/EUTerms>

Date	Signature
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## TERMS AND CONDITIONS

### Cancellation Policy

All cancellations must be made in writing and be received at the DIA EMEA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Government/Academia/Charitable/Non-Profit (full time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA EMEA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

### Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA EMEA office of any such substitutions as soon as possible.

### Photography and Video Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA EMEA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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