

# EMA EudraVigilance and Signal Management Information Day

21 November 2023 | 09:30 – 17:00 CET | #23525

European Medicines Agency, Domenico Scarlattilaan 6, 1083 HS Amsterdam, NL

## | PROGRAMME COMMITTEE

### Paolo Alcini

Head of Healthcare Data  
European Medicines Agency (EMA), EU

### Georgy Genov

Head of the Pharmacovigilance Office  
European Medicines Agency (EMA), EU

### Rodrigo Postigo

Pharmacovigilance Office,  
European Medicines Agency (EMA), EU

### Gilles Touraille

Pharmacovigilance Office,  
European Medicines Agency (EMA), EU

### Anja van Haren

EudraVigilance Coordinator  
Medicines Evaluation Board (MEB), NL

## | SPEAKERS & PANELISTS

### Sabine Brosch

Data Protection Officer,  
European Medicines Agency (EMA), EU

### Marcos Fernandez Gomez

Scientific Administrator,  
European Medicines Agency (EMA), EU

### Michelle Grimes

ICH E2D Expert Working Group member  
Head, International Pharmacovigilance  
MSD, UK

### Veronica Lipucci Di Paola

Scientific Administrator,  
European Medicines Agency (EMA), EU

### Tom Paternoster-Howe

Scientific Administrator,  
European Medicines Agency (EMA), EU

### Loris Piccolo

Scientific Administrator,  
European Medicines Agency (EMA), EU

### Luis Pinheiro

Scientific Administrator,  
European Medicines Agency (EMA), EU

### Eugène Paul van Puijenbroek

EMA signal management review team  
(SMART)  
Head of Scientific Department  
Pharmacovigilance Centre Lareb, NL

### Katharina Weber

PV Inspector and Assessor  
Austrian Federal Office for Safety in  
Health Care/AGES, AT

### Magnus Ysander

EU & UK QPPV & Head Pharmacovigilance  
Excellence,  
AstraZeneca, SE

## | OVERVIEW

One of the milestones during 2022 in the EudraVigilance database was the mandatory use of the ISO Individual Case Safety Report (ICSR) standard (ISO 27953-2:2011) based on the ICH E2B(R3) modalities and the ISO terminology on pharmaceutical dose forms and routes of administration, (ISO 11239:2012).

Following this important milestone, this information day will describe and highlight other aspects for further development in the database and initiatives driven by international activities, together with the management and maintenance of EudraVigilance for the good functioning of the EU pharmacovigilance network.

Regulation (EU) 2016/679, the General Data Protection Regulation (GDPR) applies since 25 May 2018. MAHs are controllers for the personal data processing activities carried out pursuant to the pharmacovigilance legislation including the access and further processing of ICSR data originating from EudraVigilance. The data protection activities, measures and responsibilities will be described and developed during this information day.

The European Medicines Agency (EMA) is implementing the ISO IDMP standards for the identification of medicinal products in a phased programme, based on the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referential (SPOR) data. An update of the SPOR activities will be highlighted.

According to Article 24 (3) of Regulation 726/2004, the Agency shall, in collaboration either with the MAHs or with the Member State that submitted an individual suspected adverse reaction report to the EudraVigilance database, be responsible for operating procedures that ensure the quality and integrity of the information collected. Moreover, specific quality system procedures and processes shall be in place to ensure submission of accurate and verifiable data on serious and non-serious suspected adverse reactions to the EudraVigilance database within the 15 or 90-day time frame [IR- Art 11 (1) (c)]. To support these legislative requirements, the Agency is working on the process to implement compliance reports for electronic submission of ICSRs. These reports and their implementation will be fully described during this information day.

The ICH E2D guideline was agreed at Step 4 in May 2003; In the meantime, new sources of post-approval safety information (e.g., social media, digital platforms, market research programs, patient support and assistance programs) have emerged or are more frequently utilised by marketing authorisation holders. The definitions and standards for the management of post-approval safety information are no longer sufficient to provide guidance on the current practices and needs; The E2D(R1) Expert Working Group is currently working on the revision and updates will be presented.

Other aspects such as the role of the EU QPPVs, quality control of ICSRs, pharmacovigilance inspections findings and examples of the use of artificial intelligence will be described.

## | KEY TOPICS

- EudraVigilance data protection activities
- SPOR related activities with regard to product and substance data
- Revision of ICH- E2D
- ICSRs quality control
- Pharmacovigilance Inspections
- EudraVigilance Operational activities

## | TARGET AUDIENCE

- Qualified Persons Responsible for Pharmacovigilance (QPPVs) and their deputies
- Professionals involved in Pharmacovigilance, Safety Surveillance Scientists
- Sponsors of Clinical Trials
- Individuals involved in clinical development, information management, safety databases and safety assessment.

Pharmacovigilance Information Technology Professionals



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



## AGENDA | 21 NOVEMBER 2023 | 09:30 – 17:00 CET

**09:30**            **REGISTRATION**

**09:50**            **WELCOME NOTE BY SESSION CHAIRS**  
Georgy Genov & Paolo Alcini, EMA

**10:00**            **DATA PROTECTION WITH REGARD TO EUDRAVIGILANCE**  
(25+10)            Sabine Brosch, EMA, EU

### **QUALITY ASPECTS RELATED TO EUDRAVIGILANCE**

**10:35**            **EU QPPV ROLE IN RELATION TO EUDRAVIGILANCE & SIGNAL MANAGEMENT**  
(20)                Magnus Ysander, AstraZeneca, SE

**10:55**            **PHARMAOVIGILANCE INSPECTIONS -KEY ASPECTS AND FINDINGS**  
(20)                Katharina Weber, AGES, AT

Q&A with speakers and panellists

### **11:30**            **COFFEE BREAK**

**12:00**            **ICSR DATA QUALITY (FINDINGS) – DOS AND DON'TS**  
(20)                Tom Paternoster-Howe, EMA, EU

**12:20**            **GO-LIVE OF NEW EUDRAVIGILANCE REPORTING COMPLIANCE REPORTS**  
(20)                Gilles Touraille, EMA, EU

**12:40**            **UPDATE ON THE REVISION OF ICH E2D(R1) GUIDELINE**  
(20)                Michelle Grimes, MSD, UK – ICH E2D Expert Working Group member

Q&A with speakers and panellists

### **13:00**            **LUNCH BREAK**

**14:00**            **MEDICAL LITERATURE MONITORING SERVICE – SIGNIFICANT UPDATES FOR MAHS**  
(20)                Tom Paternoster-Howe, EMA, EU

**14:20**            **SPOR ACTIVITIES WITH FOCUS ON PRODUCT AND SIGNAL DETECTION**  
(40)                Marcos Fernandez Gomez & Veronica Lipucci Di Paola, EMA SPOR team, EU

Q&A with speakers and panellists

### **15:20**            **COFFEE BREAK**

#### **FUTURE TRENDS AT EMA**

**15:50**            **THE NEW EMA SIGNAL AND SAFETY ANALYTICS PROJECT - WHAT DOES IT MEAN FOR MAHS AND NCAS?**  
(20)                Rodrigo Postigo & Loris Piccolo, EMA, EU

**16:10**            **INSIGHTS FROM THE SMART METHODS TEAM ON NEW METHODOLOGIES USED IN EV**  
(20)                Eugène Paul van Puijenbroek, Pharmacovigilance Centre Lareb, NL, EMA signal management review team (SMART)

**16:30**            **OPPORTUNITIES TO USE ARTIFICIAL INTELLIGENCE IN SIGNAL DETECTION**  
(20)                Luis Pinheiro, EMA, EU

Q&A with speakers and panellists

**17:00**            **CLOSING OF THIS INFORMATION DAY**

#### **| Disclosure Policy**

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Speakers and agenda are subject to change without notice.

# REGISTRATION FORM | ID# 23525



EMA EudraVigilance and Signal Management Information Day

21 November 2023, 09:30-17:30 CET, EMA, Amsterdam, NL

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\*All fees are subject to the applicable VAT. Payment due 30 days after registration and must be paid in full by commencement of the event.

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The DIA will be pleased to assist you with your registration from Monday to Friday between 08:30 and 17:00 CE(S)T.

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