



# EMA Risk Management Plan Information Day

Event #18594  
25 October 2018  
European Medicines Agency, London, United Kingdom

## PROGRAMME COMMITTEE

**Zaide Frias**, Head of Human Medicines Evaluation Division, EMA, EU

**Sabine Straus**, Medicines Evaluation Board, Pharmacovigilance Risk Assessment Committee (PRAC) Member

**Jordi Llinares Garcia**, Head of Scientific and Regulatory Management Department, EMA, EU

**Peter Arlett**, Head of Pharmacovigilance and Epidemiology Department, EMA, EU

**Marin Banovac**, Scientific Officer, Oncology, Haematology and Diagnostics, Scientific and Regulatory Management Department, EMA, EU

## FACULTY

**Juan Garcia Burgos**, Head of Medical and Health Information, EMA, EU

**Núria Semis-Costa**, Scientific Officer, Rheumatology, Respiratory, Gastroenterology and Immunology, Scientific and Regulatory Management Department, EMA, EU

**Priya Bahri**, Principal Scientific Administrator, Surveillance & Epidemiology Service, Pharmacovigilance Department, EMA, EU

**Roberto De Lisa**, Scientific Officer, Paediatric Medicines Office, EMA, EU

**Corinne De Vries**, Head of the Science and Innovation Support Office, EMA, EU

**Jan Petracek**, CEO, PrimeVigilance, CZ

**Inge Zomerdijk**, Pharmacovigilance Assessor, MEB, NL

**David Haerry**, European AIDS Treatment Group, BE

**James Milligan**, Vice President Patient Safety, AstraZeneca, UK

**Phillip Eichorn**, Senior Director in Worldwide Safety & Regulatory, Pfizer, UK

## OVERVIEW

The focus of this Information Day will be on providing an update of ongoing Agency's activities with regard to medicines' risk management. This Risk Management Plan (RMP) Information Day will be an opportunity to provide marketing authorisation holders (MAHs) and marketing authorisation applicants (MAAs) practical advice on RMP drafting in view of the full implementation of the RMP revision 2 template after the transitional period has elapsed, as well as to interactively exchange experiences on the revision 2 RMP format between the regulators and industry.

The increasing number of biosimilars being authorised highlighted a need to better streamline the safety specification for biologicals so that only risks that are important for risk management and relevant for the benefit-risk of the product are included in the RMP. A dedicated session of the Information Day will also serve as a platform to discuss the streamlining of safety specification for biologicals with a special focus on biosimilars.

Updates on the work on the risk management aspects of the new GVP guidance on special populations such as children and elderly will be provided.

Other topics include a trilateral session between the regulators patients and industry on risk communication and patients' access to information on the safety of medicines.

The panel is happy to answer questions from the audience submitted to [ema@diaglobal.org](mailto:ema@diaglobal.org) by 25 September 2018 latest.

## KEY TOPICS

- GVP V rev.2 practical session - regulators and industry perspective on the implementation of the revised RMP template
- Identifying safety concerns for biologicals and biosimilars
- Update on new GVP guidelines in development (Paediatrics, Older people, Pregnancy and breastfeeding)
- Risk communication

## TARGET AUDIENCE

- Individuals involved in risk management planning, risk minimisation development and post authorisation safety studies at small to medium enterprises (SMEs), MAAs / MAHs for generic products, MAAs / MAHs for innovator products and Contract Research Organisations (CROs)
- Qualified Persons responsible for Pharmacovigilance (QPPVs)
- Assessors at National Competent Authorities (NCAs)
- Risk communication experts
- Patients and Healthcare professional (HCP) group representatives

## 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 115 participants



EUROPEAN MEDICINES AGENCY  
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**08:00 REGISTRATION****08:45 WELCOME NOTE**

Zaide Frias, EMA and Sabine Straus, MEB

**09:00 SESSION 1**
**GVP V REVISION 2: PRACTICAL APPROACH ON IMPLEMENTATION OF REVISED RMP TEMPLATE**

Session chair: Sabine Straus, MEB

This session will provide practical advice and insights on the implementation of the revised RMP template from EMA, industry and regulator perspective. Based on questions received from the audience, the panel invites to an interactive discussion on the experience with the implementation of the GVP V Revision 2 template.

**GVP V and RMP Template Revision 2 – Implementation progress; updates on the EMA project Quality of the RMP submissions**

Nuria Semis Costa, EMA

**Lessons from 200 Updated RMPs**

Jan Petracek, PrimeVigilance

**Revision of GVP Module V: Experiences from the Regulators**

Inge Zomerdijk, MEB

Q&A/Panel Discussion

**10:45 COFFEE BREAK****11:15 SESSION 2**
**SAFETY SPECIFICATIONS FOR BIOSIMILARS**

Session chair: Marin Banovac, EMA

With the increasing number of biosimilars entering the market, the PRAC highlighted the need to better streamline the safety specifications for biosimilars. This session will update all stakeholders involved in ongoing EMA and PRAC activities with regards to the safety specification for biosimilars.

**EMA Recommendations on Streamlining Safety Specification for Biologicals**

Núria Semis-Costa, EMA

**Safety Concerns and Biosimilars: Challenges and Uncertainties**

Phillip Eichorn, Pfizer

Q&A/Panel Discussion

**12:30 SANDWICH LUNCH****13:30 SESSION 3**
**GVP GUIDELINES ON SPECIAL POPULATIONS**

Session chair: Priya Bahri, EMA

Pharmacovigilance guidelines (GVP) in special populations, i.e. children, older patients and women concerning pregnancy and breastfeeding, are currently being developed. The RMP Info Day will offer the opportunity to share the current status of the guidelines with a special emphasis on the impact of new guidelines on medicines risk management in these populations. Furthermore, this will be an opportunity to solicit input from stakeholders for further development specifically of the GVP on older people to enhance medicines' safety in the geriatric population.

**GVP for Paediatrics**

Roberto De Lisa, EMA

**GVP for Older People**

Priya Bahri, EMA

**GVP for Pregnancy**

Corinne De Vries, EMA

**15:00 COFFEE BREAK****15:30 SESSION 4**
**RISK COMMUNICATION**

Session chairs: Juan Garcia Burgos, EMA and Marin Banovac, EMA

In recent years, EMA has taken several measures to improve patients' access to information on the safety of medicines and on actions planned to manage the important risks of EU medicines. The session on risk communication will bring together the patients, the regulators and the industry in a trilateral discussion on risk communication and better understanding of the patients' needs and expectations in this respect.

**The Role of Regulators in Communicating Benefits and Risks**

Juan Garcia Burgos, EMA

**Patient Perspective**

David Haerry, European AIDS Treatment Group

**Effective Risk Communication- Can we Shift the Paradigm and Why it Matters**

James Milligan, Astra Zeneca

**16:30 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 #18594

EMA Risk Management Plan Information Day

25 October 2018 | European Medicines Agency | London, United Kingdom

PLEASE REGISTER [ONLINE](#) OR SEND YOUR COMPLETED REGISTRATION FORM TO DIA CONTACT CENTRE TEAM,  
E-mail: [basel@DIAGlobal.org](mailto:basel@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: Online access to presentations, 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

First Name

Company

Job Title

Address

Postal Code  City

Country

Telephone

Fax

Email\*

\*(Direct E-mail Address required for Presentation Access)

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

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**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 #18594 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.**

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

|                           |                                |
|---------------------------|--------------------------------|
| Date <input type="text"/> | Signature <input type="text"/> |
|---------------------------|--------------------------------|

## TERMS AND CONDITIONS

### Cancellation Policy

All cancellations must be made in writing and be received at the DIA 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 reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA 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. Please notify the DIA office of any such substitutions as soon as possible.

### Event Stream and recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, [click here](#).

### Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, [click here](#). You agree that your personal data will be transferred to DIA in the US.

The DIA 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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