DIA Learning

# Post-Market Surveillance and Clinical Evidence: Medical Devices and Combination Products Workshop

## Virtual Live

**5-7 March 2024, 13:00-17:30 CET**

## OVERVIEW

Post-Market Surveillance (PMS) activities including Post-Market Clinical Follow-up (PMCF) are conducted throughout the lifecycle of a medical device. These require compiling data from multiple sources, including sufficient clinical evidence to conduct a proper determination of the benefit-risk profile and to demonstrate acceptability of that profile based on current knowledge/state-of-the-art in the medical device field concerned.

In addition, medical devices including software as medical devices (SaMD) can also be used in combination with a medicinal product bringing more complexity for PMS activities and the gathering of clinical evidence.

**This virtual workshop will provide relevant information to set up a PMS system, to know it's challenges and opportunities, and to show the interdependencies between PMS, clinical evaluation, and risk management to continuously evaluate the safety and performance of a medical device and confirm the acceptability of the benefit-risk profile when used as a stand-alone device or as a constituent part of a drug-device combination (DDC) product.**

It will offer the experience from notified body, regulatory authorities and industry experts.

## LEARNING OBJECTIVES

At the end of the workshop the attendants will be able to:

- Follow the requirements of PMS for medical devices and device constituents of DDC products
- Identify the relevant clinical data needed to confirm the acceptability of the benefit-risk profile of your product
- Recognize the interdependencies and outputs loops within a PMS, clinical evaluation, and risk management process

## WHO WILL ATTEND

This course is intended for professionals working within the pharmaceutical industry in:

- Post-Market Surveillance
- Vigilance/Safety
- Regulatory Affairs
- Clinical Affairs
- Digital Health

## FACULTY

**Anna Amich (Workshop Director)**
Director, Patient Safety Device & Digital
AstraZeneca, Spain

**Alexej Agibalow**
Risk Management Expert
Escentia, Germany

**Theresa Carlson**
RA/QA Sr. Principal Advisor
Fortrea, United States

**Leon Doorn**
Regulatory Compliance Expert
Netherlands

**Laura Gámez Santín**
Head Medical Device Vigilance
Novartis, Spain

**Jenifer Hannon**
Post Market Surveillance Regulatory Lead
BSI, United Kingdom

**Elisabeth Oltmanns**
Managing Partner
Escentia, Germany

**Josep Pané**
Head of Device and Digital Vigilance and Safety
UCB, Spain

**James Whitehead**
Senior Director, Device & Digital Safety
AstraZeneca,

**Sheila Walsh**
Technical Team Manager and Clinical Team Lead (Vascular Team)
BSI, United Kingdom

**Milos Stojkovic**
Safety Process Director
F. Hoffmann-La Roche, Switzerland

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

## DAY 1

**13:00 WELCOME AND INTRODUCTION**

**13:40 SESSION 1**

### GENERAL OVERVIEW AND OBJECTIVES

*Anna Amich, AstraZeneca*

**13:50 SESSION 2**

### RISK MANAGEMENT PLAN - MANAGING RESIDUAL RISKS - EXPERIENCE FROM INDUSTRY

*Alexej Agibalow, Escentia*

- Risk Management – ISO 14971
- Production and post-production activities
- Interaction of safety-relevant information and the risk management process
- Standardisation of the interface between the risk management and PMS

**14:25 SESSION 3**

### CLINICAL DATA AND SUFFICIENT CLINICAL EVIDENCE - NOTIFIED BODY (NB) PERSPECTIVE

*Sheila Walsh, BSI*

- The necessity for clinical data under the MDR
- When clinical investigations are required and when they are exempt
- Sufficiency of clinical data in regards to Well-Established Technology (WET) and legacy devices per Article 61 6a
- Considerations of the interpretation of NBs of the word "sufficient"

**14:55 BREAK**

**15:15 SESSION 4**

### PMS AND PMCF EXPECTATIONS - NB PERSPECTIVE

*Jenifer Hannon, BSI*

- Expectations of PMS under the MDR
- Expectations of PMCF under the MDR
- Types of general/specific PMCF activities based on the question that needs answering

**15:50 SESSION 5**

### PMS SYSTEM INCLUDING PMCF - PRACTICAL IMPLEMENTATION FROM INDUSTRY

*Milos Stojkovic, F. Hoffmann-La Roche*

**16:25 SESSION 6**

### Q&A ON RISK MANAGEMENT, CLINICAL EVALUATION AND PMS INCLUDING INTERDEPENDENCIES - GROUP DISCUSSION

**17:30 END OF DAY 1**

## DAY 2

**13:00 WELCOME**

**13:05 SESSION 7**

### WHAT TO CONSIDER IN A BENEFIT-RISK ANALYSIS?

*Elisabeth Oltmanns, Escentia*

- Patient benefits and clinical risks
- Indirect clinical benefits
- Clinically relevant residual (technical) risks
- What about the user and public health?

**13:40 SESSION 8**

### CLINICAL DATA AND PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE (PRRC)

*Anna Amich, AstraZeneca*

- Responsibilities of the PRRC
- PRRC involvement on safety and performance of a device and benefit-risk profile
- Inputs/outputs from Quality Management Review board

**14:15 SESSION 9**

### PERFORMING EFFECTIVE PMS FOR A STAND-ALONE SOFTWARE MEDICAL DEVICE (SAMD)

*Leon Doorn*

- How does software differ from hardware for PMS
- What are specific considerations for software
- PMS and software version management

**14:45 BREAK**

**15:05 SESSION 10**

### WHAT DOES THE FUTURE HOLD IN EUROPE FOR AI-ENABLED MEDICAL DEVICES AND POST MARKETING MONITORING

*Leon Doorn*

- What are the requirements set out by the proposed AI Act in terms of Post-Market Monitoring
- How to ensure effective Post-Marketing Monitoring for an AI-enabled medical device (from the start of design and development)

**15:40 SESSION 11**

### INTRODUCTION TO DRUG-DEVICE COMBINATION (DDC) PRODUCTS

*Anna Amich, AstraZeneca*

**16:15 SESSION 12**

### PRACTICAL EXERCISE ON PMS AND Q&A

**17:30 END OF DAY 2**

## DAY 3

**13:00 WELCOME**

**13:05 SESSION 13**

### PMS FOR DDC PRODUCTS

***James Whitehead, AstraZeneca***

- Key regulations and guidelines governing PMS for DDCs
- Company insights on PMS activities for DDCs
- An interactive case study
- Challenges for the industry & key learnings

**13:40 SESSION 14**

### PMS FOR A CONNECTED COMBINED PRODUCT - INDUSTRY PERSPECTIVE

***Theresa Carlson, Fortrea***

**14:15 SESSION 15**

### POST-MARKET DEVICE SAFETY REPORTING FOR DDC PRODUCTS

***Josep Pané, UCB***

- Safety reporting requirements for device constituents of combination products
- Implementation opportunities

**14:45 BREAK**

**15:05 SESSION 16**

### ADVERSE EVENTS IN DIGITAL AGE

***Laura Gámez Santín, Novartis***

- The current regulatory landscape, or lack thereof
- Building a company position on the use of digital data for vigilance purposes: experience and lessons learnt

**15:40 SESSION 17**

### ADDRESSING CHALLENGES ON DDC - GROUP DISCUSSION AND Q&A

**16:50 SESSION 18**

### PRACTICAL EXERCISE

**17:20 CLOSING REMARKS**

**17:30 END OF THE WORKSHOP**

## Technical Requirements

To test your system compatibility, please click on the link:

https://diaglobal.zoom.us/test

For further information on system requirements, please visit the website:

https://www.diaglobal.org/General/System-Requirements

## Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 9 credits.

## Group Discount

**Buy 3 and Get 1 Free!**

- All 4 individuals must register and prepay at the same time – no exceptions
- DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership
- You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Terms & Conditions apply, please contact DIA for more information.

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to basel@diaglobal.org.

### Customized Professional Development for Your Team

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For more information please contact tereza.krucka@diaglobal.org

# REGISTRATION FORM Virtual Live Workshop

**Post-Market Surveillance and Clinical Evidence for MD and DDC Products # 24536**
**5-7 March 2024, 13:00-17:30 CET**

DIA Learning

## REGISTRATION FEES

Registration fee includes full admission to virtual course, electronic access to training course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

| FEES | MEMBER EARLY-BIRD valid until 9 Jan 2024 | MEMBER valid from 10 Jan 2024 | NON-MEMBER |
|---|---|---|---|
| INDUSTRY/ REPRESENTATIVE | € 1'215.00 ❑ | € 1'350.00 ❑ | € 1'610.00 ❑ |
| ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME) | NA | € 675.00 ❑ | € 935.00 ❑ |
| A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information. | | | |

**All registration fees are subject to VAT if applicable.**

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

**Payment is due 30 days after registration and must be paid in full by commencement of the course.**

## DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

**Email:** Basel@DIAglobal.org **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland
**Web:** **www.DIAglobal.org**

## 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
- Academia/Charitable/Government/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 but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. 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 https://www.diaglobal.org/general/photography-policy.

### Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy.

## ATTENDEE DETAILS

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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Attendee email required for course material access

## 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, Course ID #24536 as well as the invoice number to ensure correct allocation of your payment.
Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

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's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

| Date | Signature |
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