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

2-4 December 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 conclusion of this training course, participants 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

Workshop Director

Anna Amich
Director, Patient Safety Device & Digital
AstraZeneca, Spain

Faculty

Leon Doorn
Regulatory Compliance Expert
Netherlands

Josep Pane
Head of Device and Digital Vigilance and Safety
UCB, Spain

Milos Stojkovic
Safety Process Director, Pharmacovigilance & Scientific Development
F. Hoffmann-La Roche, Switzerland

James Whitehead
Senior Director, Device & Digital Safety
AstraZeneca, United Kingdom

Sarina Zillikens
Clinical Affairs Manager
Escentia, Germany

DIA

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

Schedule-At-A-Glance

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

Escentia speaker invited

- 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

TÜV SÜD Medical Health Services speaker invited

- 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

TÜV SÜD Medical Health Services speaker invited

- 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

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

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

PMS SYSTEM INCLUDING PMCF - PRACTICAL IMPLEMENTATION FROM INDUSTRY

Milos Stojkovic, F. Hoffmann-La Roche

13:40 SESSION 8

WHAT TO CONSIDER IN A BENEFIT-RISK ANALYSIS?

Sarina Zillikens, Escentia

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

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 - INDUSTRY PERSPECTIVE

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

Fortrea speaker invited

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

Novartis speaker invited

- 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

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!*

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.

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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.

SwAPP

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REGISTRATION FORM

Medical Devices and Combination Products Workshop # 24535
2-4 December 2024, 13:00-17:30 CET, Virtual Event

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 7 Oct 2024	MEMBER valid from 8 Oct 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 is available for organisations which are listed in the EMA SME register: https://fmapps.ema.europa.eu/SME/. Number of discounted seats are limited.			

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

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❑ **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
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TERMS AND CONDITIONS

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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

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

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Job Title

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Attendee email required for course material access

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❑ **Credit card:** Payments by VISA, Mastercard or AMEX are accepted. Other types of credit card are not accepted. You will receive a payment link in the coming days to complete the payment.

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Date	Signature