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

Robert Di Giovanni
Sr. Global Patient Safety Lead
Novartis Pharma, Switzerland

Taylor Dieringer
Quality Engineer - Risk Management
iRhythm Technologies, United States

Leon Doorn
Regulatory Compliance Expert
Netherlands

Glory Msacky
Senior Clinical Affairs and PMS specialist
Phillips-Medisize A/S, A Molex Company, Denmark

Harminder Mudhar
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AstraZeneca, United Kingdom

Ortzi Olasolo
Medical Device Consultant
Beyond Conception, Switzerland

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

Surash Surash
Clinical Reviewer
Centre for Clinical Excellence, TÜV-SÜD, UK

Sarina Zillikens
Clinical Affairs Manager
Escentia, Germany

DIA

PharmaTrain
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CENTRE OF EXCELLENCE

Schedule-At-A-Glance

DAY 1

13:00 WELCOME

13:05 SESSION 1

INTRODUCTION, GENERAL OVERVIEW AND OBJECTIVES

Anna Amich, AstraZeneca

13:50 SESSION 2

RISK MANAGEMENT PLAN - MANAGING RESIDUAL RISKS - EXPERIENCE FROM INDUSTRY

Taylor Dieringer, iRhythm Technologies

- 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

Surash Surash, TÜV SÜD

- The necessity for clinical data under the MDR
- Understanding when a clinical investigation is required
- Exploring the types of clinical data sources
- Considerations of the interpretation of NBs of the word "sufficient"

14:55 BREAK

15:15 SESSION 4

PMS AND PMCF EXPECTATIONS - NB PERSPECTIVE

Surash Surash, TÜV SÜD

- 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

15:50 SESSION 12

PMS ON DDC – DIFFERENT APPROACHES

Ortzi Olasolo, Beyond Conception

16:25 SESSION 13

PRACTICAL EXERCISE ON CREATING A PMS PLAN AND Q&A

17:30 END OF DAY 2

DAY 3

13:00 WELCOME

13:05 SESSION 14

PMS FOR DDC PRODUCTS - INDUSTRY PERSPECTIVE

Harminder Mudhar, 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 15

PMS FOR A CONNECTED COMBINED PRODUCT - INDUSTRY PERSPECTIVE

Glory Msacky, Phillips-Medisize

14:15 SESSION 16

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 17

ADVERSE EVENTS IN DIGITAL AGE

Robert Di Giovanni, 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 18

ADDRESSING CHALLENGES ON DDC - GROUP DISCUSSION AND Q&A

16:50 SESSION 19

PRACTICAL EXERCISES ON CHALLENGES ON DDC

17:20 CLOSING REMARKS

17:30 END OF THE WORKSHOP

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SwAPP

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

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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:

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