

AHED - Advanced Health Education
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/ MULTIPROFESSIONAL CARE
INTEGRATION CHALLENGES

MEDICINES AND MEDICAL DEVICES

20-I04

/ SAFETY AND RISK MANAGEMENT
IN THE REAL-WORLD
CLINICAL PRACTICE



Advanced
Health
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by NOVA Medical School

MEDICINES AND MEDICAL DEVICES

SAFETY AND RISK
MANAGEMENT IN THE REAL-WORLD
CLINICAL PRACTICE

20-104

COURSE COORDINATOR >> Ana Paula Martins, PhD

NEW DATES

COURSE PRESENTATION

Innovative therapies and medical devices the frontline of health systems' transformation into a learning system. They are supported in new risk management approaches that should increase efficiently the detection, analysis and management of preventable safety issues and therefore optimizing patients health outcomes. EU Pharmacovigilance and Risk Management Regulations are crucial for compliance requirements.

Optimizing risk management activities, developing approaches to risk mitigation and understanding the links between safety specifications, pharmacovigilance plans, risk minimization programmes and real-world studies are important topics to be specifically addressed in this 4 module intermediate-advanced course.

There are enormous challenges and tremendous opportunities for practice in this area due to the foreseen disruptive health technologies like advanced therapies, combined medications and companion diagnostics. Big data systems will dramatically change the way how research and regulatory sciences will evolve now and in the years to come.

LEARNING OBJECTIVES >> KNOWLEDGE AND SKILLS TO DEVELOP

- 1 To understand the European Legislation for Risk Management and Pharmacovigilance and review the regulatory requirements and their inclusion in the European System for Managing and analysing information on suspected Adverse Drug Reactions to Medicines.
- 2 To critically appraise within current regulatory framework and guidelines to risk management Plans.
- 3 To increase ability to implement the requirements from Good Practice on Medication Errors issued by the European Regulatory Network in 2015.
- 4 To provide in depth knowledge of Spontaneous Reporting systems, case management tools and causality assessment in Pharmacovigilance.
- 5 To analyse the application of signal detection methodology and to review documents for risk and benefit communication.
- 6 To analyse the main study designs in pharmacoepidemiology for assessing drug safety issues specifically non-experimental designs as cohort, case-control, case-crossover studies.
- 7 To develop a critical understanding of the study designs, assessment and application of post-authorization drug safety data, safety monitoring, and risk management associated with pharmaceuticals and medical devices.

TARGET AUDIENCE

Health care Professionals, Risk Management and Pharmacovigilance managers from Pharmaceutical Industry, Trainees in Pharmacovigilance Units, Master and PhD students.

ADMISSION CRITERIA

>> Academic background in Health Sciences
[PhD, Master degrees or Bachelors]

ATTENDANCE REQUIREMENTS

>> 80% attendance is mandatory for issuing attendance certificate and CME credits and/or ECTS

MAX. ATTENDEES

>> 40

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AGENDA

2020 / NOVEMBER

NOV 6TH

9:00 am - 7:00 pm

@ Nova Medical School (Campo de Santana)

MODULE 1

REGULATIONS IN PHARMACOVIGILANCE AND
RISK-MANAGEMENT IN EUROPE FOR DRUGS,
BIOLOGICS, VACCINES, MEDICAL DEVICES,
COMBINATION PRODUCTS AND COMPANION
DIAGNOSTICS.

- >> European Regulatory Framework
for medicines and medical devices
- >> Pharmacovigilance and Risk Management
in Europe/Good Pharmacovigilance Practices
- >> Spontaneous Reporting Systems
and Effectiveness of Risk Management Plans
- >> Risk Management Plans

NOV 13TH

9:00 am - 7:00 pm

@ Nova Medical School (Campo de Santana)

MODULE 2

RISK-BENEFIT ASSESSMENTS
IN PHARMACOVIGILANCE & RISK-MANAGEMENT

- >> Regulatory Framework for Measuring
Benefit-risk in Drug Therapies and Medical
Devices in Europe and European Safety
Update Report
- >> Mechanism of action in ADRs
- >> Pharmacovigilance in Paediatrics
and Pregnant Women
- >> Adverse Drug Reactions Cardiovascular,
Neurologic, Renal and Hepatic

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2020

NOV 20TH

9:00 am - 7:00 pm

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MODULE 3

EUROPEAN RISK MANAGEMENT STRATEGY &
PHARMACOVIGILANCE SYSTEM

- >> EudraVigilance and case management
- >> Causality assessment
in Pharmacovigilance
- >> Medicines under additional surveillance
- >> Medication errors
- >> Signal generations

DEZ 11TH

9:00 am - 1:00 pm

@ Nova Medical School (Campo de Santana)

- >> Seminar
- >> Historical and Future Perspective
of Pharmacovigilance
- >> Innovative Methods for Safety Assessment
and Prevention in Health Care

DEZ 4TH

9:00 am - 7:00 pm

@ Nova Medical School (Campo de Santana)

MODULE 4

REAL WORLD EVIDENCE
AND PHARMACOEPIDEMOLOGY
APPLIED TO SAFETY AND RISK MANAGEMENT
OF DRUGS AND MEDICAL DEVICES

- >> Postauthorisation safety studies
- >> Study designs for safety assessment
in the European regulatory landscape
- >> Intensive safety monitoring Vaccines Safety
in the European Regulatory context
- >> Meta-analysis for drug safety evaluation
- >> Patients registries for safety monitoring
for drugs and medical devices

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FACULTY

>> Helder Mota Filipe, PhD
>> Fátima Canedo, MSc
>> Paula Barão, MSc
>> Isabel Boaventura, PhD
>> Bruno Sepodes, PhD
>> Mário Miguel Rosa, PhD
>> João Rocha, PhD
>> Manuel Caneira, PhD

>> Carlos Alves, PhD
>> Miguel Antunes, MSc
>> Ana Paula Martins, PhD
>> Hubert Leufkens, PhD
>> Carla Torre, PhD
>> Andreia Leite, PhD
>> Francisco Batel-Marques, PhD
>> Ana da Costa Miranda, MSc
>> Diogo Mendes, PhD

CREDITS >> 4.5 ECTS



DURATION >> 40 HOURS

This event is compliant with the MedTech Europe Code of Ethical Business Practice



PRICE >> 1.190€

INCLUSIONS AND EXCLUSIONS IN PRICE

The price published for each course includes teaching fees, space rental, certificate of attendance, and materials used during the course. The price of the course doesn't include hotel accommodation, lunches, and dinners on course days, nor any other items unless specifically mentioned. Prices of courses published by AHED are exempted of VAT. Other items priced by AHED apart from courses may however include VAT.

APPLICATION, ADMISSION AND REGISTRATION

When applying for a course at AHED – Advanced Health Education, the applicant subjects personal and professional data that will be verified and assessed to check that admission criteria for that specific program are met. Once an application is approved, registration in the course is admitted and will require payment of the price published for the course.

APPLICATION FEES

Application fees are as follows:

- 100 € for courses priced above 1000 €
 - 50 € for courses priced below equal to 1000 €
- Application fees are non-refundable.

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COURSE REGISTRATION FEES

The registration stage is considered completed when the total price of the course is received by AHED.

PAYMENT OPTIONS

Payment options for application and registration include credit card (Visa, MasterCard), wire transfer in Euro, and Multibanco.

EARLY BIRD

Application fees will be discounted from the course price for registrations completed 90 calendar days before the date of the course.

For additional information, please go to in Terms and Conditions at ahed.pt

APPLICATION DEADLINE >> OCTOBER 6TH 2020

INSTITUTIONAL PARTNERSHIP



SCIENTIFIC PARTNERSHIP



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