1st TRAINING COURSE, ACTION COST 17-112 PRO EURO DILI NET

ASSESSMENT OF DRUG-INDUCED LIVER INJURY: KEY RULES AND COMMON PITFALLS. HOW TO MAKE A CLINICAL NARRATIVE

Date: 15 March 2019

Time: 08.30h to 19.15h

Venue: Aula Magna, School of Medicine, Blvd L Pasteur 32, 29071. Málaga, Spain

Registration form: https://goo.gl/forms/MspTgxQb4ts3NSNJ3

Overview

Idiosyncratic drug-induced liver injury (DILI) is an acute adverse hepatic reaction that occurs in only a small proportion of individuals exposed to a drug, it is unexpected from the known pharmacological action of the agent, leading to illness, disability, hospitalization, including life threatening liver failure and death or need for liver transplantation. DILI represents a major challenge for clinicians, the pharmaceutical industry and regulatory agencies worldwide as it stands as one of the main causes of drug attrition during development and the adoption of regulatory measures to improve clinical safety. There is a clear need for a deeper understanding of this complex and intriguing disorder.

To achieve this objective regulatory bodies and professionals from the pharmacovigilance arena should develop skills in DILI recognition through an update on the key criteria used for DILI diagnosis and its in-depth phenotyping. This course will combine conceptual talks with problem-solving learning exercises to help translate the knowledge into a real world setting.

Learning Objectives

This training course in DILI will enable to

- Make a proper DILI case definition and phenotype classification and a case narrative
- Recognize the drugs most commonly involved in DILI and the scientific evidence to support it
- Work-out the minimal elements to make a proper DILI case adjudication
- Balance the value of the diagnostic scales used for DILI assessment
- Recognize the role of liver tests monitoring in preventing/minimizing DILI risk

Assessment

The assessment is based on a written MCQ examination on the last day of the course

Scientific Program (Agenda)

Day 15 March 2019

08.30	REGISTRATION
09.00h	Introduction, opening statements and presentations

Raúl J Andrade, Guruprasad Aithal

09.15 / 09.45   Drug-induced liver injury: general concepts, interpretation of liver tests and common mistakes.

Raúl J Andrade, Spain

09.45 / 10.30   Case definition and phenotypes. Grading Severity and Predicting outcome in DILI. The benefits of Registries

Guruprasad Aithal, UK

10.30 /11.00   COFFEE BREAK

11.00 / 11.45   New approaches to DILI identification using electronic medical records

Ayako Suzuki, USA

11.45 / 13.00   How to face a DILI suspicion

A clinical algorithm for diagnostic approach:

Mercedes Robles, Spain

Clinical Vignettes

Guido Stirnimann, Switzerland

13.00 / 14,30   LUNCH

14.30 / 15.00   Minimal data elements for proper DILI adjudication. Case study on a published DILI case.

M Isabel Lucena, Spain

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15.00 / 15.45	How to prepare a case narrative
	Einar Björnsson, Iceland
15.45 / 16.15	COFFEE BREAK
16.15 / 16.45	Risk Minimization Strategies. Why DILI initiative is important
	Herve Le Louet, France
16.45 / 17.15	Causality assessment scales: strengths and weaknesses
	Miren Garcia-Cortes, Spain
17.15 / 19.00	Introduction to breakout groups for assessment of DILI cases (Spain)
	Miren Garcia-Cortes, Camilla Stephens, Aida Ortega-Alonso, Mercedes Robles-Diaz, Judith Sanabria, Spain
19.00 / 19.30	Closing remarks and Assessment (written MCQs)