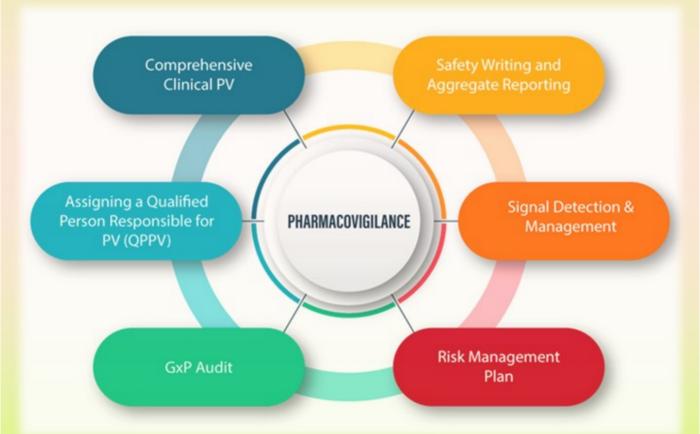




# Pharmacovigilance as a specialization and the role of the Pharmacovigilance Risk Assessment Committee (PRAC)

Sofia Trantza



Webinar for members of EIPG n conjunction with PIER and University College Cork



Wednesday 31st May 2023 at 17.00 CEST (16.00 BST)

### **About the Speaker**

Sophia Trantza is a pharmacist, specialized in Pharmaceutical Technology and Pharmacovigilance and is certified in the field of Medical Affairs. She is currently a student in the CAS Advanced Studies degree for Radiopharmacy in the University of ETH, Zurich, Switzerland. She has over 10 years' experience as a Qualified Person for Pharmacovigilance in the Pharmaceutical Industry and in parallel was ISO responsible and certified in ISO 9001: 2008, 2015 and ISO 13485.

She has entered the National Organization for Medicines (EOF) in 2016, serving as an employee in the Adverse Reactions' department and as PRAC alternate member for Greece. She currently holds the position of PRAC member, representing Greece at the European Medicines Agency (EMA), she is Assessor in the Evaluation's Department for medicinal products for human use and the responsible pharmacist in the Cosmetics' department and in the European Committee for Cosmetics and the relevant working groups.

### **Overview of Webinar**

According to the World Health Organization (WHO) pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. During the pandemic, this science went more popular than ever, and many people got familiarized with it. A very important role at the activities of this speciliazation plays the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA).

## **Learning Outcomes**

Webinar attendees will gain understanding of:

- 1. What is pharmacovigilance and what it represents for the public health.
- 2. The process of reporting adverse reactions at national and at European level.
- 3. The main activities and procedures in this discipline.
- 4. The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA).
- 5. The role and the responsibilities of PRAC Committee.
- 6. The processes that PRAC is engaged in and how the work of this Committee is reflected in these processes.

### To Join the Webinar

Please register by filling out the <u>Registration Form</u>.

Streaming details of the event will be shown on your screen at the time of your registration.

# **Continuing Education**

A certificate of attendance will be issued after the webinar. The session will be an hour of Continuing Education.