

TRAINING

MEDICINE POSTMARKETING EVALUATION RATIONALE AND METHODS

Introduction to pharmacovigilance
and pharmacoepidemiology

3-7 MARCH 2014

Université Bordeaux Segalen
BORDEAUX

tropEd



UNIVERSITÉ
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S E G A L E N

PROGRAMME

3-7 MARCH 2014

MONDAY - 3 MARCH 2014

- 09.30-12.30** | **Importance of medicines post-marketing evaluation**
Bernard Bégaud (MD, PhD – Pharmacology)
- 14.00-15.30** | **Definition and principles of pharmacoepidemiology**
Annie Fourier-Réglat (PharmD, PhD – Pharmacoepidemiology)
- 15.30-17.00** | **Advantages and limits of clinical trials and pharmacoepidemiological studies in the evaluation of medicines safety and effectiveness**
Annie Fourier-Réglat (PharmD, PhD – Pharmacoepidemiology)

TUESDAY - 4 MARCH 2014

- 09.00-10.30** | **Principles and methods to evaluate medicines utilization**
Annie Fourier-Réglat (PharmD, PhD – Pharmacoepidemiology)
- 10.30-12.30** | **Principles and methods to evaluate medicines safety**
Annie Fourier-Réglat (PharmD, PhD – Pharmacoepidemiology)
- 14.00-16.00** | **Principles and methods to evaluate medicines effectiveness**
Antoine Pariente (MD, PhD – Pharmacology)
- 16.00-17.00** | **Presentation of case studies**
Pernelle Noize (PharmD, PhD – Pharmacoepidemiology)
Hélène Géniaux (PharmD – Pharmacovigilance)

WEDNESDAY - 5 MARCH 2014

09.00-12.30 | **Preparation of restitution on case studies – student working groups**

14.00-17.00 | **Definition, principles, and organization of pharmacovigilance**
Ghada Miremont-Salamé (MD, MSc – Pharmacovigilance)

THURSDAY - 6 MARCH 2014

09.00-12.30 | **Data mining techniques: methods and role in pharmacovigilance signal detection**
Antoine Pariente (MD, PhD – Pharmacology)

14.00-17.00 | **Restitution and correction of case studies**
Pernelle Noize (PharmD, PhD – Pharmacoepidemiology)
Hélène Géniaux (PharmD – Pharmacovigilance)

FRIDAY - 7 MARCH 2014

09.00-12.30 | **Case study: examples of published signal detection studies**
Francesco Salvo (MD, PhD – Medical Toxicology)

14.00-17.00 | **Elements participating to decision-making related to medicines, measures, consequences and assessment of decisions**
Driss Berdaï (MD, MSc – Pharmacology)

LEARNING CONTENT AND OBJECTIVES

The course will cover the following topics:

-  Importance of **medicines post-marketing evaluation**
-  Definition and principles of **pharmacovigilance**
-  **Data mining techniques:** methods and role in pharmacovigilance signal detection
-  Definition and principles of **pharmacoepidemiology**
-  **Advantages and limits** of clinical trials and pharmacoepidemiological studies in the evaluation of medicines safety and effectiveness
-  Organization, roles and programs of **the main national and international institutions** in charge of medicines evaluation and surveillance
-  Elements participating to **decision-making** related to medicines, measures, consequences and assessment of decisions
-  Principles and methods to **evaluate medicines utilization**
-  Principles and methods to **evaluate medicines safety**
-  Principles and methods to **evaluate medicines effectiveness**
-  Presentation and discussion of **published pharmacoepidemiological studies**

AT THE END OF THE MODULE, PARTICIPANTS WILL BE ABLE TO:

- ✓ **Formulate** the principles and objectives of post-marketing evaluation of medicines
- ✓ **Compare** the principles and methods of premarketing (i.e. preclinical and clinical trials) and postmarketing studies (i.e. pharmacoepidemiological studies)
- ✓ **Differentiate** the role of the main institutions in charge of evaluating medicines and promoting their access according to the needs of the population
- ✓ **Debate** the requirements, aims and limits of pharmacovigilance in assessing medicines safety
- ✓ **Understand and apply** the principles of data mining techniques in pharmacovigilance
- ✓ **Critically analyze** the data elements participating to decision regarding medicines safety
- ✓ **Critically appraise** published pharmacoepidemiological studies evaluating use, risk and effectiveness of medicines
- ✓ **Compare** the main sources of data for pharmacoepidemiological evaluations (i.e. field data, claims and medical databases)

GENERAL DESCRIPTION OF THE TRAINING AND REGISTRATION PROCESS

OBJECTIVE OF THE TRAINING

To define the principles, objectives and methodological features met in pharmacovigilance and pharmacoepidemiology

Prerequisites

This training concern all **persons aiming to get an introduction to the principles and methods used in pharmacovigilance and pharmacoepidemiology**

Format of the training

5 days face-to-face training delivered in English including lectures and case studies

Location

Université Bordeaux Segalen – 146 rue Léo Saignat – 33076 Bordeaux France

Number of participants

Maximum of **15**

Training fees

Non-refundable in case of cancellation after the 3rd february 2014

Professionnals of the Pharmaceutical Industry* : **640 € for the 5 days**

Professionnals of public and private institutions* : **640 € for the 5 days**

* Agreed as a Continuous Professional Development (CPD) training

Students: **350 € for the 5 days**

Accommodations and meals are borne by the participants:
a list of hotels can be provided by the secretary (see last page)



REGISTRATION FORM - TRAINING 2014

MEDICINE POSTMARKETING EVALUATION RATIONALE AND METHODS



REGISTRATION DEADLINE: THE 3RD OF FEBRUARY 2014

Family name: **First name:**

Professional or personal address:

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Postal code: **City:**

Tel: **Fax:**

E-mail:

TRAINEE	FEES FOR THE 5 DAYS TRAINING
Pharmaceutical companies* Public or private structures*	640 €
Students	350 €

* Agreed as a Continuous Professional Development (CPD) training

CPD registration:

- YES** ☐ The attestation of CPD agreement is enclosed
NO ☐ The attestation of cost bearing endorsed by my employer is enclosed

Individual registration:

- YES** ☐ I enclosed a bank check of 350 €

INFORMATION AND REGISTRATION

The registration form must be completed and returned with the payment by the 3rd of february 2014 to:

Deborah Didio

Département des Affaires Européennes et Relations Internationales

Université Bordeaux Segalen

Case 143

146, rue Léo-Saignat - 33076 Bordeaux cedex

Tel. : +33 (5) 5 57 57 48 24

Fax : +33 (5) 57 57 15 57

e-mail: deborah.didio@u-bordeaux2.fr

Payment:

All bank checks should be made **payable to: « Agent comptable Bordeaux 2 »**

Fees are not refundable if registration is cancelled after the 3rd of february 2014