TRAINING

MEDICINE POSTMARKETING EVALUATION RATIONALE AND METHODS

Introduction to pharmacovigilance and pharmacoepidemiology

3-7 MARCH 2014
Université Bordeaux Segalen
BORDEAUX
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 Fourrier-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 Fourrier-Réglat (PharmD, PhD – Pharmacoepidemiology)

TUESDAY - 4 MARCH 2014

09.00-10.30 | Principles and methods to evaluate medicines utilization  
Annie Fourrier-Réglat (PharmD, PhD – Pharmacoepidemiology)

10.30-12.30 | Principles and methods to evaluate medicines safety  
Annie Fourrier-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)
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: _________________________________________________

Postal code: ___________________________ City: _________________________________

Tel: ___________________________ Fax: _________________________________

E-mail: ________________________________________________________________

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<thead>
<tr>
<th>TRAINEE</th>
<th>FEES FOR THE 5 DAYS TRAINING</th>
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<tr>
<td>Pharmaceutical companies*</td>
<td>640 €</td>
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<td>Public or private structures*</td>
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<tr>
<td>Students</td>
<td>350 €</td>
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*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