EU2P

EUROPEAN PROGRAMME IN PHARMACOVIGILANCE AND PHARMACOEPIDEMIOLOGY

DISCOVER THE FIRST ONLINE TRAINING PROGRAMME IN PHARMACOVIGILANCE AND PHARMACOEPIDEMIOLOGY

TABLE OF CONTENT

THE Eu2P TRAINING OFFER

THE Eu2P TRAINING OFFER

Eu2P OFFERS COURSES IN PHARMACOVIGILANCE AND PHARMACOEPIDEMIOLOGY PROVIDED AND UPDATED BY **A UNIQUE PARTNERSHIP OF SEVEN UNIVERSITIES, FIFTEEN PHARMACEUTICAL COMPANIES, THE FRENCH AND THE EUROPEAN MEDICINES AGENCIES.**

Eu2P PROVIDES FLEXIBLE AND MODULAR COURSES THROUGH ITS WEB-BASED PLATFORM. EACH TRAINEE IS IDENTIFIED AND IS GRANTED RIGHTS TO ACCESS THE E-LEARNING PLATFORM TOOLS AND RESOURCES.
BY CHOOSING Eu2P, YOU CAN LEARN ANYTIME, ANYWHERE!

Eu2P AWARDS ACADEMIC DIPLOMAS RECOGNIZED BY PRIVATE AND REGULATORY EXPERTS:

- **A MASTER PROGRAMME:**
  A POSTGRADUATE CURRICULUM ASSOCIATED TO A RESEARCH PROJECT IN ONE OR TWO YEARS LEADS TO A MASTER OF SCIENCE.
- **25 STAND-ALONE CERTIFICATES:**
  A STANDARD MODULE RUNS OVER 3 MONTHS AND LEADS TO AN ACADEMIC CERTIFICATE.
- **A PHD PROGRAMME:**
  A THESIS IN THREE YEARS ASSOCIATED TO A POSTGRADUATE CURRICULUM LEADS TO A PHD DIPLOMA.

Eu2P IS DESIGNED **FOR GRADUATE AND POSTGRADUATE STUDENTS IN HEALTH AND LIFE SCIENCES**, FOR HEALTHCARE **PROFESSIONALS** AS WELL AS FOR **NON-SPECIALISTS**.

THE Eu2P TRAINING PARTNERSHIP

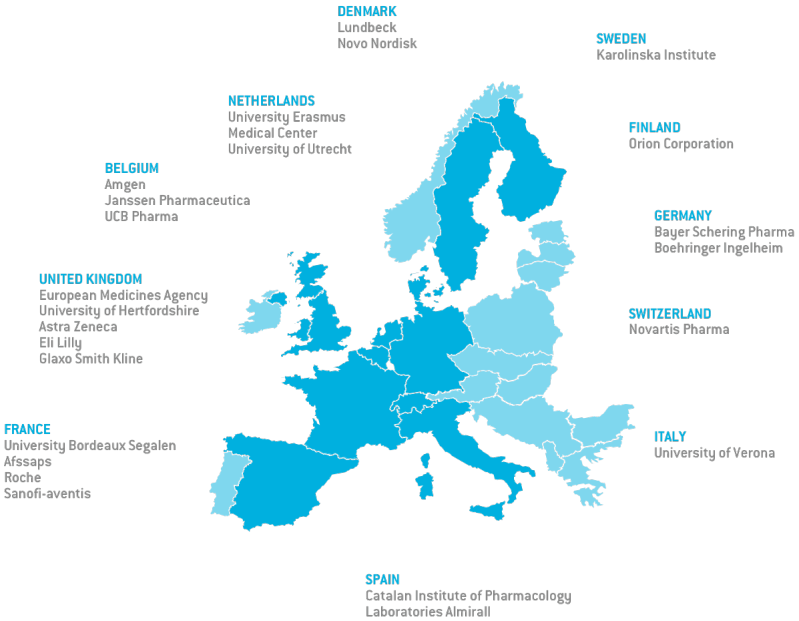
THE Eu2P TRAINING PARTNERSHIP

THE Eu2P TRAINING PARTNERSHIP IS COMPOSED OF:

SEVEN UNIVERSITIES

TWO REGULATORY AGENCIES

FIFTEEN PHARMACEUTICAL COMPANIES



THE UNIVERSITY BORDEAUX SEGALEN IS THE COORDINATING INSTITUTION FOR THE WHOLE Eu2P PROGRAMME.

AS HIGHER EDUCATION INSTITUTIONS, THE Eu2P UNIVERSITIES IMPLEMENT ALL EDUCATION ASPECTS:

- They define, provide and update skilled training contents at the introductory, intermediate and advanced levels
- They ensure that the training content meets major theoretical needs
- They transfer and evaluate knowledge and skills
- They jointly award Eu2P diplomas

AS ASSOCIATED PARTNERS, THE Eu2P REGULATORY AND PHARMACEUTICAL PARTNERS SUPPORT THE UNIVERSITIES IN THE IMPLEMENTATION, ORGANISATION AND PROMOTION OF Eu2P TRAININGS:

- They ensure that the academic content of the course meets the relevant professional needs
- They contribute to the transfer of knowledge and skills
- They offer complementary skilled courses
- They provide additional resources such as scholarships for future students
- They offer placement possibilities to perform a research project
- They are associated to the Eu2P joint diploma awards

THE COURSE CURRICULUM OFFER

D1 - BASICS FOR PHARMACOVIGILANCE AND PHARMACOEPIDEMIOLOGY

THIS DOMAIN 1 GATHERS COURSES
PROVIDED BY THE UNIVERSITY BORDEAUX SEGALEN
SUPPORTED BY THE PHARMACEUTICAL PARTNER ROCHE

TRAINING CONTENT

3 INTRODUCTORY LEVEL MODULES:
Accessible in Master year 1 and for stand-alone certificates

- Basics in epidemiology applied to pharmacovigilance and pharmacoepidemiology
- Basics in statistics applied to pharmacovigilance and pharmacoepidemiology
- Tools to do research applied to pharmacovigilance and pharmacoepidemiology

TRAINING OBJECTIVES

INTRODUCTORY LEVEL MODULES

- To make the trainees familiar and able to understand the main epidemiological and statistical principles, concepts and tools used in pharmacovigilance and pharmacoepidemiology practices and research.
- To train on the main health indices used to describe mortality and morbidity of the population.
- To learn the principles used to design and appraise observational studies.
- To master basics concepts on how to communicate written and oral scientific results

D2 - BENEFIT ASSESSMENT OF MEDICINES

THIS DOMAIN 2 GATHERS COURSES
PROVIDED BY THE AUTONOMOUS UNIVERSITY OF BARCELONA
SUPPORTED BY THE PHARMACEUTICAL PARTNER ROCHE

TRAINING CONTENT

1 INTRODUCTORY LEVEL MODULE:
Accessible in Master year 1 and for stand-alone certificates

- Basics in clinical pharmacology

2 INTERMEDIATE LEVEL MODULES:
Accessible in Master year 2, PhD and for stand-alone certificates

- Clinical and pharmacological principles applied to pharmacovigilance and pharmacoepidemiology
- Methods in clinical research, pharmacoepidemiology and in the assessment of the efficacy of medicines

1 ADVANCED LEVEL MODULE:
Accessible in Master year 2, PhD and for stand-alone certificates

- Critical appraisal of clinical trials: evidence-based medicine and its uncertainties

TRAINING OBJECTIVES

INTRODUCTORY LEVEL MODULE

- To understand the need of benefit assessment of medicines in order to fulfil patients' needs
- To develop a general knowledge of the clinical, pharmacological and epidemiological principles underlying medicines prescribing and use
- To review and become familiar with the clinical, pharmacological and epidemiological basis of medicines effects evaluation
- To understand the clinical, pharmacological and epidemiological principles of the evaluation of medicines efficacy and effectiveness

INTERMEDIATE AND ADVANCED LEVEL MODULES

- To know the scientific principles underlying the decision making process of prescribing.
- To know the methods used in epidemiological studies and in randomized clinical trials to assess the efficacy and effectiveness of medicines.
- To be aware of the limitations of scientific evidence in the benefit assessment of medicines
- To discuss and analyse the need to solve therapeutic uncertainties through clinical research.

D3 - MEDICINES PHARMACOVIGILANCE AND REGULATORY ASPECTS

THIS DOMAIN 3 GATHERS COURSES

PROVIDED BY THE UNIVERSITY OF HERTFORDSHIRE

SUPPORTED BY THE PHARMACEUTICAL PARTNERS GSK, ORION, NOVARTIS, LUNDBECK AND THE REGULATORY PARTNER THE EUROPEAN MEDICINES AGENCY

TRAINING CONTENT

1 INTRODUCTORY LEVEL MODULE:

Accessible in Master year 1 and for stand-alone certificates

- Principles of pharmacovigilance

2 INTERMEDIATE LEVEL MODULES:

Accessible in Master year 2, PhD and for stand-alone certificates

- Pharmacovigilance regulations
- Pharmacovigilance regulatory processes

TRAINING OBJECTIVES

INTRODUCTORY LEVEL MODULE

- To enable trainees to develop an understanding of the principles of pharmacovigilance from the development of the science to its place in pre and post-authorisation environment and the roles of various stakeholders within pharmacovigilance

INTERMEDIATE LEVEL MODULES

- To develop an understanding of European, USA, Japanese and major local and worldwide regulations and guidelines concerning pharmacovigilance. Emphasis will be placed on the problems of interpretation of pharmacovigilance regulations both pre- and post-authorisation.
- To enable participants (specialists) to develop an understanding of the requirements of Pharmaceutical Industry of the operational aspects of pharmacovigilance as it relates to the preparation of documents legally required by regulatory bodies. Focus will be on the adverse event reporting process within Industry, placed within the context of regulatory requirements and best practice.

D4 - MEDICINES RISK IDENTIFICATION AND QUANTIFICATION

THIS DOMAIN 4 GATHERS COURSES

PROVIDED BY THE ERASMUS MEDICAL CENTER OF ROTTERDAM

SUPPORTED BY THE PHARMACEUTICAL PARTNERS SANOFI-AVENTIS, ROCHE AND UCB

TRAINING CONTENT

2 INTERMEDIATE LEVEL MODULES:

Accessible in Master year 2, PhD and for stand-alone certificates

- Principles of identifying and recognizing adverse events and safety signals
- Substantiation and quantification of risks

1 ADVANCED LEVEL MODULE:

Accessible in Master year 2, PhD and for stand-alone certificates

- Identifying susceptibility for adverse drug reactions

TRAINING OBJECTIVES

INTERMEDIATE AND ADVANCED LEVEL MODULES

- To enhance knowledge about and make the trainees capable of identifying and quantifying risks of medicines and to interpret publications and study results.

D5 - MEDICINES BENEFIT-RISK ASSESSMENT

THIS DOMAIN 5 GATHERS COURSES

PROVIDED BY THE UNIVERSITY OF UTRECHT

SUPPORTED BY THE PHARMACEUTICAL PARTNERS ROCHE, JANSSEN, ALMIRALL AND LUNDBECK

TRAINING CONTENT

1 INTERMEDIATE LEVEL MODULE:

Accessible in Master year 2, PhD and for stand-alone certificates

- Introduction to benefit-risk assessment and pharmacoeconomics communication in decision making

3 ADVANCED LEVEL MODULES:

Accessible in Master year 2, PhD and for stand-alone certificates

- Principles of pharmacoeconomics and valuation of health states
- Methods for quantitative benefit-risk assessment of medicines
- Application of quantitative benefit-risk assessment in decision making on medicines

TRAINING OBJECTIVES

INTERMEDIATE AND ADVANCED LEVEL MODULES

- To obtain overview/basic insight into benefit-risk assessment methods (including pharmacoeconomics), the process of decision making on medicines
- To obtain detailed insight into benefit-risk assessment methods (including pharmacoeconomics), the process of decision making on medicines by different stakeholders.
- To be able to apply benefit-risk assessment methods in daily practice.

D6 - MEDICINES AND PUBLIC HEALTH

THIS DOMAIN 6 GATHERS COURSES:

PROVIDED BY THE AUTONOMOUS UNIVERSITY OF BARCELONA

SUPPORTED BY THE PHARMACEUTICAL PARTNERS AMGEN AND ROCHE

TRAINING CONTENT

1 INTRODUCTORY LEVEL MODULE:

Accessible in Master year 1 and for stand-alone certificates

- Basics in pharmacoepidemiology

3 INTERMEDIATE LEVEL MODULES:

Accessible in Master year 2, PhD and for stand-alone certificates

- Drug utilisation studies: introduction and quantitative methods
- Drug utilisation studies: introduction and qualitative methods
- The public health impact of adverse drug reactions

TRAINING OBJECTIVES

INTRODUCTORY LEVEL MODULE

- To provide basic knowledge of the evaluation of the effects of medicines from an epidemiological point of view
- To understand the limits of the available information on efficacy and risks associated with medicines
- To understand the differences between experimental studies and the actual use of medicines in clinical settings
- To know how is it possible to study the effects of medicines from a public health point of view.

INTERMEDIATE LEVEL MODULES

- To provide intermediate and advanced knowledge of the effects of medicines from a public health point of view.
- To develop theoretical and practical knowledge of the quantitative analysis of medicines utilisation.
- To develop theoretical and practical knowledge of the qualitative analysis of medicines utilisation.
- To know how to study the health and economical impact of side effects of medicines for the community.

D7 - MEDICINES RISK COMMUNICATION

THIS DOMAIN 7 GATHERS COURSES:

PROVIDED BY THE UNIVERSITY BORDEAUX SEGALEN AND THE UNIVERSITY OF VERONA

SUPPORTED BY THE REGULATORY PARTNER AFSSAPS AND, THE PHARMACEUTICAL PARTNERS LILLY AND ASTRA-ZENECA

TRAINING CONTENT

1 INTRODUCTORY LEVEL MODULE:

Accessible in Master year 1 and for stand-alone certificates

- Basics in communication applied to pharmacovigilance and pharmacoepidemiology

2 INTERMEDIATE LEVEL MODULES:

Accessible in Master year 2, PhD and for stand-alone certificates

- Information and communication about benefit-risk of medicines. Basic principles.
- Key roles and stakeholders in medicines risk communication: duties and challenges

1 ADVANCED LEVEL MODULE:

Accessible in Master year 2, PhD and for stand-alone certificates

- Case studies in medicines risk communication

TRAINING OBJECTIVES

INTRODUCTORY LEVEL MODULE

- To know the basic principles of medicines risk communication, its tools and its place in mitigating risks linked to the use of medicines

INTERMEDIATE AND ADVANCED LEVEL MODULES

- To get a clear understanding of the stakes and stakeholders' involvement in medicines risk communication and their determinants
- To have an accurate view of the way medicines risk communication works in the real life

THE Eu2P MASTER PROGRAMME ORGANISATION

THE Eu2P MASTER PROGRAMME ORGANISATION

CURRICULUM

The Eu2P Master is a 120 ECTS credits Master that runs over two years.
The Master can be entered directly into the 2nd year for postgraduate trainees.

THE MASTER INCLUDES FOR EACH ACADEMIC YEAR:

- 30 ECTS credits through the validation of theoretical content
- 30 ECTS credits through the validation of a research project

Each Master trainee must conduct a research project in parallel to the theoretical training along the academic year. This research project can be achieved within an academic, regulatory or private body.
If you are employed, you can do the research project on your employer's premises.

APPLICATION

On-line application runs each year from end of January to end of June through www.eu2p.org

MASTER ANNUAL TUITION FEES

STUDENTS	PROFESSIONALS
7,000 Euros	12,000 Euros

For professionals working in one of the Eu2P partners institutions, 20% saving are applied.

SCHOLARSHIPS

Eu2P enables scholarship application for Master trainees. Attribution of scholarship is based on merit and research interest grounds.

CALENDAR

The first and the second year master run from the end of September to early July for theoretical training and research project.

MASTER YEAR 1 - GENERAL FIGURE

THEORETICAL COURSES (30 ECTS credits)
PROJECT RESEARCH (30 ECTS credits)

Basics in clinical pharmacology	Basics in epidemiology applied to PV-PE	Basics in statistics applied to PV-PE	Tutored project	Tools to do PV-PE research & training
Basics in communication applied to PV-PE	Basics in PE	Principles of PV		

LEGEND:

■ All course modules are mandatory

MASTER YEAR 2 - GENERAL FIGURE

THEORETICAL COURSES (30 ECTS credits)
PROJECT RESEARCH (30 ECTS credits)

TRACK 1		TRACK 2	TRACK 3	TRACK 4	TRACK 5
Clinical pharmaco-logical principles of PV-PE	PV regulations	Principle of identifying and recongnising adverse events and safety signals	Introduction to benefit-risk assessment and pharmaco-economics in décision making	Drug utlization studies : introduction and quantitative methods	Information and communication about benefit-risk of medicines basics principles
Methods in clinical research, PE and in the assessment of efficacity of medicines	PV regulations processes	Substantiation and quantification of risk (1)	Principles of pharmaco-economics and valuation of health states	Drug utilization studies : qualitative methods	Key roles and stakeholders in medicine risk communication duties and challenges
Critical appraisal of clinical trials evidence-based medicine and its uncertainties		Substantiation and quantification of risk (2)	Methods for quantitative benefit-risk assessment of medicines	The public health and economical impact of ADR	Case studies in medicines risk communication
		Identifying susceptibility for ADR	Application of quantitative benefit-risk assessment in décision making on medicines		

LEGEND:

Each square counts for 3 ECTS credits

- Mandatory course modules
- Course modules for specialisation

TRACK 1: « D2 - Benefit assessment of medicines »

TRACK 2: « D4 - Medicines risk identification and quantification »

TRACK 3: « D5 - Medicines benefit-risk assessment »

TRACK 4: « D6 - Medicines and public health »

TRACK 5: « D7 - Medicines risk Communication »

THE Eu2P CERTIFICATE PROGRAMME ORGANISATION

THE Eu2P CERTIFICATE PROGRAMME ORGANISATION

CURRICULUM

Eu2P delivers either standard or extended Certificate trainings at the introductory, intermediate and advanced level.

- A standard Certificate training corresponds to 3 ECTS credits i.e. runs over 9 weeks and corresponds to a trainee workload of one day a week followed by an assessment session.
- An extended Certificate training corresponds to 6 ECTS credits i.e. runs over 18 weeks and corresponds to a trainee workload of one day a week followed by an assessment session.

APPLICATION

Three on-line application sessions are organised throughout the year.
Check regularly on Eu2P website

CERTIFICATE TUITION FEES

CERTIFICATE TYPES	STUDENTS	PROFESSIONALS
Standard (3 ECTS credits)	1,500 Euros	3,000 Euros
Extended (6 ECTS credits)	2,500 Euros	5,000 Euros

For professionals working in one of the Eu2P partners institutions, 30% saving are applied.
For students already registered with one of Eu2P academic partners, 50% saving are applied.

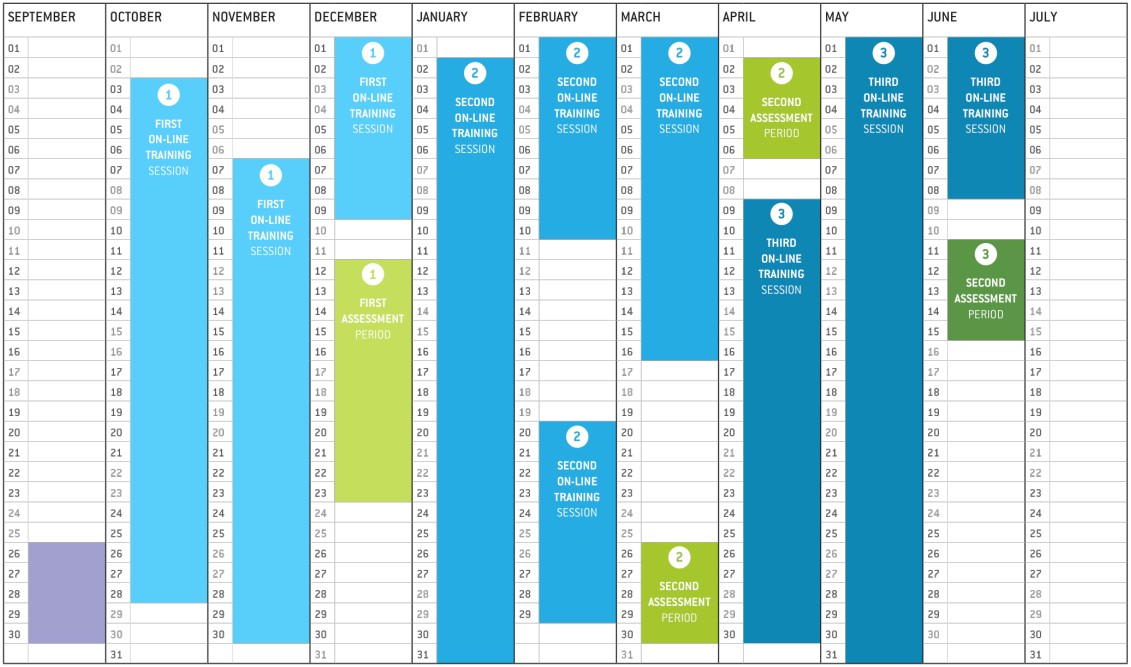
SCHOLARSHIPS

Only savings are offered for certificates to professionals working in one of the Eu2P partners institutions or to students already registered with one of Eu2P academic partners.

CALENDAR

The first certificate session runs from October to December.
The second certificate session runs from January to April.
The third certificate session runs from April to June.

MODULE CALENDAR



FOR MORE INFORMATION

WWW.Eu2P.ORG