Eu2P

EUROPEAN PROGRAMME IN
PHARMACOVIGILANCE AND
PHARMACOEPIDEMIOLOGY

BOOST YOUR CAREER WITH ONLINE TRAINING IN DRUG SAFETY

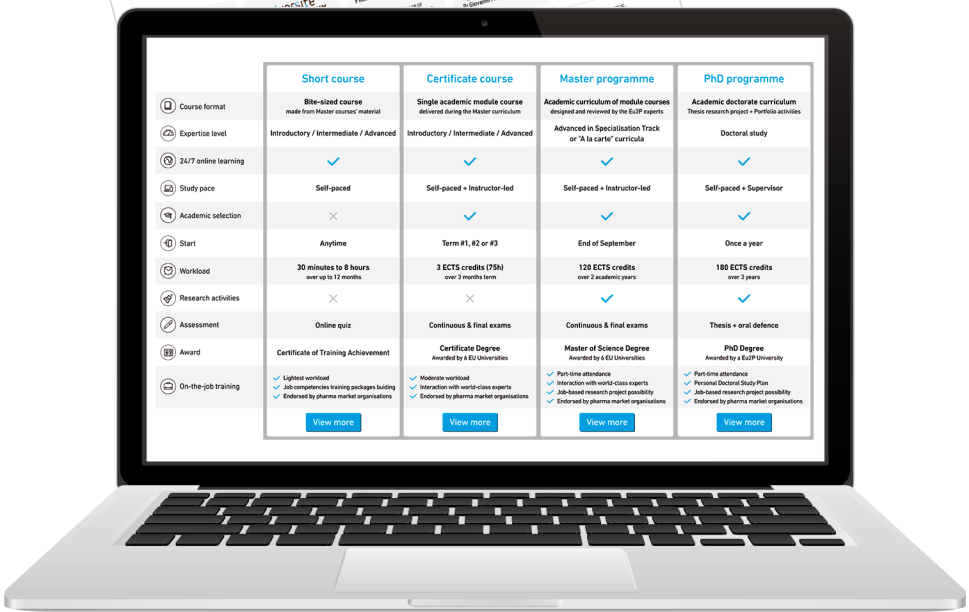
SHORT COURSES / CERTIFICATES / MASTER / PhD

Discover the Eu2P programme

THE Eu2P TRAINING OFFER

Choose academic awards designed by a strong Consortium!

7 European Universities + **2** Regulatory Agencies + **15** Pharmaceutical Companies



The Eu2P training offer

Eu2P offers courses in pharmacovigilance and pharmacoepidemiology delivered and updated by a strong partnership of six universities coordinated by the University of Bordeaux.

Eu2P offers academic courses recognised by private and regulatory experts:

Short courses

Short courses of 30 minutes to 6 hours on hot topics or focused on your needs, available over one year

25 stand-alone certificates

A standard module that runs over 3 months and leads to an academic Certificate

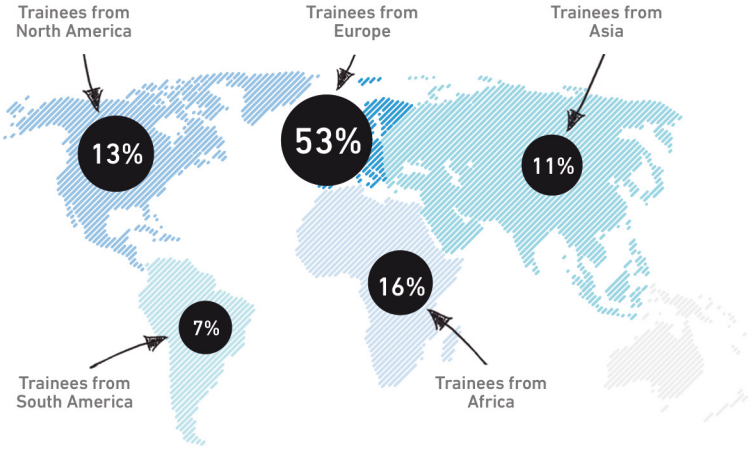
Master programme

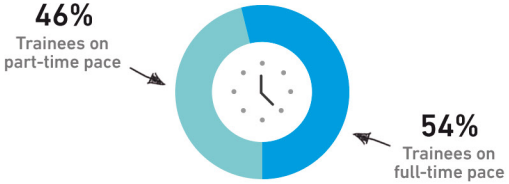
A postgraduate curriculum in one or two years associated to a research project that leads to a Master of Science degree

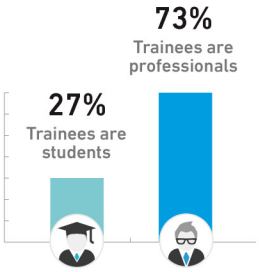
PhD programme

A thesis in three years associated to a postgraduate curriculum that leads to a PhD degree

Choose the course that best fits your profile!







Eu2P provides flexible and modular courses through its web-based platform.

Each trainee is identified and is granted access rights to the e-Learning platform tools and resources in order to interact with trainees and trainers.

By choosing Eu2P, you can learn anytime, anywhere, anypace!

Eu2P is designed:

For healthcare professionals

For graduate and postgraduate students in Health and Life Sciences

For non-specialist professionals

For companies, regulatory agencies and academic institutions

THE Eu2P COURSE CURRICULUM OFFER

Course domains

Eu2P Domain 1

Basics for pharmacovigilance and pharmacoepidemiology

Directed by the University of Bordeaux

Course 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

Academic course offer in Domain 1

Offered as

1. Basics in epidemiology

TOPICS

- Descriptive epidemiology (person, place and time)
- Observational studies in pharmacoepidemiology
- Biases in pharmacoepidemiology studies
- Causality criteria, evidence level and critical reading

C Certificate

or

M Master Y1 module

Academic course offer in Domain 1

Offered as

2. Basics in statistics

TOPICS

- Introduction to statistics and probability
- Estimates
- Statistical testing
- Introduction to multivariable linear regression

C Certificate

or

M Master Y1 module

3. Valorisation and critical appraisal in research

TOPICS

- Critical reading of scientific literature: clinical trials and observational studies
- Principles of the redaction of scientific papers and reports
- Principles of scientific posters and oral communication
- Introduction to scientific watch: principles and techniques
- Presentation of the main institutions in Health Sciences
- Principles for research funding

C Certificate

or

M Master Y1 module

● *Introductory level*

Eu2P Domain 2

Benefit assessment of medicines

Directed by the Autonomous University of Barcelona

Course 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 randomised 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

Academic course offer in Domain 2

Offered as

1. Basics in clinical pharmacology

TOPICS

- Clinical pharmacology: aims and uses in the therapeutics
- Clinical pharmacology and epidemiological evaluation of medicine effects
- The randomised clinical trials (RCT) as a method for assess the efficacy of medicines
- Basics for RCT appraisal: extrapolation of RCTs results to clinical practice

C Certificate
or
M Master Y1 module

2. Clinical and pharmacological principles

TOPICS

- Patients' therapeutic needs, medicines and society
- Patients, physicians, information and prescribing
- Clinical and pharmacological basis of therapeutics
- Variability in medicines response
- Therapeutics and medicines prescribing of medicines for selected health problems

C Certificate
or
M Master Y2 module
or
D PhD module

3. Methods in clinical research, pharmacoepidemiology and in the assessment of the efficacy of medicines

TOPICS

- Scientific methods and causality
- Statistical and methodological issues for the design and analysis of clinical trials
- Ethical issues in the development of clinical research and clinical trials
- Systematic review and meta-analysis of randomised clinical trials
- Other methods for the evaluation of the effectiveness of medicines and therapeutic interventions

C Certificate
or
M Master Y2 module
or
D PhD module

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

TOPICS

- Randomised clinical trials limitations
- Evidence-based medicine and its limitations
- Critical appraisal of randomised clinical trials limitations
- Critical appraisal of a meta-analysis of randomised clinical trials
- From therapeutic uncertainty to a research protocol

C Certificate
or
M Master Y2 module
or
D PhD module

● *Introductory level* ● *Intermediate level* ● *Advanced level*

Eu2P Domain 3

Medicines pharmacovigilance and regulatory aspects

Directed by the University of Hertfordshire

Course 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 is 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 is on the adverse event reporting process within Industry, placed within the context of regulatory requirements and best practice

Academic course offer in Domain 3

Offered as

1. Principles of pharmacovigilance

TOPICS

- Introduction to Pharmacovigilance principles
- Safety evaluation during a products lifecycle
- Labelling and risk management

C Certificate
or
M Master Y1 module

2. Pharmacovigilance regulations

TOPICS

- Pharmacovigilance regulations: concept
- The working Pharmacovigilance regulations
- Other related Pharmacovigilance regulations and guidelines
- Pharmacovigilance regulations

C Certificate
or
M Master Y2 module
or
D PhD module

3. Pharmacovigilance regulatory processes

TOPICS

- Case reporting
- Periodic reporting
- Product Labelling and Risk Management Plans
- Contractual arrangements

C Certificate
or
M Master Y2 module
or
D PhD module

● *Introductory level* ● *Intermediate level*

Eu2P Domain 4

Medicines risk identification and quantification

Directed by the Erasmus Medical Center of Rotterdam
and the University Medical Center of Utrecht

Course 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

Academic course offer in Domain 4

Offered as

1. Principles of identifying and recognising adverse events and safety signals

TOPICS

- Definition of adverse drug reactions - type of ADRs
- Detection and recognition of adverse events in clinical trials
- Adverse event coding principles and differences
- Spontaneous reporting databases
- Principles of signal detection on electronic health care databases
- Risk management plans

C **Certificate**

or

M **Master** Y2 **module**

or

D **PhD module**

Academic course offer in Domain 4

Offered as

2. Substantiation and quantification of risks

TOPICS

- Introduction: from case based reasoning to population based reasoning, examples: H1N1 vaccination, Yellow fever vaccine
- Designing a study: study designs, basic epidemiological measures, data sources, workflow to quantify risks, case and exposure identification, codes of conduct, writing a protocol
- Designing a study II: Causality from different perspectives, Causal diagrams, and Building a Statistical Analysis Plan
- Raw Data to Metrics: Elementary and advanced analysis methods with an introduction to data analysis in R
- Communication of results: communication with academia, regulators, pharmaceutical industry, writing a pharmacoepidemiological paper

C Certificate
or
M Master Y2 module
or
D PhD module

3. Identifying susceptibility for adverse drug reactions

TOPICS

- Introduction, risk factors and effect modification
- Variability in drug response and principles of pharmacogenetics/pharmacogenomics
- Assessment of pharmacogenetic influence through candidate genes and genome-wide association studies (GWAS)
- Ongoing initiatives and biological interpretation
- Successes and failures in pharmacogenetic studies

C Certificate
or
M Master Y2 module
or
D PhD module

● *Intermediate level* ● *Advanced level*

Eu2P Domain 5

Medicines benefit-risk assessment

Directed by the University of Utrecht

Course objectives

Introductory level module

- To obtain overview/basic insight into benefit-risk assessment methods (including pharmacoeconomics), the process of decision making on medicines

Intermediate and advanced level modules

- 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

Academic course offer in Domain 5

Offered as

1. Introduction to benefit-risk assessment and pharmacoeconomics in decision making

TOPICS

- Introduction
- Benefits
- Risk/Harms
- Principles and methods of comparative benefit-risk assessment
- Principles of Pharmacoeconomics

C Certificate

or

M Master Y1 module

Academic course offer in Domain 5

Offered as

2. Principles of pharmacoeconomics and valuation of health states

TOPICS

- Introduction
- Costs
- Effects
- Pharmacoeconomic analysis
- How to perform a good pharmacoeconomic evaluation

C Certificate
or
M Master Y2 module
or
D PhD module

3. Fundamentals of quantitative benefit-risk assessment methods in decision making on medicines

TOPICS

- Introduction to benefit-risk analysis methods
- Benefit/Risk assessment during life cycle of medicines
- Measures based on statistics/simulation
- Health outcomes models

C Certificate
or
M Master Y2 module
or
D PhD module

4. Advanced quantitative benefit-risk assessment methods in decision making on medicines

TOPICS

- Multi-criteria decision analysis
- Conjoint analysis
- Personalised benefit-risk assessment

C Certificate
or
M Master Y2 module
or
D PhD module

● *Introductory level* ● *Intermediate level* ● *Advanced level*

Eu2P Domain 6

Medicines and public health

Directed by the Autonomous University of Barcelona

Course 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

Advanced level module

- To know how to study the health and economical impact of side effects of medicines for the community

Academic course offer in Domain 6

Offered as

1. Basics in pharmacoepidemiology

TOPICS

- Patients, medicines and prescribing in society. Life cycle of medicines
- The knowledge-building process of the effects and adverse effects of medicines during their development and clinical use
- Overview of studies to detect and to evaluate the risk associated with therapeutic interventions Scope, uses and limitations
- The need to monitor the medicines prescribing process
- Introduction to the study of the use of medicines in clinical practice

C Certificate
or
M Master Y1 module

2. Drug utilisation studies: introduction and quantitative methods

TOPICS

- Measurement of drug use
- Overview of drug utilisation studies DUS
- Quantitative measures of drug utilisation
- Design of quantitative DUS
- How to read papers on quantitative DUS

C Certificate
or
M Master Y2 module
or
D PhD module

3. Drug utilisation studies: qualitative methods

TOPICS

- Sources of data and standards to compare with
- Methods to identify how medicines are used in the community (1) - prescription vs indication and indication vs prescription
- Methods to identify how medicines are used in the community (2) - cohort and case-controls studies as a source of drug utilisation data
- Design of qualitative DUS: Objectives, methods and discussion of proposals
- How to read papers on qualitative DUS Limitations of DUS

C Certificate
or
M Master Y2 module
or
D PhD module

● *Introductory level* ● *Intermediate level*

Academic course offer in Domain 6

Offered as

4. The public health impact of adverse drug reactions

TOPICS

- Data generalisation: from particular cases to population impact-1, the interpretation of the results of clinical trials and meta-analyses from the public health point of view
- Data generalisation: from particular cases to population impact-2, examples of the value of observational studies and meta-analyses of observational studies in the evaluation of the public health impact of medicines use
- Public health impact - Case: Hormone replacement therapy
- Public health impact beyond case-control studies
- The importance of the denominator: Case-population studies, the future of pharmacovigilance

C **Certificate**

or

M **Master** (Y2) **module**

or

D **PhD module**

● *Advanced level*

Eu2P Domain 7

Medicines risk communication

Directed by the University of Bordeaux and the University Luigi Vanvitelli of Naples

Course objectives

Introductory level modules

- 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

Academic course offer in Domain 7

Offered as

1. Basics in communication

TOPICS

- Which knowledge and skills are useful for communication?
- Concrete examples of communication: what do we retain?
- Why communicate?
  Nature and importance of communication
  Personal and social dimension of communication
- Face to face between doctor and patient
  How to find the right word?

C Certificate

or

M Master Y1 module

Academic course offer in Domain 7

Offered as

2. Information and communication about benefit-risk of medicines. Basic principles.

TOPICS

- Principal actors in communication on medicines risk, of traditional and new forms of communication, of routes of communication and their evolution through time
- Basis of risk communication process
- Regulatory responsibilities and requirements concerning medicines risk communication
- Communication of actual and alleged risks associated to medicines: three different scenarios

C Certificate
or
M Master Y2 module
or
D PhD module

3. Key roles and stakeholders in medicines risk communication: duties and challenges

TOPICS

- Historical perspective : evolution of concept of risk communication, social impact of drug risk communication
- Risk perception: actual vs perceived and factors influencing perception, population vs individual risk perception
- Concept of uncertainty: how to deal with this in risk communication
- Nature and importance of communication of risk of medicines: accessibility of data, conflict of interest and independent information
- Regulatory agencies' strategies to address the challenges of risk communication

C Certificate
or
M Master Y2 module
or
D PhD module

4. Case studies in medicines risk communication

TOPICS

- Hepatitis B vaccine in France, pandemic influenza vaccines, HRT and cancer: what can we learn? What could have been done?
- Communication aspects based on drug withdrawals: e.g. rofecoxib, rosiglitazone, benfluorex, what can we learn? What could have been done?
- How to measure the effectiveness of risk communication?

C Certificate
or
M Master Y2 module
or
D PhD module

Introductory level *Intermediate level* *Advanced level*

THE Eu2P SHORT COURSES PROGRAMME ORGANISATION

Gain rapid and accurate expertise through the Eu2P Short courses!

Your training progress reaches 100%

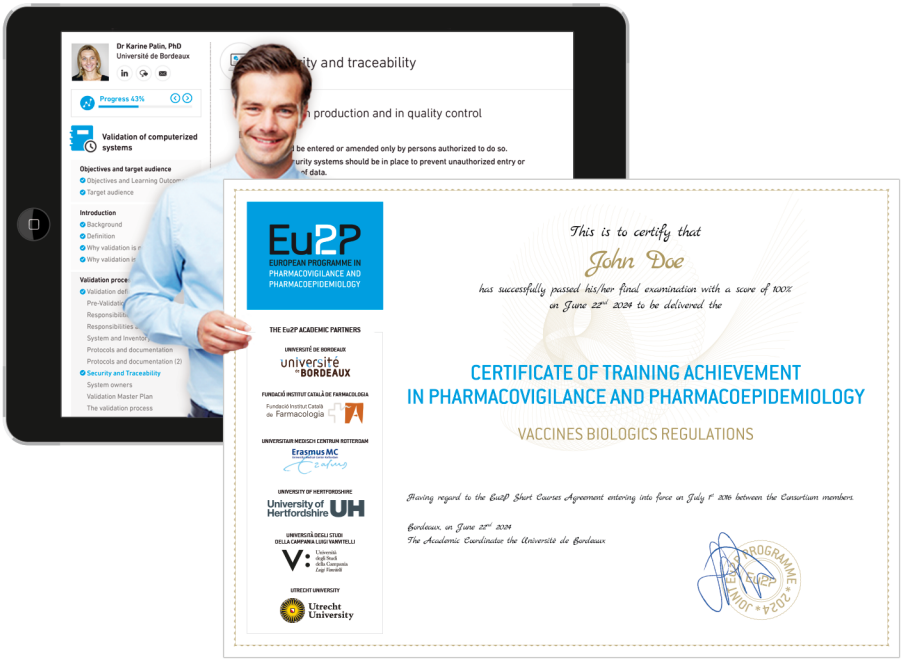
Your graded evaluation reaches at least a 80% good score

Learning content
over 30 minutes to 6 hours

Final evaluation
by multiple choice questions

Eu2P Certificate
of training achievement

1 year full-access



The Eu2P short courses programme organisation

Get a Certificate of Training Achievement

The Eu2P short course is a training **designed for professionals** who want to **get an up-to-date, quick and solid knowledge**. This programme leads to **Awards in pharmacovigilance and pharmacoepidemiology** jointly acknowledged by the European Universities working together as Eu2P partners.

Get a valuable Certificate for job market

A recognised quality for audit inspections

Eu2P programme ensures and controls up-to-date knowledge, expertise and qualification of medicines-related collaborators, **from individuals to large teams**.

Designed for experts by experts

The Eu2P Short Courses have been **built by the academic, regulatory and industrial Eu2P partners**. The short courses are **grounded in real job market** and today's practices.

Eu2P programme is being noticed and **recognised worldwide as an excellent means to get medicines-related jobs**.

Choose a flexible online programme

Awarded for e-learning quality, Eu2P online courses **can be attended from home or work**. The course workload **runs from 30 minutes to 6 hours**. The learning activities **can be followed according to your wish**. You can start a learning activity then stop and start another one, then come back later to the one you have firstly opened.

The Certificate is **awarded after a final assessment**.

Enjoy affordable prices

 Students & Professionals	 Companies
Annual registration for one short course per person from 100 € to 500 €	**Custom package** Quote on request

Eu2P supports worldwide pharmaceutical companies for their in-house training plans and provides quotes tailored to their needs in terms of content, duration and number of collaborators.

Find detailed
informations on this offer
in the Eu2P short courses leaflet

THE Eu2P CERTIFICATE PROGRAMME ORGANISATION

Improve your professional competencies through the Eu2P academic Certificate diploma!

Live lectures

Forums

Tutoring
& Live sessions

Eu2P Certificate
European academic diploma

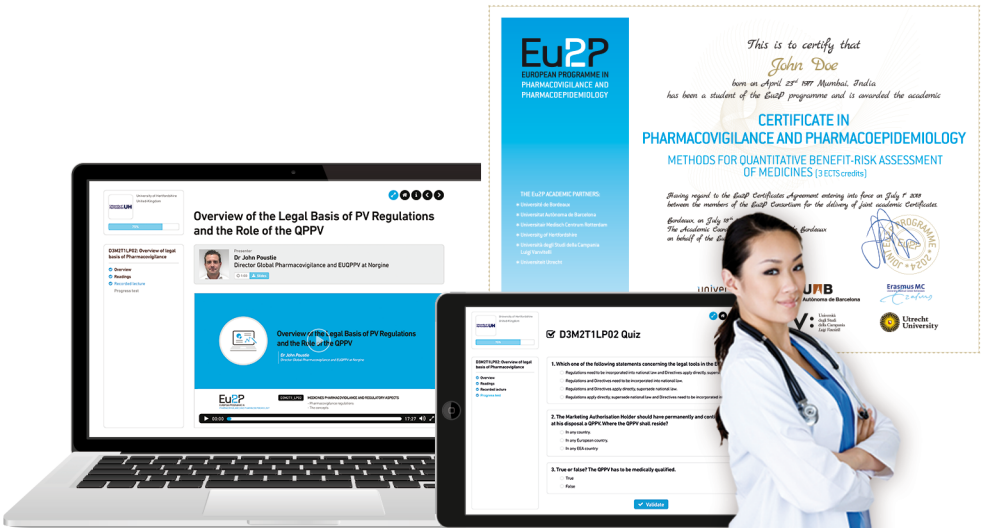
Certificate course
3 ECTS credits workload

Graded examination
to validate your certificate programme

Continuous assessment

Final examination

3 months



The Eu2P Certificate programme organisation

Get a European academic Certificate

The Eu2P Certificate leads to **academic Awards in pharmacovigilance and pharmacoepidemiology jointly delivered by the European Universities** working together as Eu2P partners.

Standard and extended Eu2P certificates learning achievements are **recognised as respectively 3 and 6 ECTS credits**.

Get a valuable Certificate for job market

Graded expertise level

You can choose between **introductive, intermediate or advanced Certificate courses** level fitting your background and needs!

A recognised quality for audit inspections

Eu2P programme ensures and controls up-to-date knowledge, expertise and qualification of medicines-related collaborators, **from individuals to large teams**.

Designed for experts by experts

The Eu2P Certificates have been **built by the academic, regulatory and industrial Eu2P partners**. These certificates are **grounded in real job market** and today's practices.

Eu2P programme is being noticed and **recognised worldwide as an excellent means to get medicines-related jobs**.

Choose a flexible online programme

Awarded for e-learning quality, Eu2P online courses are followed **at home and on job premises** at your convenience. The average course **workload is one day a week over a 3 or 6 months period** (depending on the course ECTS credits).

The Certificate diploma is **awarded after a final assessment session**.

Enjoy affordable prices

Tuition fees are **adjusted to student or professional** status.
Savings on regular fees can be offered under eligibility conditions.

Students	Professionals	Companies
1,500 €	3,000 €	Quote on request

Get savings

Partners' saving

Each **Eu2P partner benefits from a special price** on Eu2P tuition fees for their students or employees!

Savings for Certificate fees	
Student in a Eu2P University	**- 50%**
Employee in a Eu2P agency, company or affiliate	**- 30%**

Reward programme

Gain up-to 20% of savings when studying with Eu2P!

Eu2P gives you reward points each time you register to a Eu2P Certificate: one point amounts to one euro. You can redeem these points and get savings on next course tuition fees!

Apply on-line

Check upcoming Certificates on www.eu2p.org

Calendar

On-line application sessions are organised throughout the year according to the Certificates calendar:

- A **first** Certificate session runs **from October to December**
- A **second** Certificate session runs **from January to April**
- A **third** Certificate session runs **from April to June**

Admission criteria

The application procedure and the selection process are the same for all candidates, regardless of whether you come from Eu2P partners or not, from European or third countries.

More info **about application P55**

To be eligible, you must:

- **be fluent in English**
- **be familiar with computer use and have Internet access**
- **submit a complete on-line application**, together with all supporting documentation required (diplomas, certificates, letter of motivation...)

Pre-requisites depend on the chosen module: please refer to each Certificate description page on www.eu2p.org.

THE Eu2P MASTER PROGRAMME ORGANISATION

Strengthen your profile through the Eu2P Master of Science!

Theoretical content
30 ECTS credits by year

Research project
30 ECTS credits by year

Tutoring
& Live sessions

Live lectures

Forums

Tutored project

Graded examination
to validate 60 ECTS credits by year

Continuous assessment

Final examination

Project presentation

Eu2P Master of Science degree
120 ECTS credits over 2 years

The Eu2P Master programme organisation

Get a European Master of Science degree

120 ECTS credits over 2 years

The Eu2P Master is an **academic post-graduate training in pharmacovigilance and pharmacoepidemiology** that leads to a **MSc degree jointly awarded by the European Universities** working together as Eu2P partners.

The Eu2P 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.

Your curriculum specialisation

In second year, choose a Master specialisation among:

- Benefit assessment of medicines
- Medicines risk identification and quantification
- Medicines benefit-risk assessment
- Medicines and public health
- Medicines risk communication

or select "à la carte" modules to match specific needs

Get a valuable Master degree for job market

The Eu2P Master degree curriculum has been **built by the academic, regulatory and industrial Eu2P partners**. Eu2P courses are **grounded in real job market and today's practices**. The Master research projects can be performed in public or private environments.

Eu2P programme is being noticed and **recognised worldwide as an excellent means to get medicines-related jobs**.

Choose a flexible online programme

Awarded for e-learning quality, Eu2P online courses are followed **at home and on job premises** at your convenience.

Master Year 1 or 2 curriculum can be performed **on a full or part-time** basis to suit your time availability.

The Master can be entered **directly into the 2nd year for postgraduate trainees**.

Get savings and grants

Master annual tuition fees

Students	Professionals
7,000 € per year	12,000 € per year

Partners' saving

Each **Eu2P partner benefits from a special price** on Eu2P tuition fees for their employees!

Savings for Master year fees	
Employee in a Eu2P agency, company or affiliate	**- 20%**

Reward programme

Gain up-to 20% of savings when studying with Eu2P!

Eu2P gives you reward points each time you register to a Eu2P Master programme: one point amounts to one euro. You can redeem these points and get savings on next course tuition fees!

Master grants

Eu2P offers a **limited number of grants to Master selected applicants** to cover partial Master tuition fees.

Eu2P grants are awarded by the Eu2P consortium and private organisations on the appraisal of the applicant's status regarding:

- Academic performance
- Professional ambition and environment
- Personal situation
- Any special and financial circumstances that may affect training performance

Apply on-line

Calendar

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

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

Admission criteria

The application procedure and the selection process are the same for all candidates, regardless of whether you come from Eu2P partners or not, from European or third countries.

More info **about application P55**

To be eligible, you must:

- **be fluent in English**
- **be familiar with computer use and have Internet access**
- **submit a complete on-line application**, together with all supporting documentation required (diplomas, certificates, letter of motivation...)

If you apply to the full Master (entry in Year 1), you must:

- have at least a **Bachelor degree or an equivalent certified level in Health or Life sciences**

If you apply to Master Year 2, you must:

- hold a **Master Year 1 level or an equivalent certified level in Health or Life sciences including credits in basic pharmacology, epidemiology and statistics**

or

- **be employed, have a graduate level in Health or Life sciences and 3 years of relevant professional experience in Pharmacovigilance and Pharmacoepidemiology**

Master Year 1 curriculum

The Master Year 1 trainee must **validate the theoretical and the practical trainings to progress to the second year programme** of the Master in Pharmacovigilance and Pharmacoepidemiology.

Theoretical courses (30 ECTS credits)

Basics in epidemiology	Basics in statistics	Valorisation and critical appraisal in research	Basics in clinical pharmacology
Principles of pharmacovigilance	Basics in pharmaco-epidemiology	Basics in medicines risk communication	Analysis and synthesis of health data

Each course module is appraised through **continuous and/or final assessment**. The Master Year 1 trainee must at least **obtain the "pass" grade in each module to validate the theoretical training part** of the Master first year programme.

Project research (30 ECTS credits)

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.

This research project is assessed through three separate assessments:

- the overall **research project conduct**
- the **research project written report**
- the **oral defence** of the research project report

The Master Year 1 trainee must at least **obtain the overall "pass" grade for the research project to validate the practical training part** of the Master first year programme.

Master Year 2 curriculum

The Master Year 2 trainee must **successfully complete the theoretical and the practical trainings to be awarded the Eu2P Master in Pharmacovigilance and Pharmacoepidemiology**.

Theoretical courses (30 ECTS credits)

TRACK D2		TRACK D4	TRACK D5	TRACK D6	TRACK D7
Clinical pharmaco-logical principles	Pharmaco-vigilance regulations	Principle of identifying and recognising adverse events and safety signals	Introduction to benefit-risk assessment and pharmaco-economics in decision making	Drug utlisation 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 efficacy of medicines	Pharmaco-vigilance regulations processes	Substantiation and quantification of risks (1)	Principles of pharmaco-economics and valuation of health states	Drug utilisation 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 risks (2)	Fundamentals of quantitative benefit-risk assessment methods in decision making on medicines	The public health impact of adverse drug reactions	Case studies in medicines risk communication
		Identifying susceptibility for adverse drug reactions	Advanced quantitative benefit-risk assessment methods in decision making on medicines		

Each course module is appraised through **continuous and/or final assessment**. The master Year 2 trainee must at least **obtain the "pass" grade in each module**, whether their course modules are mandatory or complementary.

■ *Mandatory course modules* ■ *Course modules for specialisation*

For this second year of Master, **two teaching scenarios are proposed to trainees: "Specialised Master" vs "A la carte Master"**.

Specialised Master

The whole black modules row is mandatory

One specialisation track column is chosen among:

- **TRACK D2 = "Domain 2 - Benefit assessment of medicines"**
- **TRACK D4 = "Domain 4 - Medicines risk identification and quantification"**
- **TRACK D5 = "Domain 5 - Medicines benefit-risk assessment"**
- **TRACK D6 = "Domain 6 - Medicines and public health"**
- **TRACK D7 = "Domain 7 - Medicines risk communication"**

Complementary modules have to be selected among remaining modules **to overall validate 30 ECTS credits**

"A la carte" Master

This track is composed of **four modules of your choice** among the Master specialisations (blue modules)

The whole black modules row is mandatory

Complementary modules have to be selected among remaining modules **to overall validate 30 ECTS credits**

Project research (30 ECTS credits)

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.

This research project is assessed through three separate assessments:

- the **research project supervisor evaluation**
- the **research project written report**
- the **oral defence** of the research project report

The Master Year 2 trainee must at least **obtain the overall "pass" grade for the research project to validate the practical training part** of the Master second year programme.

THE Eu2P PhD PROGRAMME ORGANISATION

Deepen your knowledge through the Eu2P PhD degree!

Portfolio activities
60 ECTS credits over 3 year

Thesis research
120 ECTS credits over 3 years

Course content
local & distant learning

Conferences
participation or organisation

Bibliography
publication & literature

Research project
hosted in research location

Doctoral Board
& tutoring supervisors

Doctoral study plan

Video-conferencing

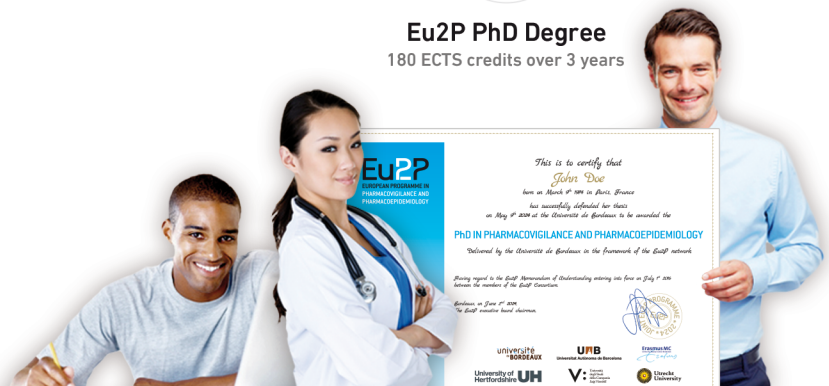
Research project placement

Thesis research writing

Graded examination
to validate the portfolio activities

Thesis oral defence
to validate the thesis research

Eu2P PhD Degree
180 ECTS credits over 3 years



The Eu2P PhD programme organisation

Get a valuable academic PhD degree

180 ECTS credits over 3 years

The Eu2P PhD programme is an **academic doctorate curriculum in pharmacovigilance and pharmacoepidemiology**. It leads to a **PhD degree awarded by one of the Eu2P Academic Partners under the authority of the relevant National Ministry of Higher Education** or ad hoc authority.

The whole Eu2P PhD curriculum covers **3 consecutive years**, for a **total of 180 ECTS credits**, including:

- **120 credits** gained progressively **by researching and writing a thesis**
- **60 credits** for secondary **PhD portfolio activities** carried out at any given moment during the research period.

Yearly overview of the PhD curriculum

Type of activity		ECTS credits (number/year)	Total of ECTS (credits/year)
Thesis research	Bibliographic knowledge	10	40
	Advanced research training	30	
Portfolio activities	Eu2P workshop	4	20
	Eu2P local and distant learning	6	
	Seminars & workshops participation	10	

Your curriculum specialisation

PhD students are **driven by a supervising team** related to one of the Eu2P Academic partners for their thesis, but also to carry out their advanced project research, portfolio activities or simply to meet them and benefit from their knowledge. All these activities are detailed in their **personal Doctoral Study Plan**.

Get a valuable post-graduate degree for job market

Eu2P courses are grounded in real job market and today's practices and research projects can be performed in public or private environments.

Eu2P programme is being noticed and **recognised world-wide as an excellent means to get medicines-related jobs and improve regulatory sciences**.

Choose an on-the-job PhD programme

The Eu2P PhD is **open to applicants who hold a post-graduate diploma in Pharmacovigilance and Pharmacoepidemiology** (e.g. Master of Science), **from both EU and non-EU countries, without limitation in terms of age and nationality**. Applicants may belong to Universities who are not part of the Eu2P PhD network.

PhD curriculum should be completed on a **full-time basis for 3 consecutive years** with a sufficient funding.

It can be carried out **in parallel to a professional occupation**.
Trainees must ensure that they shall be able to complete their research work and defend their PhD thesis **within an absolute maximum of 3 years** beginning with the date of initial registration in the doctoral programme.

Get savings and grants

PhD annual tuition fees

Students	Professionals
4,500 € per year	6,000 € per year

Partners' saving

Each **Eu2P partner benefits from a special price** on Eu2P tuition fees for their employees!

Savings for PhD year fees	
Employee in a Eu2P agency, company or affiliate	**- 20%**

PhD grants

Eu2P offers a **limited number of grants to PhD selected applicants** to cover partial PhD tuition fees.

Eu2P grants are awarded by the Eu2P consortium and private organisations on the appraisal of the applicant's status regarding:

- Academic performance
- Professional ambition and environment
- Personal situation
- Any special and financial circumstances that may affect training performance

Apply on-line

On-line application runs each year through www.eu2p.org

More info **about application P55**

Admission criteria

The Eu2P PhD is **open to applicants from both EU and non-EU countries**, without limitation in terms of age and nationality.

Applicants may also belong to Universities who are not part of the Eu2P PhD network.

To be eligible, you must:

- **satisfy the entrance requirements for admission to the doctoral programme** (3rd cycle within the European Higher Education and Research Area)
- **have solid background in Pharmacovigilance and Pharmacoepidemiology** documented on the basis of your transcripts and your **Master of Science degree** in Pharmacovigilance and Pharmacoepidemiology

Doctoral study plan

The definition of the PhD topic is carried out in the Doctoral Study Plan in **several stages by updating the research project for which the student has been selected** and subject to remarks and suggestions along the whole duration of the thesis. The Doctoral Study Plan is consequently **subject to supervision and validation by the Eu2P degree-awarding institution through the Eu2P Doctoral Board members** and the approval of their related local doctoral school.

Supervision of the doctoral study plan

The Eu2P Doctoral Board sets the standards that the doctoral student must achieve and approves for each student, an academic plan and a project programme involving mobility called "Doctoral Study Plan".

For this purpose, the Doctoral Board appoints during the first induction month a **PhD supervisor in line with the student Research project synopsis**. The **PhD supervisor must belong to a Eu2P Academic Partner** and hold an accreditation or an equivalent level to supervise doctoral thesis such as full professor.

In the first three months of the programme, the PhD supervisor oversees the student's progress, strengths or weaknesses, and guides him/her to the preparation of the **Doctoral Study Plan** that is **submitted to the Doctoral Board at the end of the first trimester**.
The PhD supervisor in particular helps the student in the adoption of the most appropriate methodology to carry out his/her research successfully and guides him/her in the necessary research and drafting of a final thesis. There must be at least **two meetings a year gathering the PhD student and the supervisor**. Video-conferencing facilities may be used for meetings. The doctoral student may also benefit from other forms of peer monitoring in hosting academic and research centres.

Setting up and annual validation of the doctoral study plan

A **Doctoral Study Plan must be established** for each selected Eu2P PhD Student.

Eu2P members explicitly invite **innovative project proposals** which are prepared to strike out into **new fields**. Within the programme, public and private Eu2P members can **provide expert supervision and academic accompaniment** in a wide variety of fields and their interconnections.

The **Doctoral Study Plan drawn up during the first term of the PhD curriculum between the PhD student and his/her supervisor**, must detail:

- The **thesis research project supervision** such as appointment rules, names and roles of the supervisor
- The **thesis research project conduct locations**, the description and scientific justification of the mobility within the Hosting academic and research centres
- The **research activities main lines and expected results**
- The **programmed portfolio activities**

The final validation of the initial Doctoral Study Plan is the last **mandatory step needed before the student can actually finalise his/her registration** with the awarding Eu2P Academic Partner.

The Doctoral Study Plan **must be yearly updated and validated together with the PhD student and supervisor**. Each annual update **must be sent to the Eu2P Central Office** to be recorded and available for consultation by the Doctoral Board and each related doctoral school of Eu2P Academic Partners.

Doctoral study location and mobility

The Eu2P PhD student is advised to make the most of the Eu2P consortium possibilities and **build a close research network among the Eu2P partners**. Each **PhD student is based primarily at one Eu2P Home academic institution depending on his/her PhD supervisor**.

The student is strongly encouraged to **work at least 6 months of the programme at another public or private Hosting Institution**.

The Eu2P PhD student has the opportunity to **perform the thesis research project** in the premises of:

- A **Eu2P Academic Partner**
- An **Higher Education Institution** which it is not a Eu2P partner

or

- A **non-Higher Education Institution**, which may or may not be a Eu2P partner

In all cases, the Eu2P PhD student **must be supervised by the PhD supervisor appointed by the Doctoral Board**, belonging to a Eu2 Academic Partner, and be a full or associate professor.

When the student is conducting research in another location than the supervisor institution, a **local tutor is appointed by the supervisor**. In any case, **the tutor must be a full or associate professor** or equivalent with **full authority to graduate PhD** i.e. must have an academic accreditation to supervise research.

Mobility to a public or private institution must be justified in the Doctoral Study Plan.

For PhD students currently pursuing in parallel their work at one of the Eu2P Associated Partner's premises, the mobility requirement may be adapted in the Doctoral Study Plan, upon specific agreement granted by the Eu2P Doctoral Board.

PhD portfolio activities

Doctoral Activities

In order to enhance the students' employability and **to improve their written/oral communication skills**, the Doctoral Board has added portfolio activities so that the **future Ph. Doctors are also fully operational as global academics**. The academic plan of doctoral students comprises the carrying out of portfolio activities.

All the activities below are **strongly recommended** to the Eu2P doctoral students, but only **60 ECTS credits** worth of activities are validated for their degree; this can be done at any stage during the whole duration of the Doctorate.

Doctoral Activities	ECTS credits (number)
Producing an article for publication in a recognised journal	10
Producing a review for publication in a recognised journal	10
Participating or organising a conference, symposium...	3
Teaching experience at higher-education level	3
Completing Eu2P training courses and summer school	From 3 to 6

Completion of Eu2P training courses

The PhD student must justify the follow up and completion of the theoretical training along their project research work for at least a total amount of **20 ECTS credits along the three years of PhD** registration.

Students may **either follow modules chosen from the Eu2P web-based training** offer among the seven domains **or follow local face-to-face Eu2P Academic partner courses** during the annual Summer schools.

THE Eu2P PROCESS TO APPLY FOR A TRAINING PROGRAMME

The Eu2P process to apply for a training programme

Application

The on-line process

Eu2P registration tool enables you to **apply on-line to any Eu2P training**.

The Eu2P application process must be **fully completed** on-line.
You are asked to upload all the needed documents within this on-line application.

To apply for Eu2P programme, you have to:


Choose one training programme to apply for


Login to your "My Eu2P" account, or create one if needed


Provide required application data


Pay for application fees: **25 €**

The paper process

The Eu2P application process must be fully completed on-line.

Nevertheless, **if you can not upload needed documents**, please print your on-line application fully completed and **send it by postal mail with the copy of all needed documents** to the following address:

Eu2P Central Office

Université de Bordeaux
146 rue Léo Saignat - Case 36
33076 Bordeaux cedex
FRANCE

Selection

Once your on-line application file is complete, it is sent to the respective pedagogical Board.

The **Board ranks Eu2P applicants** for each of the training:

- **Eligible list**: you are eligible for immediate registration.
- **Waiting list**: you could be eligible, provided that some "Eligible list" applications are cancelled.
- **Non-eligible list**: your application data are not approved for registration.

You will be warned about your application status by the Eu2P Central Office by e-mail.

Registration

Once you are informed about your selection status by e-mail, **you are invited to confirm your registration** as follows.

- **You are eligible:** you need to confirm your registration before a deadline and to pay for tuition fees to validate your registration
- **You are on waiting list:** you need to confirm your position on the waiting list

If you are non-eligible, you can contact the Eu2P Central Office for further explanations.

JOIN AND FOLLOW US TO STAY INFORMED

ON Eu2P WEBSITE

ON Eu2P SOCIAL NETWORK

- eu2porganization
- @Eu2P
- Eu2P.org
- Eu2P

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