How to apply on-line and benefit savings dedicated to ISoP members?

Admission criteria

The application procedure and the selection process are the same for all candidates.

To be eligible, you must:

- **be a verified ISoP member**
- **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...) to apply for Certificates or Master programme

Pre-requisites depend on the chosen training programme and module: please refer to each programme description through www.eu2p.org.

Calendar

Short courses

There is no particular calendar for the short courses. Once purchased on-line and the user account created, the training is accessible.

Certificates

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**

Check upcoming Certificates on www.eu2p.org

Master 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

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Eu2P

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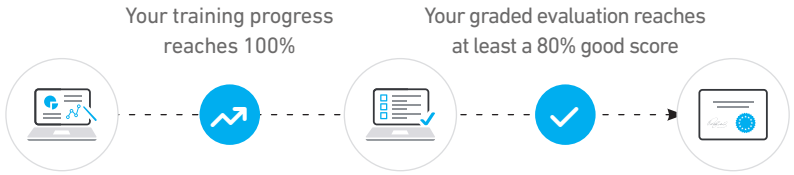
ISoP

The Eu2P short courses catalogue

GAIN UP TO 40% OF SAVINGS!
ISoP Members: from 60€ to 300€ (instead of ~~100€ to 500€~~)

For more information, contact **Dr Karine Palin**: eu2p.office@eu2p.org



Course format and duration

- Short courses are divided in several learning activities such as recorded lecture, reading, quiz, and forum that altogether **run over 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.
- **Once open, your training remains accessible until completion, and within one year**.

Attendance and progress report

- **The Eu2P central office can quantify and analyse** your own training attendance, workload and quiz progress per learning activity and per short course.

Evaluation and award

- When **your training progress reaches 100%**, you **perform an online graded evaluation** on your whole training content.
- This evaluation consists in a **quiz covering all your learning activities**.
- The training **evaluation is successful if you reach at least a 80% good score**.
- You **then receive an official Eu2P certificate** for your achieved competencies.

Apply on-line

- Select the courses to add to the cart on https://www.eu2p.org/short-courses/overview
- Create your account as a verified ISoP member
- Pay on-line the order and enjoy starting your training programme

Basics for Pharmacovigilance and Pharmacoepidemiology

General short courses

	Exclusive ISoP Members Fees
1. Principles in Epidemiology	**5h 300€**
2. Epidemiología para los no epidemiólogos (in spanish)	**5h 300€**
3. Basis in statistics	**5h 300€**

Short courses designed for the North American market

4. US/EU regulations: principles and comparison	**3h 180€**
5. Overview of the Legal Basis of PV Regulations and the Role of the QPPV	**3h 180€**
6. Principles of Labeling and Description of United States Prescribing Information (USPI)	**3h 180€**
7. Pharmacovigilance in Combination Products and Regulations	**3h 180€**
8. From individual cases to the community impact of adverse drug reactions	**2h 120€**
9. Aggregate reporting in the US	**2,5h 150€**

Medicines Benefit assessment

General short courses

	Exclusive ISoP Members Fees
1. Heterogeneity of treatment effect in clinical trials	**2h 120€**
2. Selecting outcomes: Surrogate endpoints	**2h 120€**
3. Fundamentals of the adaptative clinical trials	**2h 120€**
4. Fundamentals of the network meta-analysis	**2h 120€**
5. Composite outcomes in clinical trials	**2h 120€**
6. Early stopping rules in clinical trials	**2h 120€**
7. Non inferiority approach in clinical trials	**2h 120€**
8. Recruitement strategies in clinical trials	**2h 120€**

Medicines Benefit-Risk assessment

General short courses

	Exclusive ISoP Members Fees
1. Drug life cycle as a tool in drug policy analysis	**1h**
2. Main challenges of health economics and outcomes research	**2h 120€**

Short courses designed for the North American market

3. Principles and methods of benefit-risk assessment in decision-making of medicines	**2h 120€**
4. Role of benefit-risk assessment and pharmaco-economics in decision-making of medicines	**2,5h 150€**
5. Concepts in Risk Management	**3h 180€**
6. Organization for risk management in the industry	**2h 120€**
7. Risk Evaluation and Mitigation Strategy (REMS)	**2,2h 130€**

External databases/RWD/RWE

Short courses designed for the North American market

	Exclusive ISoP Members Fees
1. FDA Adverse Event Reporting System (FAERS)	**2,5h 150€**
2. FDA System	**2,5h 150€**
3. Health care records from large databases as a tool to study the use of medicines	**2h 120€**
4. Integrating Pharmacovigilance and consumption data analysis - uses, limitations and potentiality	**2h 120€**

Medicines Risk identification and quantification

General short courses

	Exclusive ISoP Members Fees
1. Introduction to risk management plan (RPM)	**1h 60€**
2. Concepts in risk management	**3h 180€**
3. Pharmacovigilance plan versus risk minimisation plans	**3h 180€**
4. Organisation for risk management in the industry	**3h 180€**
5. Methods and new initiatives for signals detection	**6h 300€**

Medicines and public health

General short courses

	Exclusive ISoP Members Fees
1. Health care records from large databases as a tool to study the use of medicines	**2h 120€**
2. Integrating Pharmacovigilance & consumption data analysis - uses, limitations & potentiality	**2h 120€**
3. From individual cases to the community impact of adverse drug reactions: measuring tools	**2h 120€**
4. From individual cases to the community impact of adverse drug reactions: limitations	**2h 120€**
5. Drug interaction risks: the value of concomitant medication	**2h 120€**
6. Drug misuses risks: the effects of inappropriate use of the target medicine	**2h 120€**

Medicines Risk communication

General short courses

	Exclusive ISoP Members Fees
1. Basis of risk communication with special focus on risk communication on medicines	**2h 120€**
2. Understand communication challenges facing the regulatory agencies	**2h 120€**
3. How can risk communication be minimized?	**2h 120€**
4. Concept of risk communication throughout modern time	**2h 120€**
5. How do risk perception and risk communication hang together	**2h 120€**
6. Risk perception. How to deal with it in risk communication?	**2h 120€**
1. Communicating emerging safety risks of marketed medicines	**2h 120€**
2. A case study: the pandemic influenza vaccine	**2h 120€**
3. How to measure the effectiveness of risk communication?	**2h 120€**

Medicines Pharmacovigilance and regulatory aspects

Regulations outlines

	Exclusive ISoP Members Fees
1. Pre-marketing pharmacovigilance legislation	**2h 120€**
2. Post-marketing pharmacovigilance legislation	**2h 120€**
3. EudraVigilance & EVMPD	**1,5h 90€**
4. Development Safety Update Report (DSUR)	**1h 60€**
5. International Harmonisation Initiatives	**0,5h**
6. Guidelines for Good Pharmacoepidemiology Practices	**6h 300€**
7. Materiovigilance regulations	**1h 60€**
8. Contractual Agreements in PV	**1,5h 90€**

International regulations

	Exclusive ISoP Members Fees
9. US regulations	**2h 120€**
10. Japanese regulations	**2h 120€**
11. French regulations (in French)	**2h 120€**
12. Canadian regulations	**2h 120€**

European Union regulations

	Exclusive ISoP Members Fees
13. GVP Module I - Pharmacovigilance V Quality Management System	**4h 400€**
14. GVP Module II - Pharmacovigilance System Master File (PSMF)	**2h 120€**
15. GVP Module III - Pharmacovigilance Inspections	**1h 100€**
16. GVP Module IV - Pharmacovigilance Audits	**2h 120€**
17. GVP Module V - Risk Management System	**2h 120€**
18. GVP Module VI - Management and Reporting of Adverse Reactions to Medicinal Products	**4h 400€**
19. GVP Module VII - Periodic Safety Update Report (PSUR)	**3h 180€**
20. GVP Module VIII - Post-Authorisation Safety Studies (PASS)	**4h 400€**
21. GVP Module IX - Signal Management	**1h 100€**
22. GVP Module XVI - Risk Minimisation Measures	**3h 180€**
23. Validation of Computerized systems	**1h**

Pharmacovigilance in practice

	Exclusive ISoP Members Fees
24. Signal detection	**1,5h 90€**
25. Management and reporting of Adverse Drug Reactions (ADR)	**4h 400€**
26. Gestión y Notificación de RAM (in spanish)	**4h 400€**
27. Risk Management Plans (RMP) and European Union regulatory perspective	**2h 120€**
28. Principles of labeling and Summary of Product Characteristics (SmPC)	**3h 180€**
29. Role of the Qualified Person responsible for Pharmacovigilance (QPPV)	**3h 180€**

Pharmacovigilance for Biologics designed for the North American market

	ISoP
30. Vaccines Biologics Regulations	**3h 180€**
31. Gene therapy	**3h 180€**
32. Pharmacovigilance for HCT/Ps	**3h 180€**
33. Targeted Therapeutics	**3h 180€**

The Eu2P certificates catalogue

GAIN UP TO 30% OF SAVINGS!
ISoP Members: from 2,100 € to 3,500 € (instead of ~~3,000€ to 5,000€~~)

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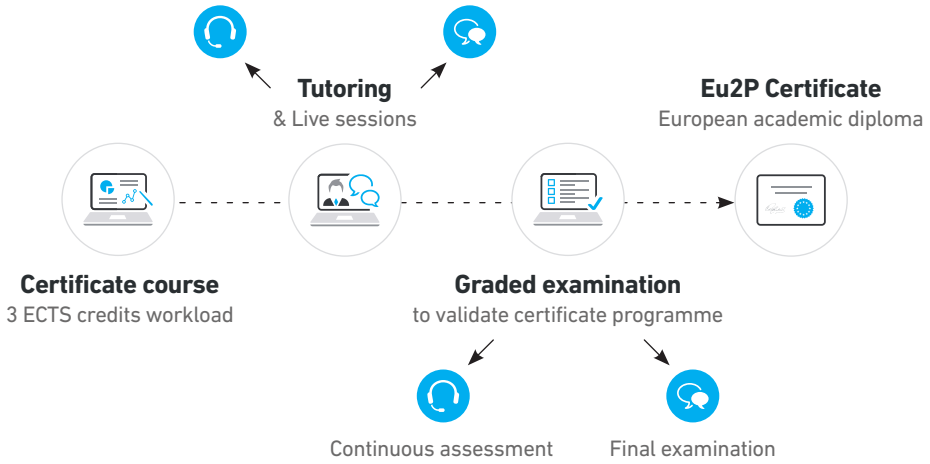

Get an academic Certificate

- 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 **introductory**, **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**.

Apply on-line

Calendar

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

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- **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.

DOMAIN 1: Basics for pharmacovigilance and pharmacoepidemiology

1. Basics in epidemiology

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Descriptive epidemiology (person, place and time)
2. Observational studies in pharmacoepidemiology
3. Biases in pharmacoepidemiology studies
4. Causality criteria, evidence level and critical reading

2. Basics in statistics applied to drug evaluation

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Introduction to statistics and probability
2. Estimates
3. Statistical testing
4. Introduction to multivariable linear regression

3. Valorisation and critical appraisal in research

Over 6 months / 3,500 € for ISoP members

Module parts:

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

Introductory level

DOMAIN 2: Benefit assessment of medicines

1. Basics in clinical pharmacology

Over 3 months / 2,100 € for ISoP members

Module parts:

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

2. Clinical and pharmacological principles

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Patients' therapeutic needs, medicines and society
2. Patients, physicians, information and prescribing
3. Clinical and pharmacological basis of therapeutics
4. Variability in medicines response
5. Therapeutics and medicines prescribing of medicines for selected health problems

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

Over 3 months / 2,100 € for ISoP members

Module parts:

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

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

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Randomised clinical trials limitations
2. Evidence-based medicine and its limitations
3. Critical appraisal of randomised clinical trials limitations
4. Critical appraisal of a meta-analysis of randomised clinical trials
5. From therapeutic uncertainty to a research protocol

Introductory level Intermediate level Advanced course level

DOMAIN 3: Medicines pharmacovigilance and regulatory aspects

1. Principles of pharmacovigilance

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Introduction to Pharmacovigilance principles
2. Safety evaluation during a products lifecycle
3. Labelling and risk management

2. Pharmacovigilance regulations

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Pharmacovigilance regulations: concept
2. The working Pharmacovigilance regulations
3. Other related Pharmacovigilance regulations and guidelines
4. Pharmacovigilance regulations

3. Pharmacovigilance regulatory processes

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Case reporting
2. Periodic reporting
3. Product Labelling and Risk Management Plans
4. Contractual arrangements

Introductory level Intermediate level

DOMAIN 4: Medicines risk identification and quantification

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

Over 3 months / 2,100 € for ISoP members

Module parts:

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

2. Substantiation and quantification of risks

Over 6 months / 3,500 € for ISoP members

Module parts:

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

3. Identifying susceptibility for adverse drug reactions

Over 3 months / 2,100 € for ISoP members

Module parts:

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

Intermediate level Advanced course level

DOMAIN 5: Medicines benefit-risk assessment

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

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Introduction
2. Benefits
3. Risk/Harms
4. Principles and methods of comparative benefit-risk assessment
5. Principles of Pharmacoeconomics

2. Principles of pharmacoeconomics and valuation of health states

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Introduction
2. Costs
3. Effects
4. Pharmacoeconomic analysis
5. How to perform a good pharmacoeconomic evaluation

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

Over 3 months / 2,100 € for ISoP members

Module parts:

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

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

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Multi-criteria decision analysis
2. Conjoint analysis
3. Personalised benefit-risk assessment

Introductory level Intermediate level Advanced course level

DOMAIN 6: Medicines and public health

1. Basics in pharmacoepidemiology

Over 3 months / 2,100 € for ISoP members

Module parts:

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

2. Drug utilisation studies: introduction and quantitative methods

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Measurement of drug use
2. Overview of drug utilisation studies DUS
3. Quantitative measures of drug utilisation
4. Design of quantitative DUS
5. How to read papers on quantitative DUS

3. Drug utilisation studies: qualitative methods

Over 3 months / 2,100 € for ISoP members

Module parts:

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

4. The public health impact of adverse drug reactions

Over 3 months / 2,100 € for ISoP members

Module parts:

1. 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
2. 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
3. Public health impact - Case: Hormone replacement therapy
4. Public health impact beyond case-control studies
5. The importance of the denominator: Case-population studies, the future of pharmacovigilance

DOMAIN 7: Medicines risk communication

1. Basics in medicines risk communication

Over 3 months / 2,100 € for ISoP members

Module parts:

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

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

Over 3 months / 2,100 € for ISoP members

Module parts:

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

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

Over 3 months / 2,100 € for ISoP members

Module parts:

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

4. Case studies in medicines risk communication

Over 3 months / 2,100 € for ISoP members

Module parts:

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

Introductory level Intermediate level Advanced course level

DOMAIN 8: Certificates designed for the North American market

1. Basic Pharmacovigilance and Pharmacovigilance Regulations

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Pharmacovigilance Regulations
2. Labeling and Combination Products
3. Adverse Drug Reporting

2. Pharmacovigilance for Biologics

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Vaccine Pharmacovigilance
2. Gene Therapy
3. Pharmacovigilance for Human Cells, Tissues and Cellular and Tissue-Based Products
4. Targeted therapy

3. External databases - RWD - RWEs

Over 3 months / 2,100 € for ISoP members

Module parts:

1. FDA System
2. Databases

4. Benefit-Risk Assessment

Over 3 months / 2,100 € for ISoP members

Module parts:

1. Benefit-risk assessment of medicines
2. Risk Management

Introductory level Intermediate level

The Eu2P Master programme

GAIN UP TO 20% OF SAVINGS!
ISoP Members: 9,600€ per year (instead of ~~12,000€~~)

For more information, contact **Dr Karine Palin**: eu2p.office@eu2p.org

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, you choose a Master specialisation among 5 domains ; or "A la carte Master" modules to match your 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**.

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 ame for all candidates.

To be eligible, you must:

- **be a verified ISoP member**
- **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**

You are a graduate applicant?

Apply for Master Year 1

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

Research project

30 ECTS credits

Graded examination

The trainee must validate the theoretical and the practical trainings to progress to the 2nd year

- Continuous assessment
- Final examination
- Project presentation

You are a postgraduate applicant?

Apply for Master Year 2

Theoretical courses*

30 ECTS credits

1 Specialised Master OR **2 "A la carte" Master**

1 Specialised Master

- The whole black mandatory modules
- One specialisation track line to choose among:
  - D2: "Benefit assessment of medicines"
  - D4: "Medicines risk identification and quantification"
  - D5: "Medicines benefit-risk assessment"
  - D6: "Medicines and public health"
  - D7: "Medicines risk communication"
- Complementary modules to overall validate 30 ECTS credits

2 "A la carte" Master

- The whole black mandatory modules
- Complementary modules of your choice to overall validate 30 ECTS credits

TRACK D2	Clinical pharmacological principles	Methods in clinical research, PE and in the assessment of efficacy of medicines	Critical appraisal of clinical trials: evidence-based medicine and its uncertainties	
	Pharmacovigilance regulations	Pharmacovigilance regulations processes		
TRACK D4	Principle of identifying and recognising adverse events and safety signals	Substantiation and quantification of risks (1)	Substantiation and quantification of risks (2)	Identifying susceptibility for adverse drug reactions
TRACK D5	Introduction to B/R assessment and pharmacoeconomics in decision making	Principles of pharmacoeconomics and valuation of health states	Fundamentals of quantitative B/R assessment methods in decision making on medicines	Advanced quantitative B/R assessment methods in decision making on medicines
TRACK D6	Drug utlisation studies : introduction and quantitative methods	Drug utilisation studies: qualitative methods	The public health impact of adverse drug reactions	
TRACK D7	Information and communication about B/R of medicines. Basics principles	Key roles and stakeholders in medicine risk communication duties and challenges	Case studies in medicines risk communication	

Research project

30 ECTS credits

Graded examination

The trainee must validate the theoretical and the practical trainings to be awarded

- Continuous assessment
- Final examination
- Project presentation

Eu2P Master of Science degree

120 ECTS credits

*Tutoring

Each course module is tutored

Live sessions ← → Forums

● *Mandatory modules:* 3 ECTS ●● *Complementary modules: 3 ECTS - 6 ECTS* ● *Specialisation track line*