

Title	EU2P European Master Regulations – AS22
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EU2P EUROPEAN MASTER REGULATIONS

SUMMARY OF CHANGES

General changes

A correction has been made to section 3 and Appendices I and II have been updated. Changes include amendments to the modular assessment review.

(Amendments to version 04.0, UPR AS22, are shown in italics.)

Structure

SECTION	TITLE
	EU2P EUROPEAN MASTER REGULATIONS
	APPENDICES:
	APPENDIX I - EU2P EUROPEAN MASTERS REGULATIONS
	APPENDIX II - EU2P EXTERNAL REVIEW OF ASSESSMENT

- 1 The Academic Board of the University of Hertfordshire has approved arrangements and programme-specific regulations for the management and delivery of a programme to be offered jointly with the following members of the EU2P Consortium¹:

University of Hertfordshire, and
Erasmus Universitair Medisch Centrum, Rotterdam and
Universitat Autònoma de Barcelona, Spain, and
Université Victor Segalen Bordeaux (University of Bordeaux), and
Universiteit Utrecht, Netherlands (University of Utrecht), and
the Second Università Degli Studi Di Napoli (UNINA 2), Naples, Italy.
- 2 The programme leads to the following:

'Certificate in Pharmacovigilance and Pharmacoepidemiology'
'Master in Pharmacovigilance and Pharmacoepidemiology'

to be awarded jointly by the Consortium members listed in section 1.
- 3 The regulations referred to in section 1, form part of the University's regulatory framework and are, therefore, part of the UPR series, as Appendix I of this document (UPR AS22).
- 4 Appendix II concerns modular external assessment review.

Sharon Harrison-Barker
Secretary and Registrar
Signed: **24 February 2020**

¹ **Academic Board Minute:** 52.2.3, 15 June 2011, refers (approved by Chairman's Action on 19 July 2011); approved by Chairman's Action on 2 September 2015.
Standing Working Party Minute: 357.4, 7 February 2018

Eu2P MASTER REGULATIONS

INCLUDING THE MASTER TRAINEE'S CODE OF RIGHTS AND OBLIGATIONS

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01- GENERAL PROVISIONS & DEFINITIONS

INTRODUCTION

These Regulations are reviewed annually by the Eu2P Executive Board and should be approved by each Eu2P Academic Partner. The Regulations should be read in conjunction with the guidelines and regulations published by each of the Eu2P Academic Partners specifically those relating to local study, assessment, academic appeals and complaints, as well as with the Eu2P Standard Operating Procedures and the Eu2P Terms of Sales. All Eu2P Master Trainees and trainers are provided with a copy of the Eu2P Master Regulations via their on-line account and each Eu2P Master Trainee is required to endorse on-line such a document before starting the Master training. Trainees, whether in Master year 1 or 2 of the Master programme, are subject to these Regulations, which also detail their rights and obligations once registered on the Master programme.

PURPOSE OF THE MASTER PROGRAMME AND OF THE MASTER REGULATIONS

The purpose of the Eu2P Master programme is to provide Trainees with the specific knowledge, skill and experience required to work in the Pharmacovigilance and Pharmacoepidemiology field. The programme will enable them to conduct scientific work, to critically assess and integrate scientific findings and knowledge, and to act responsibly. In order to achieve the overall intent of the programme, the Eu2P Master Programme benefited from a very close collaboration between academic, regulatory and professional experts to link research and instruction through a network of six universities of high repute (Bordeaux, Barcelona, Rotterdam, Utrecht, Hertfordshire, Verona and Stockholm), two regulatory agencies and fifteen pharmaceutical companies throughout Europe. The purpose of this document is to provide a clear framework of regulation for Eu2P Master Trainees throughout their study at Eu2P. It also enables Trainees to understand how the programme is managed and administered. Regulations make clear minimum requirements and standards for students and staff.

DEFINITIONS

For the purpose of good understanding, the following terms shall have the meaning ascribed to them herein:

- “Academic Advisor” means the member of the Academic Partner who supervises the Trainee’s research project.
- “Academic Misconduct” means any action or attempted action by a Trainee that may result in the creation of an unfair academic advantage or an advantage or disadvantage to another member of the academic community.
- “Cheating” means any attempt by a Trainee to gain an unfair, improper or dishonest advantage in the assessment process.
- “Collusion” means any situation where there is evidence of the representation by a Trainee individual of work which he or she has undertaken jointly with another person as having been undertaken independently of that person
- “Domain” means a set of Modules that are educationally gathered in terms of education field or expertise related to Pharmacovigilance and Pharmacoepidemiology.
- “Domain director” means the representative of an Academic Partner, who is in charge of the consistency of the Modules and the research project general organization within a domain.
- “Domain co-director” means the representative of an Academic Partner or of an Associated Member, supporting the Domain Director in the Modules general organization within a domain.
- “Eu2P General Conditions of Use” means the terms and conditions that bind all users of the Eu2P website.
- “Eu2P Privacy Policy” means the terms and conditions applying to all Eu2P users as regards their rights and obligations towards privacy issues.
- “Eu2P e-learning platform General Conditions of Use” means the terms and conditions that bind all Trainees and trainers when using the Eu2P e-learning platform.

- “Live Teaching Sessions” means the training sessions relating to the theoretical content of the curriculum that are either face-to-face or synchronous sessions on the e-learning platform.
- “Master research project Guidelines” means the common Guidelines set up by the Executive Board and used in Eu2P to provide common rules toward the selection, writing and assessment of the Eu2P Master research project.
- “Module” means a unit of study, which develops a set of one or several learning outcomes through “Training areas”.
- “Module coordinator” means a representative of an Academic Partner designated by the related Domain Director. S/he is responsible for the day-to-day management of a module including all aspects of teaching, learning and assessment.
- “Other Academic Misconduct/Assessment Offences” relates to Evidence that a student failed to comply with an Academic Partner’s assessment and examination regulations, other than those offences falling under the categories of cheating, collusion and plagiarism.
- “Plagiarism” means the misappropriation or use of others ideas, intellectual property or work (written or otherwise) without acknowledgement or permission.
- “Research project Director” means the supervisor appointed within the hosting institution during the research project placement.
- “Student” means a Trainee enrolled in the Eu2P Master programme, who has been enrolled in an academic programme no later than in the last two years preceding her/his application to Eu2P and who is not engaged in a full-time professional occupation.
- “Training area” means a set of one or more “learning paths” that may be composed of teaching, learning and assessment sessions.
- “Track or teaching track” means a speciality (or option) chosen in the second year of the Eu2P Master.
- “Trainee” means the student or professional enrolled into the Eu2P Master programme.

02- MASTER TRAINEE'S REGISTRATION & CURRICULUM

ADMISSION AND REGISTRATION

All the rules and procedures concerning selection and admission to the Eu2P Master programme are defined under “the Eu2P Terms of Sales” and have been acknowledged by the applicant when validating the on-line application.

They are part of the present Master Regulations and are binding upon the parties in case of any conflict arising because of the selection and / or admission process.

Once selected by the Executive Board and payment of the annual Master fees is secured the Trainee is registered by the Eu2P Central Office.

The Eu2P central office forwards all necessary information for registration to take place in each Eu2P Academic Partner.

The Eu2P central office provides the Trainee with the Eu2P ISIC student card (International Student Identity Card).

Registration as a Eu2P Master Trainee entitles students to participate in Modules (either face-to-face or by e-learning), sit examinations within the chosen study programme and to use the different Eu2P universities' facilities.

If the Trainee is withdrawn from the Eu2P Master programme during the course of the academic year, they will not receive any refund of tuition fees.

STANDARD PERIOD OF STUDY

The standard period of study including the Master's assessment process is normally two years.

- The standard period of study for 60 ECTS credits is one academic year (one standard academic year runs from the last week of September to the first week of July),
- Such annual standard period may be extended to two academic years,
- Such annual standard period may be extended by the Eu2P Programme Examination Board taking into account exceptional circumstances duly evidenced by the Trainee (e.g. long illness)

The Executive Board defines each year the Eu2P programme calendar to detail the different training, holidays, revision, assessment, re-assessment and project research periods.

Eu2P reserves the right to alter the agenda of any training due to circumstances beyond its control without being obliged to refund Trainees. All trainees will be consulted about any material change at the earliest opportunity.

In exceptional circumstances, training can be cancelled or postponed by the trainers. In these circumstances Eu2P will use reasonable endeavours to notify Trainees of the cancellation or postponement of training. However, Eu2P cannot guarantee that Trainees will be informed of such cancellation before the date of the training.

ECTS CREDITS VALUE

ECTS credits means European Credit Transfer and Accumulation System (ECTS) credits. It is a European academic standard for comparing the study attainment and performance of Trainees of higher education across the European Union. For successfully completed trainings, ECTS credits are awarded with the view of obtaining a qualification. In the Eu2P Master programme, one ECTS credit represents 25 hours of Trainee's workload.

TRAINING ATTENDANCE

For all Trainees, attendance of at least eighty per cent of the Eu2P Live Teaching Sessions for the theoretical part and during the research project placement period is required for graduation. Such attendance requirement may be fulfilled using recorded teaching sessions facilities.

Upon request, a dispensation from the attendance requirement may be granted at the discretion of the Domain Director for up to 20% of the Live Teaching Sessions. Any absence beyond 20% should be a matter of discussion for the Programme Examination Board. The Trainee shall present her/ his request by a formal letter explaining the reasons under which s/he claims for dispensation: the letter shall need to be addressed to the Domain Director involved in the dispensation request. In the event that the Trainee does not meet the attendance requirement for the programme and no serious adverse circumstances exists, the Programme Examination Board may at their discretion withdraw the Trainee from her/his programme of study.

For Trainees benefiting from a Eu2P grant for tuition fees, attendance to all Live Teaching Sessions is compulsory. All absences must be justified. Absences amounting to more than ten per cent of the Live Teaching Sessions may entail the full or partial withdrawal of the grant, according to the decision taken by the Executive Board.

THEORETICAL TRAINING

The theoretical training is composed of face-to-face training and web-based training.

FACE-TO-FACE TRAINING

The only face-to-face training session organized during the Eu2P Master curriculum is the Fresher's week. It is a training session that happens at the beginning of each Master year to have the opportunity to meet all Eu2P Trainees and main lecturers. Especially, the Freshers' week introduces the Trainee to the programme structure and use of the e-learning platform. Each domain lecturers' team provides face-to-face lectures for half a day to introduce the modules' contents and related learning objectives. The Freshers' week takes place in the last week of September for three days in a European location. This location is confirmed by the Eu2P central office to the Trainees by the third week of July.

Each enrolled Master Trainee should participate in the Freshers' week. If it is not possible for a Trainee to attend, the Trainee should access all the Freshers' week training materials made available through the e-learning platform including any web based resource material.

WEB-BASED TRAINING

Eu2P provides its theoretical training content through a web-based learning management system called the Eu2P e-learning platform. All theoretical training material will be made available to the Trainee through that platform. However, due to the specificity of the e-learning format, the Trainee does not have any guarantee on the training (live sessions) availability in areas with time zone different from the GMT one.

Each Trainee is identified and is granted rights to access the Eu2P e-learning platform tools and resources.

Trainees are reminded that minimal IT skills and equipment are required for use of the Eu2P e-learning platform. Non-complying with any of the criteria relating to broadband access, IT equipment and to an efficient web browser could lead to user experience problem that would not be under Eu2P responsibility.

Trainee's services within the platform include:

- Access to training resources (course content, documents, tests, work assignments, revising resources such as recorded video lessons)
- Training sessions attendance (web meeting, chat or voice over IP conference)
- Training contents sharing with trainers (work assignments) and other Trainees (group work)
- Interaction with trainers and other Trainees (forum, chat, conference meeting)
- Monitoring of personal progression and test scores
- Information about course events (platform announcements, agenda, email alerts)
- Feedback about courses (course survey)
- User support from the e-learning platform team

Trainee's coaching within the platform is provided through:

- Trainer teams
- Lecturers who provide online courses and can daily interact with their Trainees and evaluate their learning competencies on-line
- Facilitators who coach Trainees throughout the e-learning part of their training programme
- Administrative staff who communicate with trainers and Trainees to inform them about course programme events and course schedule via email or an internal agenda
- Technical & support staff who train and help platform users in their activities within the e-learning platform

PRACTICAL TRAINING

Each Master Trainee must conduct a research project in parallel to the theoretical training along the academic year.

OBJECTIVES OF THE MASTER RESEARCH PROJECT

The objectives of the Master research project are:

- To provide the Trainee with an opportunity to use her/his academic and/or professional knowledge and skills,
- To apply theories of the field of the Master specialisation, if any, in real-life settings,
- To demonstrate the Trainee's ability to carry out a defined task, solve it in a set period of time and adequately report the results of this work in a written report and in an oral presentation.

IDENTIFICATION AND SELECTION OF THE MASTER RESEARCH PROJECT

To conduct their Master research project, Trainees are placed in a host organization that may be part of the Eu2P Consortium or be external to the Eu2P Consortium. The research project period has a workload corresponding to 30 ECTS credits.

Following her/his Master registration, the Eu2P Trainee has to search and select a placement to enable them to conduct their research project. In cases of difficulty the Eu2P Master Consortium may support the trainee in finding a placement: the Eu2P offers may come from Eu2P partners as well as from other partners as soon as their capacity to direct research project is recognized by the Eu2P Executive Board. In particular, the potential Research Project Director should have a postgraduate degree in the field as well as an experience in research project tutoring and supervision.

The Trainee has to communicate with her/his future Research Project Director, belonging to the host institution, in order to complete a standardized and concise "Master research project synopsis". This Master research project synopsis indicates the following information: title, location, duration, name of the Research Project Director, summary of objectives, methods and expected participation of the

Trainee. A template of the Master research project synopsis is provided by the Eu2P central office.

The Master research project synopsis has to be sent to the Eu2P central office. The Executive Board will then nominate the Academic Advisors for all Master research projects.

SUPERVISION OF THE MASTER RESEARCH PROJECT

The Eu2P Executive Board validates:

- The Master research project synopsis,
- The Research project director,
- The Research project host institution,

Then the Executive Board designates the Eu2P Domain related to the Master research project field in order to nominate an Academic Advisor and Institution responsible for the project research.

In the event that the research project takes place in the academic institution of the Research Project Director, the latter may also serve as the Academic Advisor.

The Research Project Director has:

- To provide the Trainee with the resources to be successful in her/his mission
- To inform the Trainee of the rules, codes and culture of the Research project host institution including protocol for ethical approval
- To enable the Trainee's integration into the Research project host institution and provide access to necessary information
- To advise on and approve the research project outline
- To monitor the Trainee's work regularly and to be accessible to the Trainee
- To advise on the organisation of the project research work and methodology to be used
- To comment on draft and advise on the final form of the written research project report
- To advise the Trainee on the preparation of the research project oral defence

- To assess the scientific and methodological quality of the work done
- To advise the Trainee with respect to her/his professional project.

The Trainee has:

- To be present at the Research project host institution during the research project placement period. In some exceptional cases however the Trainee may not be physically present at the Research project host institution: in such cases, the Trainee shall be supervised on a distant basis.
- To respect the discipline and rules of the Research project host institution, in particular with respect to working times and health, ethical approval and safety rules in force within the institution
- To maintain progress in accordance with the agreed schedule of work, including completion of any written work and the attendance of any scheduled live session
- To decide when the standard of the report is sufficient to submit for assessment
- To comply with the Master research project guidelines provided by the Eu2P central office.

The Academic Advisor has:

- To agree on the research project synopsis
- To advise on any problem that may occur between the Trainee and the Research project director
- To advise on any methodological problem that the Trainee may face during his/ her research project work.

To assess the scientific and methodological quality of the work done

RESEARCH PROJECT AGREEMENT

A research project agreement is then established between:

- The Trainee
- The Research Project Director
- The legal representative of the Research Project Director institution, if different from the legal representative of the Academic Advisor institution
- The Academic Advisor belonging to the related Domain team
- The legal representative of the Academic Advisor institution

The research project agreement should indicate clearly:

- The expected learning outcomes and the related number of ECTS credits
- The location of the research project placement
- The period of the placement
- The synopsis of the research project
- The Trainee's rights and duties, and in particular, the confidentiality rules and ethical approval regulations to be followed by the Trainee at the research project placement

The template of the Research project agreement is provided by the Academic Advisor institution.

A copy of the Research project agreement signed by all the parties must be sent to the Eu2P central office.

MASTER RESEARCH PROJECT GUIDELINES

The Master research project guidelines are provided to the Trainee by the Eu2P central office. These guidelines are set up and regularly updated by the Eu2P Executive Board.

The Master research project guidelines provide detailed information on:

- The general learning outcomes related to practical training
- The structure and format of the research project written report
- The structure and format of the research project oral defence
- The grading criteria used in relation to the expected Module learning outcomes and who is responsible for this, i.e. the roles of the Academic Advisor and of the Research Project Director
- The calendar of the periods of submission and review of the written report
- The calendar and organisation of the periods of research project oral defence

03- MASTER TRAINEE'S ASSESSMENT

The Master's assessment process leads to the award of the Eu2P Master degree in Pharmacovigilance and Pharmacoepidemiology. The aim is to determine whether the Trainee has a fundamental understanding and mastering of her/his field of study, has the ability to apply scientific methods and findings and has acquired the specialised knowledge necessary for practising in the professional environment. The Eu2P Master assessment rules are described in the following sections. In case of change in the Eu2P Master assessment policy, the Regulations will be accordingly updated for the following academic year.

GENERAL RULES

The Eu2P Master assessment process encompasses grade-based and pass / fail assessment and a research project defence for each year of study.

Module-specific assessment and research project work is organised along the course of study and should be completed within the standard annual period of study.

All Module-specific assessment and research project reports/oral presentations are conducted in English.

The Module assessment format is determined in advance by the Module coordinator: it can be written or oral through computer-based procedures.

The grade for each Module assessment is determined by the respective Module coordinator, based on her/his local grading system.

Local grades are then:

- Converted into the Eu2P ECTS grading system according to the following table approved each year by the Eu2P Programme Examination Board.
- Only the first decimal place after the decimal is used when calculating the grades; all further decimal places are dropped without rounding off.

For the 2017-2018 academic year, the Eu2P grading table is as follows:

Eu2P grades translation		Université de Bordeaux	University of Hertfordshire	Universiteit Utrecht	Erasmus Universiteit Medisch Centrum Rotterdam	Universitat Autònoma de Barcelona	Università degli Studi della Campania Luigi Vanvitelli
A+	Excellent	16,0 - 20	80 - 100	8,5 - 10	8,5 - 10	8,0 - 10	29 - 30 lode
A	Very Good	14,0 – 15,9	70 - 79	7,5 - 8,4	7,5 - 8,4	7,0 - 7,9	27 - 28
B	Good	12,0 – 13,9	60 - 69	7,0 - 7,4	7,0 - 7,4	5,6 - 6,9	23 - 26
C	Pass	10,0 – 11,9	50 - 59	5,5 - 6,9	5,5 - 6,9	5,0 - 5,5	18 - 22
F	Fail	0 - 9,9	0 - 49	0 - 5,4	0 - 5,4	0 - 4,9	0 - 17

The Programme Examination Board regularly reviews the assessment process and at least once a year within the deadline fixed by the annual Eu2P calendar.

The Trainee is informed by the Eu2P central office of the grades earned in individual Modules.

The Trainee may repeat Eu2P specific Modules assessments s/he failed, according to the respective Module Coordinator University rules as described in the section “Repeating the Master assessment process”.

MASTER YEAR 1 GRADE

The Eu2P Master year 1 grades are obtained following the Modules and the research project assessment.

The Trainee has to pass all Modules s/he was enrolled on under the following conditions:

- Each Module assessment has to be passed i.e. obtain a minimum of “pass”
- No compensation between Modules is permitted
- The trainee has to obtain a minimum average grade of “pass” for the research project assessment (cf. Research Project Assessment hereunder)
- The trainee has to satisfy the minimum attendance requirements for all Master year 1 modules.

The Trainee has satisfied the requirements for the Eu2P Master year 1 assessment process when s/he has obtained a pass in theoretical and practical training assessments, met all attendance requirements and accrued 60 ECTS credits.

The successful first year Trainee is then allowed by the Eu2P Programme Examination Board to enter the second year of the Master.

MASTER YEAR 2 GRADE

The overall Master year 2 grades are obtained following the Modules and the research project assessment.

The Trainee has to pass all Modules s/he was enrolled on, under the following conditions:

- Mandatory Modules i.e. the first six mandatory theoretical modules and the modules chosen by the Trainee according to the selected track: need to be successful in each mandatory Module assessment i.e. obtain a minimum of “pass” - no compensation between mandatory Modules is permitted
- Complementary Modules i.e. the remaining theoretical modules chosen by the Trainee: need to be successful in each Module assessment i.e. obtain a minimum of “pass” - no compensation between complementary Modules is permitted
- The trainee needs to obtain a minimum average grade of “pass” for the research project assessment (cf. Research Project Assessment hereunder)
- The trainee has to satisfy the minimum attendance requirements for all Master year 2 modules.

The Trainee has satisfied the requirements for the Eu2P Master year-2 assessment process when s/he has obtained a pass in theoretical and practical training assessments, met all attendance requirements and accrued 120 ECTS.

The successful second year Trainee is then conferred with the Eu2P Master degree by the Eu2P Programme Examination Board.

RESEARCH PROJECT ASSESSMENT

The research project work is assessed according to the Master research project Guidelines that are set up and regularly updated by the Eu2P Executive Board.

The Trainee must submit her/his report within the deadline annually set up by the Executive Board and which is communicated to her/him through the Eu2P central office.

It is the Trainee's responsibility to decide after consultation with the Research Project Director whether the standard of the report is sufficient to submit for assessment. The Research Project Director's approval of the final form of the submission should not be taken as an indication of the outcome of the assessment and may not form the basis of an appeal.

The Trainee must orally defend her/his report either face-to-face or using videoconference facilities, according to the oral defence calendar that is communicated by the Eu2P central office no later than two weeks before the fixed date.

For the research project assessment, the members of Eu2P Executive Board who are involved in the project via the Academic Advisory roles appoint two experts ("The Examiners"). One of the Examiners should belong to the Eu2P Consortium but distinct from the Academic Advisor. The Examiners should reflect the public-private partnership of the Eu2P Consortium.

The research project assessment grade is the average of the three following grades, each component of which has to achieve a minimum pass grade:

- One grade relates to the research project written report (Master Thesis).
 - Each of the two Examiners gives one grade. The average of these two grades weights 40% of the global research project grade.
- One grade relates to the research project oral defence.
 - Each of the two Examiners gives one grade. The average of these two grades weights 40% of the global research project grade.
- One grade relates to the overall research project appraisal.
- The research project Director and by the Academic Advisor give one grade each. The average of these two grades weights 20% of the global research project grade.

In the event that the Director and/ or the Academic Advisor is in the impossibility to give his/ her appraisal grade, the Eu2P Programme Examination Board delegates the Eu2P Central office to organise an alternative grading process, by contacting the closest professional colleague of the missing evaluator.

FAILURE IN THE EU2P MASTER ASSESSMENT PROCESS

EU2P REFERRAL AND RE-ENROLMENT OPPORTUNITY POLICY

Referral is defined as a reassessment opportunity for Trainees who have been unsuccessful at their first attempt (that is, trainees who have received an F grade).

Such re-assessment possibilities must however take place within the relevant Module Coordinator University calendar and the common calendar deadline set up in the annual Eu2P calendar.

- Trainees who are successful in referred assessment(s) will be awarded a capped module grade of 50%, a C Pass Grade.
- Trainees who are unsuccessful in a referred assessment (that is, at second attempt) will not be given further opportunity to submit for assessment. If they are unsuccessful in a referred assessment they will be given the opportunity to re-enrol on that module.

Re-enrolment is defined as the opportunity for a Trainee to repeat a module that was previously failed at first and second attempt. In offering re-enrolment, the Eu2P Programme Board considers that the Trainee requires substantial further study in the module and that it is normal for that Trainee to repeat all assessment elements, irrespective of his or her overall performance.

In cases where the Eu2P Programme Examination Board decides that it is not a requirement to repeat all assessment elements, it will, in consultation with the relevant Module Coordinator identify the elements to be repeated.

Following re-enrolment on any module, the numeric grade(s) awarded will be those actually achieved in the assessment.

RESEARCH PROJECT ASSESSMENT

The Trainee may be proposed to rewrite her/his research project report and/or to present a second oral defence of her/his work if s/he has not succeeded in obtaining an overall grade of pass for the research project assessment.

Such re-assessment possibilities must however take place within the common calendar deadline set up in the annual Eu2P calendar.

The grade of the re-assessed project is capped at the pass mark.

04- ACADEMIC MISCONDUCT

(Based on previous Eu2P Regulations, the Education and Examination Regulations of the Pharmaceutical Sciences Department of Utrecht University, the University of Hertfordshire Assessment and Examinations rules)

DEFINITIONS

As a common rule among the Academic Partners, Academic Misconduct is defined as any action or attempted action by a Trainee that may result in the creation of an unfair academic advantage or an advantage or disadvantage to another member of the academic community. More particularly and for the purpose of these Eu2P Regulations, the following definitions will apply:

CHEATING

This is an attempt to gain an unfair, improper or dishonest advantage in the assessment process where on the balance of probability it could reasonably be construed that a Trainee intended to gain an unfair, improper or dishonest advantage.

Cheating includes:

- Impersonation - either where a Trainee allows any other person to take an assessment on their behalf or to present themselves as being that student or where a current Trainee takes an assessment on behalf of another Trainee;
- Obtaining or attempting to obtain unauthorised access to examination papers;
- The copying of, or attempting to copy, the work of another candidate in the examination or other in class assessment, whether by getting access to what he or she has written or is writing or by asking him or her for information in whatever form;
- The use of aids including internet search, papers, books, notes, personal notes or revision notes in any form, or other devices of any kind other than those permitted in the instructions of the

examination paper, with the intention of using such item or, in fact, using such item. This includes, for example, unauthorised information stored in the memory of a pocket calculator, mobile telephone, computer, personal organiser or any other device;

- Requesting a temporary absence from an examination room (or any other room in which a formal assessment is taking place) with the intention of gaining, or attempting to gain, access to information that may be relevant to a formal assessment;
- False statements made in order to receive special considerations by the Eu2P Programme Examination Board or to obtain extensions to deadlines or exemption from work;
- Assisting or attempting to assist another Trainee to gain or attempt to gain an unfair, improper, or dishonest advantage in the assessment process;
- The purchase or theft of material submitted for assessment.

COLLUSION

This covers the following situations:

Where there is evidence of the representation by a Trainee individual of work, which he or she has undertaken jointly with another person as having been undertaken independently of that person.

OTHER ACADEMIC MISCONDUCT AND OFFENCES

This covers the following situations:

Where there is evidence that a Trainee failed to comply with one Eu2P Academic Partner assessment and examination regulations, other than those offences falling under the sections relating to cheating, collusion, plagiarism and includes:

- The falsification of data including the creation of false written materials or statistical data or its alteration, for example, by the invention of the statistics presented or the invention of quotations or references;
- The duplication of assessed work – the submission of broadly similar work completed by the Trainee for academic credit as part of the same programme without express acknowledgement of the previous submission;
- The removal of an examination script or examination stationery or other materials from the examination room (or any other room in which a formal assessment is taking place);
- Failure to comply with the instructions of an invigilator;
- The introduction into the examination room of any personal notes or revision notes in any form or stationery;
- Permitting or assisting another to present work that has been copied or paraphrased from Trainee's own work without attribution or as if it were the work of the other;
- Breach of professional confidentiality;
- Failure to obtain ethics approval prior to undertaking work involving human participants;
- Failure to comply with the terms and conditions of an ethics approval granted for work involving human participants.

PLAGIARISM

This is the representation by an individual of another person's work (including another student) as their own or use of another person's work without acknowledgement including:

- The importing of phrases from another person's work without using quotation marks and identifying the source;
- Making a copy of all or part of another person's work and presenting it as the Trainee's own work by failure to disclose the source;
- Without acknowledgement of the source, making extensive use of another person's work, either by summarising or paraphrasing the work merely by changing a few words or by altering the order in which the material is presented; paraphrasing must be marked as such (by explicitly linking the text with the original author, either in text or a footnote), whereby the impression is not created that the ideas expressed are those of the Trainee;
- The use of the ideas of another person without acknowledgement of the source or the presentation of work which substantially comprises the ideas of another person and which represents these as being the ideas of the candidate;
- Resubmission of the Trainee's own earlier work without source references, and allowing this to pass for work originally produced for the purpose of the course, unless this is expressly permitted in the course or by the lecturer;
- Submitting papers obtained from a commercial institution (such as an internet site offering excerpts or papers) or having such written by someone else in return for payment.

CONSEQUENCES OF ACADEMIC MISCONDUCT

Allegations of cheating, plagiarism, collusion and other academic misconduct as defined in the Eu2P Master Regulations should be made, in writing, by the respective examiner or Module coordinator to the appropriate person in the partner organisation where the module is delivered.

Similarly, allegations of such academic misconduct in the course of the research project work (from the synopsis writing phase, to the oral defence) through deception or the use of inadmissible materials or aids (e.g. Fraud, Plagiarism), shall be made in writing, by the examiner or the Academic Advisor to the appropriate person in the partner organisation of the Eu2P Academic Advisor's institution.

An investigation will be carried out in accordance with local partner regulations using the Eu2P Report Template for the Reporting of Assessment Offences –. The Eu2P Programme Examination will on completion submit the Report with recommended action to the Chair of the Eu2P Programme Examination Board for consideration.

The Board at their absolute discretion will impose one of the academic penalties identified as follows from minor to major penalty:

1. No penalty – Grade awarded remains
2. Written Warning
3. Award of an F Grade - Fail allowing a referral opportunity
4. Award of an F Grade - Fail but no referral opportunity. The student has to repeat the Module(s)
5. Withdraw from Programme

In all assessment offence cases, the following indicators of seriousness should be taken into account by the Board when deciding on an appropriate academic penalty.

In the cases of **plagiarism** whether

- There is a similarity index of 10% or more, excluding citations and bibliography
- The plagiarism is verbatim copying or highly derivative*;
- The assessment is highly derivative* without any referencing or whether it is highly derivative but mainly footnoted or acknowledged in the bibliography;
- The plagiarised parts are dispersed throughout the assessment or are in one section;
- Analytical content/academic opinion has been plagiarised or is whether the plagiarised section(s) purely descriptive;
- The conclusion has been plagiarised;
- The Trainee admits or denies the offence;
- There have been any previous offences

* In relation to plagiarism, the term highly derivative assumes the source(s) are used verbatim or closely paraphrased.

In the cases of **collusion**, consideration should be given to

- The instructions given to the Trainees – did the assessment involve any initial element of group/collaborative work;
- Whether there appears to be collusion in relation to more than 10% of the assessment material;
- Similarity of wording;
- Whether the structure of the answer is the same/similar;
- Whether the development of the argument/ critical content is very similar;
- Whether the conclusion is very similar;
- Whether the student admits or denies the offence;
- The number of previous offences.

Plagiarism / collusion will be deemed to amount to cheating where the Trainee has bought or stolen an answer, including buying or stealing an answer from a fellow or former student.

In the cases of **cheating** consideration should be given to

- The seriousness of the offence.
- The number of previous offences
- The extent of the advantage gained
- Whether the student admits or denies the case

In the event that cheating is found proven the minimum penalty would be a fail grade in the particular assessment.

05- EXTENSION OF AN ASSESSMENT PERIOD

EXTENSION OF AN ASSESSMENT PERIOD

A Trainee may be permitted an extension to an assessment deadline, at the discretion of the relevant Module coordinator according to the local rules of the Academic Partner.

Where the Module coordinator is satisfied that the conditions required in his local University Regulations have been met, a new submission deadline will be set and as long as such re-assessment takes place within the annual Eu2P calendar.

A Trainee who fails to submit material for assessment by the deadline without an extension according to the Module coordinator's local rules will be regarded as having attempted the examination, and will be awarded a grade in accordance with the Academic Partner regulations for that examination or other type of assessment.

Such a Trainee may, at the discretion of the relevant board of examiners or in some Eu2P Academic Partners' institution, the Module Coordinator be permitted to attempt the examination again or be granted a retrospective extension to the assessment deadline if the regulations in place in his local University for the programme permit such reassessment or deadline extension and as long as such re-assessment takes place within the annual Eu2P calendar.

SPECIFIC RULES FOR EXTENSION OF RESEARCH PROJECT REPORT SUBMISSION AND ORAL DEFENCE

A Trainee may be granted an extension to the research project report (whether in Master year 1 and in Master year 2) submission deadline, at the discretion of the relevant Academic Advisor and of the Research Project Director, upon receipt of a letter in which the Trainee cites reasons and provides independent evidence that would justify an extension (e.g. for illness or other good cause) and as long as such re-assessment possibility takes place within the annual Eu2P calendar.

The Trainee who fails to submit her/his Research project report or submits it after the deadline and has not made a request for an extension as described above, will receive a grade in accordance with the Academic Partner regulations for that assessment. Such a Trainee may, at the discretion of the relevant Academic Advisor and the Research Project Director or the Academic Partner Module board of examiners, be permitted to attempt the assessment again as long as such re-assessment possibility fits within the annual Eu2P calendar. A Trainee may be granted an extension to the research project report oral defence deadline, at the discretion of the relevant Academic Advisor and the Research Project Director, upon receipt of a letter in which the Trainee cites reasons and provides independent evidence that would justify an extension (e.g. for illness or other good cause) and as long as such re-assessment possibility fits within the annual Eu2P calendar.

The Trainee who fails to defend her/his Research project report within the set deadline and has not been granted an extension as described above, will receive a grade in accordance with the Academic Partner regulations for that assessment. Such a Trainee may, at the discretion of the relevant Academic Advisor and the Research Project Director or the Academic Partner Module board of examiners, be permitted to attempt the assessment again as long as such re-assessment possibility fits within the annual Eu2P calendar.

06- MASTER DIPLOMA AWARD

GRANTING OF ECTS CREDITS

The granting of the credits corresponds to the various components of the Master programme and is conditional on success in the related Modules and research project assessments.

AWARD OF THE JOINT DEGREE

The Trainee admitted into the Eu2P Master and having successfully completed the Master assessment requirements, i.e. when s/he has obtained a pass in theoretical and practical training assessments (120 ECTS credits) and satisfied all attendance requirements, shall be awarded a joint Master degree from the Eu2P Academic Partners. The Trainee who does not meet these requirements will receive a certificate of attendance.

The Trainee is awarded a Master of Science degree "with distinction" if s/he has met all following requirements:

- The Trainee must only have grades A and B
- The Trainee must have passed all the assessments without any retake
- The Trainee must have at least 80% of grades A.
- The Trainee must have passed the Research Project Assessment with an A+ level.

The Trainee is awarded a Master of Science degree "with commendation" if s/he has met all following requirements:

- The Trainee must have passed all the assessments without any retake
- The Trainee must have at least 80% of grades B or above.
- The Trainee must have passed the Research Project Assessment with an A level.

The Eu2P Master Consortium aim is to deliver a unique joint Master degree and a diploma supplement. Such a joint degree is recognised in each of the issuing Eu2P Academic Partners countries with the same validity as has a local national Master degree, following completion of all recognition & accreditation processes in each of countries involved.

The Eu2P joint degree award is made under the individual legal responsibility of the signing Eu2P Academic Partners. The joint diploma is printed and issued by the Université de Bordeaux. It is signed by all Eu2P Academic Partners Presidents / Rectors or equivalent, and include the logos of all Eu2P Academic Partners. The title of the degree is the following: “Master of Science in Pharmacovigilance and Pharmacoepidemiology”.

AWARD OF A CERTIFICATE

The successful Master Trainee shall be sent a certificate by the Eu2P central office within two months of the Programme Examination Board meeting stating the overall assessment results.

EUROPEAN DIPLOMA SUPPLEMENT

A European Diploma Supplement (DS) in English is delivered to the successful Eu2P Trainee to improve international transparency and facilitate the academic and professional recognition of qualifications. The DS corresponds to the standard European document issued alongside the Master degree diploma to provide a detailed description of the qualification.

This document should be distributed to the successful Trainee following the decision of the Eu2P Programme Examination Board. Information dealing with programme details and results obtained include ECTS credits and provide a detailed description of the qualification, mobility, and research project periods and recognises the achievement of the joint Eu2P award.

REVOCATION OF THE MASTER'S DEGREE

Should it be confirmed by a Partner after the publication of results that a Trainee has committed an assessment offence on an examination or her/his research project report, the Programme Examination Board will need to review in the light of the evidence submitted the original decision made.

Prior to taking its decision, the Programme Examination Board shall give the particular Trainee an opportunity to present in writing her/his case to the Chair of the Board.

If the case is found proven, the Programme Examination Board reserves the right to withdraw an award from any of its graduates. The grounds for such action might include, but are not necessarily limited to the following: an assessment offence; a Trainee's behaviour that would devalue the nature of the award or otherwise discredit the whole Eu2P programme.

07- MASTER TRAINEE'S OBLIGATIONS

GENERAL POINTS

The Eu2P Trainee has certain obligations in addition to those derived from her/his registration at the different universities partners of the Eu2P Master Consortium.

Registration imposes the following obligations:

- The Trainee must actively participate in the courses, submit in a timely manner any assigned homework and fulfil at their best ability the examination requests, respecting academic honesty and integrity.
- In particular, and concerning academic integrity and honesty standards, the Trainee must not cheat nor indulge in cheating, collusion, and /or plagiarism (i.e. submitting an assignment that contains work that is not the Trainee's one, without indicating the correct sources of such parts).
- The Trainee must comply with the general standards and rules of decency and respect when interacting with fellow Trainees or members of Eu2P Master Consortium, or when using any of the Eu2P universities' facilities. Unacceptable behaviour includes, but is not limited to, sexual harassment and intimidation, aggression and violence, discrimination.
- The Trainee must follow instructions and rules of her/his trainers. In particular, Eu2P reserves the right to refuse admission or to require a Trainee to leave a face-to-face training or a live training sessions on the e-learning platform if her/his behaviour is considered disruptive, likely to cause damage, nuisance, offence or injury, or is otherwise unacceptable. Eu2P may on occasion have to conduct security searches to ensure the safety of Trainees and the venue. The unauthorised use of photographic and recording equipment is prohibited. Mobile phones must be switched off during a face-to-face or during a live training.

- Face-to-face trainings may be filmed by Eu2P. Trainees attending a face-to-face training consent to filming and sound recording as members of the audience. These recordings may be distributed to the public via on-demand video archives on the Eu2P website.
- When on site of one of the Eu2P Academic Partners, the Trainee must follow the rules of such university, in particular those relating to the management and care of university facilities and buildings.
- When the Trainee is convened for a face-to-face examination by a given Module coordinator, such Trainee must follow the examination rules set out by the Academic Partner to which the Module coordinator belongs (in particular rules on ID proof, conduct during examination session, use of documentation, cheating)
- When the Trainee is convened for an on-line examination by a given Module coordinator, such Trainee must follow the examination rules set out by the Module coordinator.
- When on research project placement, the Trainee must follow the rules of the Host institution, must comply with the Master research project Guidelines and with the research project agreement terms.
- The Trainee must follow regulations displayed on the Eu2P e-learning platform concerning the responsible use of IT resources, and also strive to prevent nuisance from undesired use of these facilities. In particular, the Trainee must comply with the Eu2P e-learning platform General Conditions of Use and the Eu2P Privacy Policy.
- In addition, study programme-specific codes of conduct may apply, for example in relation to dealing with patient data. The related module coordinator will inform the Trainee of this.

TRAINEE' S PERSONAL EXPENSES

TRAINING MATERIAL EXPENSES

The Eu2P training programme extensively uses web-based tools and communication technologies. Therefore, each Trainee must be equipped with computer equipment and Internet access.

LIVING EXPENSES

During the Eu2P training, the Trainee must ensure that s/he has adequate funds to cover her/his living expenses.

The Trainee needs to budget for the academic year the following potential expenses:

- Accommodation
- Utility bills (Gas, electricity and water, telephone, internet and mobile)
- Food
- General living costs (clothes, books, insurance, networking, socialising, ground transportation, etc.)

TRAVEL EXPENSES

Eu2P Module examination may require additional travel expenses.

During the Master programme, Trainees are invited to attend face-to-face meetings during the Freshers' week, in a European location. Travel related expenses must be borne by each Trainee.

SOCIAL SECURITY & HEALTH INSURANCE OBLIGATIONS

Concerning social security & health insurance, the Trainee enrolled in the Eu2P Master shall be informed by the Eu2P central office that s/he is required to follow the rules in force at the hosting institution for the research project and subscribe to a personal insurance.

Each Eu2P Academic Partner undertakes to provide appropriate information to the Trainee for her/his registration in the national health system or for the provision of other kinds of health insurance that may be required either before her/his arrival at the hosting institution.

08- MASTER TRAINEE'S RIGHTS

GENERAL POINTS

The Eu2P Trainee has certain rights in addition to those derived from her/his registration at the different universities members of the Eu2P Master Consortium.

Registration will confer the following rights:

- The Trainee has a right to:
 - Participate in courses within the chosen study programme
 - Support and assistance from Eu2P training teams
 - Academic freedom and autonomy in her/his intellectual pursuits and interests
 - Be treated with courtesy and respect.
- The Trainee has a right to reasonable notice of the general content of the course; however, due to the specificity of the e-learning format, the Trainee does not have any guarantee on the training (live sessions) availability in any area with time zone different from the GMT one.
- The Trainee has a right to reasonable notice of what will be required of her/him, and the criteria upon which her/his performance will be evaluated. The Trainee has a right to have her/his performance evaluated promptly, conscientiously, and without prejudice or favouritism.
- The Trainee has a right to participate in Eu2P aspects affecting Trainees' affairs through Trainees' feedback and membership on appropriate meetings of the Eu2P Executive Board.
- The Trainee has a right to perform a student course evaluation by way of an online survey.
- The Trainee has a right to submit a complaint to the relevant Academic Partner if they feel they are not treated reasonably and in accordance with the local Academic Partner's by a member of Eu2P faculty or if disagreeing with a decision as described in the section 09.

- The Trainee has a right to be free from illegal discrimination and sexual harassment.
- The Trainee has a right to benefit from reasonable disability-related arrangements as specified in an agreed study needs agreement and support related to a potential disability situation both during the admission process and his/her period of study within Eu2P.
- The Trainee has a right to examine and communicate ideas by any lawful means but within lawful parameters.
- The Trainee has a right to privacy and confidentiality subject to the Eu2P privacy and security policy and to each Eu2P University rules and regulations.
- The Trainee has a right to protection against unauthorized disclosures of confidential information contained in her/his educational records. The Trainee has a right to examine and challenge information contained in her/his educational records as described in the section 10.
- The Trainee has a right to use of student facilities offered within any of the Eu2P Academic Partners during their term of study.

SERVICES

Each Eu2P Academic Partner agrees to provide all reasonable assistance to the Trainee helping her/him with incoming procedures such as finding housing, having access to language courses, libraries, canteens, study rooms and computer facilities or providing help to incoming Trainees with formalities such as permits of stay.

The main contact points shall be the respective Eu2P Academic Partners International Offices.

The Eu2P Academic Partners undertake to cover each Trainee admitted to the Eu2P Master programme with public liability insurance coverage for any accidents incurred within the university buildings and third party liability for damage that they may involuntarily cause to a person or their properties.

TRAINEE'S INVOLVEMENT IN EU2P GOVERNANCE

Representatives of Eu2P Trainees are invited to the Executive Board meetings when the agenda of the Executive Board requires such attendance. Such representatives are elected by their fellow Trainees during the Freshers' week on the following basis:

- One to two representatives (depending on the annual Trainees' intake importance) of the trainees enrolled in both the first and the second year of the Master.
- Eu2P Trainees will be informed on the election process of Trainee representatives by the Eu2P central office within one month following the start of the course.

09- MASTER TRAINEE'S COMPLAINTS AND APPEALS

COMPLAINTS

INFORMAL PROCESS

When a Trainee has a complaint, s/he is advised to raise the matter directly with those concerned in the first instance. The procedure of the Academic Partner concerned should be followed. Each Academic Partner will consider such complaints fairly and do their best to resolve any difficulties.

If a Trainee is dissatisfied with the response to an informal complaint or request, then a formal written complaint should be made in accordance with the procedures laid down by the Academic Partner concerned.

FORMAL COMPLAINTS

Complaints involving one particular Academic Partner

The Trainee wishing to complain about a specific training, service or facility provided by a given Eu2P Academic Partner shall invoke the complaint procedure of that institution.

Detailed information about the corresponding complaints process at each institution will be obtained from the Modules Coordinators where necessary.

The Trainee may obtain assistance in preparing complaints from the appropriate advisory body at each institution.

Complaints involving the whole Eu2P Consortium

The Trainee wishing to complain about the overall organisation of the Master shall address her/his complaint to the Executive Board, which will deal with it during its review meetings under the following process:

The Trainee who feels that s/he has been wrongly affected by a particular aspect of the Master organisation, may ask to have her/his prejudice taken into account and remedial action be taken, by sending within ten calendar days of the date of the particular event or notification of such particular aspect affecting her/his personal situation, a request for action, at the following address:

eu2p.office@eu2p.org

The Executive Board will consider the complaint and notify the Trainee of its decision within 30 calendar days of receipt of the Trainee's complaining e-mail.

In the event that a trainee has had his or her request dismissed by the Executive Board then a trainee may, in limited circumstances, make representations to the vice-Chancellor or nominee at the Université de Bordeaux.

Representations which have to be submitted via the Eu2P central office can be made only on the grounds that exceptional circumstances apply.

The grounds on which trainees are permitted to lodge an appeal against a recommendation or decision made by the Executive Board in the context of a student complaint are limited. The Complainant may request a review by the Vice-Chancellor or nominee where he or she (the Complainant):

- Wishes information not already brought forward at an earlier stage or new information which may be relevant to the case, to be considered,
- Believes that there has been procedural irregularity or bias.

The Executive Board will advise the Trainee of the legal remedies available to her/him pursue her/his complaint before a judicial or arbitral instance. Such remedies include the ability of the Trainee to access the UK Office of the Independent Adjudicator in limited circumstances.

ACADEMIC APPEALS

The Trainee wishing to appeal against a decision relating to the assessment process within the remit of a specific module shall invoke the appeals procedure of the given Eu2P Academic Partner institution. Detailed information about the corresponding appeals process at each institution will be obtained from the Modules Coordinators where necessary.

The Trainee may obtain assistance in preparing an appeal from the appropriate advisory body at each institution.

In the event that the Trainee wishes to make an appeal relating to a decision made by the Eu2P Programme Examination Board, the trainee should submit the request in writing to the Chair of the Executive Board within 10 working days of the published decision.

The grounds on which trainees are permitted to lodge an appeal against a recommendation or decision made by the Programme Examination Board are limited to the following:

- That the Eu2P Programme Examination Board had been advised beforehand of medical or other serious adverse circumstances and failed to appreciate their significance when arriving at their decision or recommendation.
- That there was a material administrative error or procedural irregularity associated with the conduct of the board and/or proceedings were not conducted in accordance with the approved Master Regulations.
- That there was inconsistency on the part of the Eu2P Programme Examination Board.

The written submission should include:

- A summary of the case and grounds for requesting the review;
- The date on which the decision/recommendation was taken by the Eu2P Programme Examination Board
- Any relevant documentary evidence.

In the event that a Trainee has had his or her request dismissed by the Executive Board then a Trainee may, in limited circumstances, make representations to the vice-Chancellor or nominee at the Université de Bordeaux.

Representations that have to be submitted via the Eu2P central office can be made only on the grounds that exceptional circumstances apply.

The grounds on which Trainees are permitted to lodge an appeal against a recommendation or decision made by the Executive Board are limited to the following:

- That the correct procedure has not been followed and/or that all the relevant circumstances have not been considered and/or there is new evidence not previously considered by the Eu2P Executive Board.
- That the Trainee believes that there has been procedural irregularity or bias.

In limited circumstances a Trainee may have access to the UK Office of Independent Adjudicator.

10- MASTER TRAINEE'S RECORDS

GENERAL - CONFIDENTIAL CHARACTER OF THE TRAINEE'S RECORDS

The privacy and confidentiality of the Trainees' records shall be preserved as outlined in the Eu2P privacy and security policy and in the privacy policies applicable in each Eu2P University according to relevant local laws.

The official Trainee's records shall be maintained only by members of the Eu2P central office and Eu2P Universities staff employed for that purpose. In particular, members of this administration and instructional staff will have access to the Trainees' records for legitimate purposes such as Trainee advising, administrative planning and statistical reporting.

ACADEMIC PERFORMANCE

The Eu2P central office gathers in one individual file all marks obtained by a Trainee in her/his different Modules examination sessions and research project(s) assessment. Copy of her/his file is addressed to the different Eu2P universities academic offices for transcript in each local Trainee's file system.

ACCESS TO RECORDS

Access to the Trainee's official records and files is guaranteed to every Trainee subject to the limitations provided by each relevant local law of any Module coordinator or Academic Advisor.

Upon completion of the Master assessment process, the Trainee will receive feedback commensurate with the regulations of the Academic Partner(s) with responsibility for the assessment concerned. With regards to the research project assessment, the Trainee may apply to the chairman of the Programme Examination Board within one month of the assessment for feedback on the assessment

A Trainee may apply to the chairman of the Programme Examination Board within one month of the communication of each module results for access to her/his files. The chairman of the Programme Examination Board shall determine the place and time of such access.

Trainees' records will not contain information regarding the Trainee's race, religion, disability, political opinions, social opinions, or membership in any organisations other than honorary and professional organizations directly related to the educational process.

Records of behavioural or academic misconduct and subsequent sanctions that may have been imposed will be maintained in the relevant Eu2P Academic Partner and in the Eu2P central office.

11- CONFIDENTIALITY ISSUES & INTELLECTUAL PROPERTY RIGHTS

PROFESSIONAL SECRECY AND NON-DISCLOSURE

All research projects placements require that the Trainee exercises professional secrecy. A specific clause of confidentiality is signed by the Trainee and the hosting institution as part of the research project agreement.

INTELLECTUAL PROPERTY

USE OF RESULTS BY ANY OF THE RESEARCH PROJECT AGREEMENT PARTY

If the research project results in the creation of a work that may be publishable or protected by any other copyright or industrial property rights (including software), it belongs to the research project parties to formally agree on the terms and conditions of such dissemination activities.

In particular, a contract shall specify the scope of the rights assigned, any exclusivity, the intended use, the media used and the duration of the assignment, and if applicable, the amounts of compensation to be paid in consideration of the assignment.

This clause applies to all research projects undertaken within the Eu2P Master framework.

DISSEMINATION OF RESULTS BY EU2P ACADEMIC PARTNERS

During the assessment process of the research project
Access to the research project written and oral report is only granted to the members involved in the related assessment process and to the Eu2P central office.

Following the assessment process

Unless specific conditions limit public access, partial or full versions of the research project report may be disseminated by Eu2P through multimedia tools.

12- QUALITY OF THE MASTER PROGRAMME

The Eu2P training programme aims at achieving high academic standards.

This is ensured by:

- A strong expertise within Eu2P
- Domains responsibility relies on selected academics, experts in their fields, major and highly skilled professionals belonging to pharmaceutical companies and regulatory agencies.
- All Eu2P Academic Partners have Masters degree awarding powers.
- All Eu2P Academic Partners are located in European countries that have signed up to the Bologna Agreement.
- A robust quality assurance system
- Eu2P Academic Partners have overall responsibility for the academic standards and quality of the programme; this responsibility is exercised and overseen through the Executive Board.
- Eu2P Partners develop quality guidelines and standard operating procedures that cover the main quality items described in the ENQA report on "Standards and Guidelines for Quality Assurance in the European Higher Education Area".
- Eu2P Academic Partners recognise the equivalence of each Academic Partner's quality assurance procedures. When the Trainee studies under the responsibility of a Module coordinator, the related institutional quality assurance protocols apply.
- Eu2P Partners implement a monitoring tool of post-graduation career and graduate rate.

EU2P TRAINING CONTENT & DELIVERY QUALITY

Eu2P implements a cross-quality review of all the modules training material under the final approval by the Executive Board. Trainees' feedback is secured on each domain training material & delivery through a report form to be completed on conclusion of each course and before the final assessment. Participants are asked to evaluate the work of the trainers by means of an anonymous questionnaire.

The same assessment is conducted for the whole Master Programme, with a questionnaire designed also to gather suggestions to improve the programme.

Former participants and their organizations are also regularly contacted in order to gather suggestions and appraisals relating to the Master programme implementation

EU2P ASSESSMENT QUALITY

Eu2P pays a particular attention to the fairness and quality of its assessment process.

This is insured by two complementary processes:

- The Eu2P Programme External Examiner: an independent Eu2P Programme External Examiner is appointed by the University of Hertfordshire to have oversight of the whole programme assessment and to ensure its equity.
- A cross-partner module assessment review. This is undertaken by the Eu2P Programme External Examiner to confirm the academic standards of all compulsory modules across all partners are consistent with master's level study and that there is appropriate and consistent assessment of trainees. This review is conducted according to a specifically developed «Standard Operating Procedure for Module External Examiner Review of Examinations and/or Assessments».

13- Eu2P MASTER GOVERNANCE

THE EU2P EXECUTIVE BOARD

As regards the Eu2P Master, the Executive Board shall be responsible for its organisation and the collaboration within the Eu2P Master Consortium.

It is composed of:

- One member from each of the Eu2P Academic Partner
- One member from each of the Eu2P Associated Partner

As long as those institutions have signed one the Eu2P Diplomas Agreements.

Additional experts or qualified persons may be invited by any member of the Executive Board to attend its meetings with a role of non-voting advisor.

Its main activities are:

- To define and to update the general course prerequisites, optional and mandatory course contents, course levels, and to identify learning pathways according to level and course type,
- To define the Eu2P Master registration features e.g. tuition fees,
- To deal with all financial aspects of the Eu2P Master programme, including financial relationships between the Eu2P partners
- To define and update the study regulations (in particular the main rules of Academic progress and assessment of Trainees as detailed in Section 7)
- To review all applications to the Eu2P Master and selecting Trainees to be enrolled in the Eu2P Master programme
- To define the Eu2P grants and discounts/savings policy
- To choose among the selected applicants those entitled to benefit from a Eu2P grant

- To define the modalities to be fulfilled by Trainees for progressing from the Master year 1 to the Master year 2 and for completing the Eu2P Master Programme
- To define the tutoring, research projects and Trainee mobility
- To facilitate research projects opportunities
- To overall define the course planning and lecturer mobility
- To annually define the Eu2P calendar (application, selection, training, and assessment sessions)
- To involve additional lecturers and facilitators
- To define and update the Eu2P Master quality policy
- To treat any Eu2P complaint by a Eu2P Trainee relating to the Trainees' selection or to the overall organisation of the Eu2P Programme
- To treat any appeal by a Eu2P Trainee relating to a decision made by the Eu2P Programme Examination Board

THE EU2P PROGRAMME EXAMINATION BOARD

The Eu2P Programme Examination Board manages the progress from year 1 to year 2 and the Master awards.

It is composed of:

- Academic representatives from each Eu2P Academic Partner
- The Eu2P Programme External Examiner

The Eu2P Programme Examination Board ensures that the assessment process is conducted in accordance with Eu2P Programme regulations and with each University Module Coordinator local rules.

The Programme Examination Board tasks include:

- To define and update the assessment regulations and make sure they are in accordance with the Study regulations defined by the Executive Board,
- To receive the Modules assessment results from the relevant Domain Directors,
- To consider the assessment results achieved by Trainees, and to confirm (i) progression from Year 1 to Year 2 of the programme and (ii) the award of a Master Degree,
- To consider the Eu2P programme external examiner's annual report and the cross-partner moderation reports and recommendations.

THE EU2P CENTRAL OFFICE

The Eu2P Central Office is in charge of the management and coordination of the overall Eu2P Master programme organisation and the preparation of all necessary reports under the control of the Eu2P Executive Board.

This central office is based in the Université de Bordeaux premises with dedicated personnel for internal and external administration, management, collaborative agreement, student complaint, communication, IT, multimedia and e-learning platform related tasks.


The Trainee can contact the Eu2P central office:

- By e-mail at eu2p.office@eu2p.org
- By postal mail at the following address:



Eu2P CENTRAL OFFICE
Université de Bordeaux
146 rue Léo Saignat - Case 36
33076 Bordeaux cedex
FRANCE

The Eu2P Central Office is responsible for all operational activities and provides information and support for:

- Course catalogue database and calendar
- Candidate application, selection and enrolment
- Trainee and trainer services (Visa, insurance, accommodation facilities...)
- Trainees database
- Trainer needs
- Tuition fees, grants and discounts
- E-learning platform access and use
- Research project and mobility
- Exams organisation
- Qualification processes
- Quality procedures
- Communication activities (web, newsletter, booklets, events...)
- Alumni follow-up

	Eu2P-SOP-AOT-002		
	Module External Review of Assessment		
	Version	0.3	
	Supersedes	n/a	
	Effective date	2018-12-10	
	Next review date	2020-12-10	

Signatures

Printed Name	Function	Signature	Approval date
Francesco Salvo	Process Owner		2018-12-10
Philomena Shaugnessy	Quality Officer		2018-12-10

Revision Record

Rev	Date	Author/Reviewer	Remarks
1	2012-07-25	Jo Cahill	Initial draft
2	2013-09-05	Annie Fourrier-Réglat	Corrections
3	2013-09-12	Eu2P office (Christa Naboulet & Karine Palin)	Corrections
4	2013-09-25	Jo Cahill	Corrections and improvements – Final version
5	2017-10-03	Jo Cahill	Corrections and improvements – Updated version
6	2018-01-31	Eu2P office (Christa Naboulet & Karine Palin)	Corrections
7	2018-02-05	Jo Cahill	Corrections and improvements – Final updated version
8	2018-12-01	Eu2P office (Christa Naboulet & Karine Palin)	Corrections
9	2018-12-10	Philomena Shaughnessy	Corrections and improvements – Final updated version

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Purpose

Amendment to the Eu2P Standard Operating Procedure for Module External Examiner Review of Examinations and/or Assessments.

This Eu2P procedure, which initially came into effect on 25th, September 2013 was updated in April 2018. Its purpose is to allow the External Examiner to have an oversight of the standard of marking and, where appropriate, moderation, across all partners to ensure that this is across the programme. Since the 2017/2018 academic this has been performed through the review of research project modules in Year 1 and 2: as these were keystone activities undertaken by all Eu2P Academic Partners. This was agreed by the Eu2P Executive Board in 2017.

In practice however, problems were encountered as most projects were submitted at the end of June and provisional results from partner institutions only received by the Eu2P Office over the summer period, after the Programme Examination board was held. This meant that there was little or no work available for External Examiners to review before the Board. Given this, at the Executive Board on the 28th September 2018 it was agreed that the policy required review: it was agreed that an amendment to the procedure was required in order that the External Examiners had an adequate representative sample of work to review. It was decided that the review of one compulsory taught module delivered by each academic partner would enable the External Examiners to have a view of marking and moderation standards operating across all Eu2P Academic Partners.

Philomena Shaughnessy has discussed the proposal with the two current external examiners and both support the revised policy.

The revised process is detailed below:

Process

- Appropriate samples of summative trainee work should be reviewed by the external examiner from at least one compulsory module delivered by each of the Eu2P Academic Partners at the end of the respective term assessment period.

- For each submitted compulsory module, a sample of individual trainee's work needs to be sent to the Eu2P Office. The sample of trainee work selected for each module should where possible, include examples from the top, middle and bottom grades awarded.
- The amount of trainee work submitted should equate to the square root (or as near to as possible) of the number of individual students on the module. For example, if there are 16 trainees on a module the work of 4 trainees should be sent to the Eu2P Office. For modules with 5 or less trainees studying on them, all the trainees' work from that module must be sent to the Eu2P Office.
- Any piece of assessment from the trainees sampled, which is worth 30% or more of the module mark must be submitted. Where there are multiple pieces of assessment in a module, none of which equate to 30% of the mark, the partner must select enough work to represent at least 30% of the overall module mark (for example 3 pieces of work worth 10% of the overall module mark = 30%). The pieces of work selected must be the same assessment component for each trainee in order to allow the External Examiner to directly compare assignment components.
- The work must be sent with the following:
 - The assessment guidelines for the module assessment which were given to the trainees; or if appropriate each element of assessment.
 - The assessment/grading criteria for the assessment or if appropriate each element of assessment, with details of the weighting for each part of the assessment, and details of which components of the module assessment are being sent.
 - The feedback on the assessed piece(s) of work with the grade awarded for each element and the overall module grade. The mark awarded by the partner and the Eu2P translation grade using the equivalency table should be made clear.
 - The spread sheet with the overall grades for ALL students on the module not just those sampled.
 - Detail and outcome from any internal moderation process, if appropriate.
 - Contact details of the module leader/coordinator.

Failure to include all material may result in a delay of proceedings including the board of examiner meeting.

- Following review of the module assessments, a report (See Appendix 1) will be completed by the module external examiner and returned to the Eu2P Office for distribution to all partners and action as appropriate. Where action is required by the partner a response should be made to the module external examiner to ensure transparency of process and that the audit trail for proceedings is clear. The report will be considered at the Eu2P Programme Examination Board.

Document History

Document Version	Description of Major or Relevant Change
1.0	Initial version
2.0	Updated version 2.0
3.0	Updated version 3.0

Appendix 1

Eu2P Cross Partner Module External Examiner Report

To be completed by the Module External Examiner

Name of External Examiner		
Collaborative Partner – please tick all that apply	Erasmus Universiteit Medisch Centrum Rotterdam	<input type="checkbox"/>
	Universitat Autònoma de Barcelona	<input type="checkbox"/>
	Université de Bordeaux	<input type="checkbox"/>
	Università degli studi della Campania, Luigi Vanvitelli	<input type="checkbox"/>
	Universiteit Utrecht	<input type="checkbox"/>
	University of Hertfordshire	<input type="checkbox"/>
Modules examined	Module Title	Please tick as appropriate
	D1M1 Basics in epidemiology D3M2 Pharmacovigilance regulations D4M1 Principles of identifying and recognizing adverse events and safety signals D5M1 Introduction to Benefit-Risk assessment and pharmacoeconomics in decision making D6M2 Drug utilization studies: Introduction & quantitative methods or D2M2 Clinical and Pharmacological Principles D7M2 Information and communication about benefit-risk of medicines. Basic principles	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

1. Academic standards	Agree	Partly Agree	Dis-agree	N/A
The grades awarded for assessments were appropriate and consistent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The standards achieved across all partners are comparable with those on Masters programmes elsewhere.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
From the evidence available to me as an external examiner, the partner's processes for assessment are sound and fairly conducted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I was given the opportunity to moderate an appropriate sample of marked student work from each partner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I was provided with sufficient information, in a timely manner, to allow me to carry out my duties as an External Examiner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Please explain here your reasons for answering 'Disagree' or 'Partly Agree' to any of these questions, or whether you wish to bring any other matters to the attention of the School:</i>				

2. Response to previous reports	Agree	Partly Agree	Dis-agree	N/A
I have received an appropriate response to issues raised in my previous cross partner module external examiner report	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Please explain here your reasons for answering 'Disagree' or 'Partly Agree':</i>				

3. Recommendations to the Module team(s) and/or Executive Board

Please list key points that you recommend are addressed in the next assessment period. Recommendations specific to a particular partner should be made clear. Please also list any substantive issues that you recommend the Executive Board addresses

NAME OF EXTERNAL EXAMINER:

Signature:

Date

Please return the completed report by:

Please return to the Eu2P Office at Bordeaux