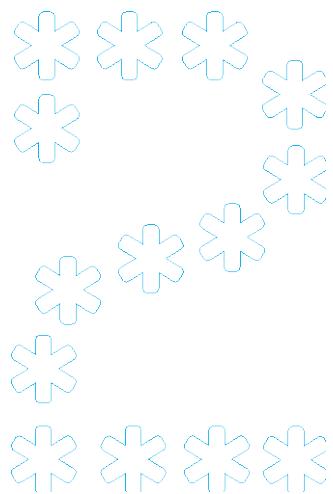




EUROPEAN PROGRAMME IN
PHARMACOVIGILANCE AND
PHARMA~~C~~OEPI~~E~~MI~~O~~LOGY



DIPLOMA AGREEMENT FOR A MASTER DEGREE IN PHARMACOVIGILANCE AND PHARMA~~C~~OEPI~~E~~MI~~O~~LOGY

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**Diploma agreement for a Master degree in Pharmacovigilance and
Pharmacoepidemiology (Eu2P Master)**

BETWEEN

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM (EMC), whose administrative offices are at Rotterdam, Netherlands hereby represented by its Board Dean Prof.dr. Stefan Sleijfer,
And

UNIVERSITÀ DEGLI STUDI DELLA CAMPANIA, LUIGI VANVITELLI (UNICAMPANIA), Napoli, Italy, whose administrative offices are at Napoli, Italy at hereby represented by its Rector Prof. Giovanni Francesco Nicoletti,

And

UNIVERSITAT AUTÒNOMA DE BARCELONA (UAB), whose administrative offices are at Bellaterra (Cerdanyola del Vallès), Spain hereby represented by its Rectora Dra. Margarita Arboix Arzo,

And

UNIVERSITÉ DE BORDEAUX (UB), whose administrative offices are at Bordeaux, France hereby represented by its President Prof. Dean Lewis,

And

UNIVERSITEIT UTRECHT (UU), whose administrative offices are at Utrecht, Netherlands, hereby represented by its Dean of the Faculty of Science, Prof. dr. I.W.C.E. Arends,

And

UNIVERSITY OF HERTFORDSHIRE HIGHER EDUCATION CORPORATION (UH), whose administrative offices are at Hatfield, United Kingdom hereby represented by its Vice-Chancellor Prof. Quintin McKellar,

Acting as the Eu2P Academic Partners,

And

Bayer AG (BAYER) whose administrative offices are at Muellerstrasse 178, 13353 Berlin, Germany hereby represented by Montse Soriano Gabarro, MD, MSc,

And

CYTEL whose administrative offices are XXXXXX, represented by XXXXXX

And

Jazz Pharmaceuticals whose administrative offices are at Wing B, building 5700, Spires House John Smith Drive, Oxford Business Park South, OX4 2RW, United Kingdom, represented by Rajbinder Bhogal,

And

Sanofi-Aventis Recherche & Développement (Sanofi) whose administrative offices are at 82 avenue Raspail, Gentilly 94250, France, represented by Catherine Baillis,

And

TAKEDA Pharmaceutical Company Limited whose administrative offices are 1 Kingdom Street Paddington London W2 6B, United-Kingdom, represented by Veronique Kugener,

Acting as the Eu2P Associated Partners,

The Eu2P Academic Partners, and the Eu2P Associated Partners forming altogether the Eu2P Consortium.

1 Description of the Programme

The members of the initial Eu2P Consortium, that include the Academic and Associated Partners, have entered into a collaborative educational project (the Eu2P project) in order to develop a European training and education platform in Pharmacovigilance and Pharmacoepidemiology so as to improve the understanding of medicines-related outcomes (utilisation, benefit and risk), the quality of the studies conducted for these outcomes, and to provide tools and methods for decision-making and communication related to medicines benefit and risk.

These goals have been firstly achieved under the umbrella of the Innovative Medicines Initiatives Joint Undertaking (IMI JU¹), through the carrying out of the Eu2P project agreed upon with the IMI JU. In order to implement these activities, the members of the initial Eu2P consortium had acceded to the Eu2P Grant Agreement² signed with the IMI JU Board and signed altogether a Eu2P project agreement, regulating their relationships in the Eu2P project framework.

The Academic and Associated Partners have since 2016 extended their collaboration beyond the framework of the IMI JU and beyond the initial calendar. The first delivered activities were indeed further implemented both in maintaining the current training programme offer but also by extending and improving it, by possibly integrating new accredited courses and/ or diplomas, new pedagogy findings, new e-learning techniques, or new partners.

It was in this context that some members of the initial Eu2P Consortium had signed an agreement detailing the new Eu2P Master organisation set up, that entered into force on July 1st 2016, and which has since been renewed, also integrating new partners.

The previous agreement reaching its end of validity on June 30th, 2024, the Parties have therefore agreed to renew their collaboration by entering into this new Master agreement.

Five annexes are attached to complete the present Master Agreement and form an integral part thereof.

Annex 1: Financial aspects

The financial aspects of the Eu2P Master programme are provided in the Master Agreement *Annex 1*.

Annex 2: Eu2P Master curriculum

Details of the registration, course curriculum, periods of study, assessment rules and research project are provided in the Master Agreement *Annex 2*.

Annex 3: Trainees codes of rights and responsibilities

In relation to the Trainees, the *Annex 3* gathers the Master Trainee's code of rights and responsibilities, describing rights and responsibilities of Trainees.

Annex 4: Accession Form

This is a template of a legally binding document signed between the Eu2P Master Consortium and an external public or private body that wishes to be part of the Eu2P Master Consortium.

¹ "IMI JU" means the Innovative Medicines Initiative Joint Undertaking, a community body established by Council Regulation No 73/2008 of 20 December 2007.

² Grant Agreement No 115014 entered into with the IMI JU for the undertaking of the Eu2P project.

Annex 5: Joint Master degree

This is the template of the joint Master degree that will be issued by the Coordinating institution, according to the Master Agreement Article 9.1.

2 Definitions

Any word(s) or expression(s) appearing in this Diploma agreement shall have the meaning ascribed to them herein unless such word(s) or expression(s) are defined in the Eu2P Memorandum of Understanding (MoU) in which case they shall be interpreted, in case of inconsistencies, in accordance with the definition of such word(s) or expression(s) included within the Eu2P Memorandum of Understanding, ultimate priority being given to the Eu2P MoU definitions.

“Academic Partner” means a Higher Education Institution³, which is a party to this Agreement and which jointly delivers and awards the Eu2P training programmes with the other Eu2P Academic Partners.

“Accession Form or Annex 4” means a legally binding document signed between the Eu2P Master Consortium and an external public or private body that joins the Eu2P Master Consortium as a new partner. A template of an Accession Form is annexed to the present Master Agreement. It constitutes the Annex 4.

“Annex 1” means the Financial Technical Annex, describing the main rules relating to the financial aspects of the Eu2P Master programme.

“Annex 2” means the Eu2P Master internal regulations detailing the Eu2P Master curriculum content and organisation between the Eu2P Academic Partners.

“Annex 3” means the Master Trainee’s code of rights and responsibilities, describing rights and responsibilities of Trainees with reference to the academic component as well as the administrative requirements and the services available.

“Annex 5” means the template of the joint Master degree that will be issued by the Coordinating institution, according to the Master Agreement Article 9.1

“Associated Partner” means a public or private body, which is a party to this Agreement and that participates to or provides support to the activities carried out by the Eu2P Consortium.

“Course Coordinator” means the institution in charge of the consistency of the topics content and responsible:

- For organising training formats (choice of lecturers, tutors, content update, ...)
- For coaching the Trainee’s work
- For implementing assessment sessions.

When the Course Coordinator is an Academic Partner, the Course Coordinator equals the Module Coordinator.

When the Course Coordinator is a Course Provider Partner, the course delivery and respective assessment activities will be undergone under the pedagogical responsibility of the Academic Partner to which such course is related to.

³ HEI is an establishment providing higher education and recognized by the competent national authority of a participating country as belonging to its system of higher education.

“Course Provider Partner” means an individual or a public or private body, which is a Party to this agreement and which participates in the training and tutoring activities under the pedagogical responsibility of one or several Eu2P Academic Partner(s).

“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 a Eu2P Academic Partner, who is in charge of the consistency of the Modules and the research project general organization within a Domain.

“Eu2P Executive Board” or “Executive Board” means the decision-making board that is in charge of defining rules relating to the training offer, training issues, selection procedures, research mobility, administration, promotion, quality assurance and enhancement, development strategy and legal matters.

“Eu2P Programme External Examiner” means the external expert appointed by the University of Hertfordshire (UH) to have oversight of the whole programme assessment.

“ECTS” means European Credit Transfer and Accumulation System (ECTS). 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 validated with the view of obtaining a qualification. In the Eu2P Consortium, one ECTS represents 25 hours of Trainee’s workload.

“Eu2P Consortium” or “Consortium” means the gathering of all Academic and Associated Partners involved in the Eu2P training and research programme, without the intention to create any Partnership, agency or joint venture amongst them, nor to establish any other legal entity constituted amongst any or all of them and having signed the Eu2P Memorandum of Understanding (MoU).

“Eu2P Master Consortium” means the gathering of all Academic Partners and Associated Partners involved in the Eu2P Master programme, without the intention to create any membership, agency or joint venture amongst the Academic Partners and Associated Partners, nor to establish any other legal entity constituted amongst any or all of them.

“Eu2P Memorandum of Understanding” or “Eu2P MoU” is the general agreement signed between the members of the Eu2P Consortium that gives the new framework of collaboration to implement concrete training and research activities, by way of additional agreements such as this Master Agreement.

“Module” means a set of one or several learning outcomes within a dedicated Domain.

“Module coordinator” means a representative of an Academic Partner designated by the related Domain Director. This person is in charge of the consistency of the topics content and responsible:

- For organising training formats (choice of lecturers, tutors, content update, ...)
- For coaching the Trainee’s work
- For implementing assessment sessions.

“Party/ Parties” means the Academic and Associated Partner(s) having signed the present Master Agreement.

“Professional” means a Trainee enrolled in the Eu2P Master programme, who is concomitantly engaged in a full-time professional occupation.

“Programme Examination Board” means the board set up to ensure that the Master study rules are enforced in accordance with Eu2P own regulations and with each University Module Coordinator local rules. This Board will approve selection, grade translation, progression and award.

“Research project” means the work undertaken in a host institution by the Trainee during each year of the Master curriculum. It consists in performing research, analysis and development on a specific subject. The methods and results of the work lead to a written report that is also presented orally.

“Research project academic Advisor” means the member of the Academic Partner who advises the Trainee on the Research project.

“Research project Director” means the supervisor appointed within the hosting institution during the Research project placement.

“Specialisation” means a speciality chosen in the second year of the Eu2P Master.

“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 his/her application to Eu2P and who is not engaged in a full-time professional occupation.

“Trainee” means the Student or the Professional enrolled in the Eu2P Master programme.

3 Legal Framework

Any subsequent change in one or several of the following laws or conventions will automatically apply to the present diploma agreement and will be binding upon the relevant Eu2P Academic Partner(s).

3.1 French regulations

- Articles L 613-1 du Code de l'Education
- Having regard to the transmission of the present Agreement to the French Ministry of Higher Education, Research and Innovation,
- Having regard to the French Education Code, in particular Articles L. 123-7 and D.123-15 to D.123-22 referring to the missions of public higher education in international matters and articles L613-17 to D613-25 relating to degrees awarded within an International partnership,
- Having regard to the ministerial circular number 20015-012 of March, 24th 2015 fixing the national framework leading to the awarding of national degrees,
- Having regard to the Decree of 25 April 2002 relating to the national Masters' degree,
- Having regard to the Decree of 19 July 2022 awarding UB the right to award the French degree concerned by the present agreement,
- Having regard to the decision of UB Board of Director dated December 13, 2021 delegating power to the President of the University,
- Having regard to the decision of UB Board of Director dated April 16, 2019 concerning fee waivers,
- Having regard to the recommendation of the UB Commission Formation et Vie Universitaire relating to the present Agreement dated ... / ... / 20...,
- Having regard to the recommendation of the UB Conseil de Collège Santé relating to the present Agreement dated ... / ... / 20...,
- Having regard to the recommendation of the Conseil UF Santé relating to the present Agreement dated ... / ... / 20...,

3.2 Dutch Regulations

- Artikel 7.3c van de Wet op het hoger onderwijs en wetenschappelijk onderzoek
- Dutch Higher Education Act: 'WHW 7.11 lid 1 and 5'

3.3 English Regulations

- University of Hertfordshire own regulation: UPR AS14: Structure and Assessment Regulations – Undergraduate and Taught Postgraduate Programmes,
- University of Hertfordshire regulation UPR AS12: Assessments and Examinations (Undergraduate and Taught Postgraduate),
- University of Hertfordshire regulation UPR AS17: Academic Quality
- University of Hertfordshire regulation UPR AS22
- Section 76 of the Further and Higher Education Act 1992

3.4 Spanish Regulations

- Real Decreto nº 1393/2007 de 29 de octubre (ordenación de las enseñanzas universitarias oficiales),
- Real Decreto 861/2010 de 2 de julio, por el que se modifica el Real Decreto 1393/2007, de 29 de octubre, por el que se establece la ordenación de las enseñanzas universitarias oficiales
- Ley Orgánica 6/2001, de 21 de diciembre, de Universidades.
- Ley Orgánica 4/2007, de 12 de abril, que modifica la LO 6/2001, de Universidades

3.5 Italian Regulations

- Legge 19 novembre 1990, n. 341 "Riforma degli Ordinamenti didattici universitari";
- Legge 14 gennaio 1999, n. 4 "Disposizioni riguardanti il settore universitario e della ricerca scientifica, nonché il servizio di mensa nelle scuole";
- D.M. 3 novembre 1999, n. 509 "Regolamento recante norme concernenti l'autonomia didattica degli Atenei"
- D.M. 22 ottobre 2004, n. 270 "Modifiche al regolamento recante norme concernenti l'autonomia didattica degli Atenei, approvato con Decreto del Ministro dell'Università e della Ricerca scientifica e tecnologica 3 novembre 1999, n. 509"

3.6 Eu2P Conventions

- Eu2P MoU signed by the members of the Eu2P Consortium
- Eu2P Certificates Agreement
- Eu2P Short Courses Agreement

4 Cooperation aspects

4.1 The Coordinating institution

The Université de Bordeaux acts as the Academic Coordinating institution of the Eu2P Consortium regarding the delivery of the Eu2P Master. The Coordinating institution shall neither be entitled to act or to make legally binding declarations, on behalf of any other party nor to modify their rights, obligations or general attributions beyond the one described herein, without the prior written consent of the other Parties.

4.2 The Academic Partners (including the Coordinating institution)

The Academic Partners shall perform and complete their share of the Eu2P Master degree programme in accordance with the requirements and Modules coordination share set out in the Annex 2.

Each Academic Partner shall organise and implement the Eu2P Master programme activities in its own institution, and specifically:

- The delivery and promotion of the Eu2P Master programme
- The performing and supervision of all necessary accreditation steps through local or national accreditation procedures in order to deliver the curriculum and, where possible, to jointly award the Master degree
- The management of the funds collected and distributed by the Coordinating institution
- Regarding the Trainees:
 - Visa request: each Academic Partner shall help to obtain the documents required by its national immigration policy, by providing all the explanations and documents helpful for the applicants
 - Academic admission and registration
 - Advice on accommodation organization
 - Advice on insurance obligations

Financial aspects relating to the management, share and use of the income deriving from the Master activities between the Academic Partners are described under the Financial Technical Annex 1. This document shall be reviewed annually by the Executive Board and shall be enforceable between the Eu2P Master Consortium members upon decision of the Executive Board, and without the need to renegotiate the whole Eu2P Master Agreement. Each Academic Partner shall be responsible for its own training cost deriving from the Master programme implementation.

4.3 The Associated Partners

The description of the commitments and benefits for Associated Partners to be part of the Eu2P Master Consortium is given under the Financial Technical Annex 1. This document shall be reviewed annually by the Executive Board and shall be enforceable between the Eu2P Master Consortium members upon decision of the Executive Board, and without the need to renegotiate the whole Eu2P Master Agreement.

4.4 The Boards

4.4.1 The Eu2P Executive Board

(1) The Eu2P Executive Board (the "Executive Board") has been established by the Eu2P MoU for the whole Eu2P Consortium functioning.

(2) The general tasks of the Eu2P Executive Board are the following:

- The Executive Board has the central decision-making role in the Eu2P structure, projects and activities.
- The Executive Board conducts discussions and takes decisions regarding scientific, operational and financial aspects of concrete activities that may derive from the MoU.
- The Executive Board decides on any request for new membership to the Eu2P Consortium.
- The Executive Board is responsible for the determination of policies and decision-making in relation to the overall strategy of the Consortium and the initial review of any disputes between the Parties relating to the execution of the MoU.
- Additional roles will be attributed to the Executive Board, along the signature of the Diplomas' Agreements deriving from the MoU.

(3) As regards the Eu2P Master, the Executive Board shall be responsible for its organisation and the collaboration within the Eu2P Master Consortium. The related Executive Board tasks shall include:

- 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 the Eu2P grants and savings policy
- To choose among the selected applicants those entitled to benefit from a Eu2P grant
- To define the research projects organisation
- 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 (See section 8)

(4) The Executive Board is comprised of:

Permanent voting members:

- One member from each of the Parties, under the condition that the Party has also signed at least one of the Diplomas' Agreements deriving from the Eu2P MoU.

A deputy alternate is appointed for each of the voting members of the Executive Board. The alternate must belong to the same organisation as the main member. Changes in the name of a member shall not affect the validity of the composition of the Executive Board.

Additional non-voting members:

- One member from each of the signing parties of the Eu2P MoU but not part of any of the Diplomas' Agreements deriving from the MoU.
- The Eu2P External Examiner.
- The representative of the UH Centre for Academic Quality Assurance.
- Any 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.
- A deputy alternate is also appointed for each of the non-voting members of the Executive Board. Such alternate must belong to the same institution as the main member. Change in the name of a non-voting member does not affect the validity of the composition of the Executive Board.
- The representative of Eu2P Trainees shall be invited to the Executive Board meetings when the agenda of the Executive Board relating to the Eu2P Master requires such attendance. Such representative shall be elected by their fellow Trainees on the following basis: one representative of the Trainees enrolled in both the first and the second year of the Master.

(5) Organisations and frequency of meetings

- Meetings take place face-to-face or via telephone or videoconference.
- Meetings are closed to the public. Members of the Executive Board and their alternates shall observe confidentiality for the meeting's proceedings.
- In order for an Executive Board meeting to be quorate there shall be present or duly represented all of the Academic Partners.
- The member representing the Coordinating institution shall act as the chairperson of the Executive Board.
- The Executive Board shall meet at least twice a year. The chairperson may convene additional meetings with at least a two-months' prior notice.

(6) Decisions of the Executive Board

The Executive Board is responsible for ensuring compliance with the provisions of this Diploma agreement. The Executive Board may delegate routine tasks to the chairman.

Decisions are normally taken by consensus. In the event that efforts to reach consensus fail, the Executive Board may take decisions by a simple majority vote. Each member has one vote subject to the following:

Voting rights of permanent members:

- The Academic Partners have voting rights for any decision that the Executive Board is in charge of.
- The Associated Partners have voting rights, except for any decision relating to Trainees' selection, grading, academic quality, assessment and award of academic diplomas, nor for any decision relating to the financial management of funds among the Academic Partners.

In the event of a tie vote, the chairperson has a second or casting vote.

4.4.2 The Eu2P Programme Examination Board

(1) A Eu2P Programme Examination Board (the "Programme Examination Board") is established for the Eu2P training programmes. The Programme Examination Board shall ensure that the selection process and assessment process is conducted in accordance with Eu2P Programme regulations and with each University Module Coordinator local rules.

(2) The Programme Examination Board tasks shall include:

- To review all applications to the Eu2P Master and select Trainees to be enrolled in the Eu2P Master programme
- To define and update the Study regulations
- To define and update the assessment regulations, including 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 receive the approved 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 (cf. Section 7.2)
- To produce and publish at the start of each academic year a schedule of dates for exams, retakes and Programme Examination Board meeting(s).

(3) The Programme Examination Board is comprised of:

- One academic member from each of the Academic Partners,
- The Programme External Examiner.

Since a valid decision of the Programme Examination Board shall engage the Partners, the voting Partner's representative shall take every precaution to ensure his/her decision is in agreement with his/her institution practices and legal obligations. If needed, a further delay could be granted in order to obtain the approval of the legal authority of the Academic Partner.

Additional non-voting members:

- Representatives of the Eu2P Academic Partners administration may be co-opted to assist to the Programme Examination Board meetings when necessary, with no-voting rules powers.

(4) An alternate shall be appointed by the relevant Eu2P Partners institutions for each of the members of the Programme Examination Board. Such alternate must belong to the same organisation as the main member. Changes in the name of a member shall not affect the validity of the composition of the Programme Examination Board.

(5) Decisions of the Programme Examination Board are normally taken by consensus. In the event that efforts to reach consensus fail, the Board may take decisions by a simple majority vote. Each member has one vote.

In the event of a tie vote, the chairman has a second or casting vote.

(6) Frequency of meetings

The Programme Examination Board shall meet at least once a year face-to-face or on-line to consider the examination 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.

Additional meetings may be convened by the chairman with at least a two-months notice.

(7) Organisations of meetings

Meetings take place face-to-face or via telephone or videoconference.

Meetings are closed to the public. Members of the Board, their deputies, the examiners and assistant examiners observe confidentiality of the proceedings of the meetings.

In order for a Programme Examination Board meeting to be quorate there shall be present or duly represented at least four of the Academic Partners.

4.5 The Eu2P Central Office

An existing Eu2P Central Office based in the Université de Bordeaux premises with dedicated and qualified personnel is maintained to take charge of the management, coordination and communication related to the Eu2P Consortium organisation, training programme and activities.

As regards the Eu2P Master, the Eu2P Central Office takes charge of the management and coordination of the overall Eu2P Master Programme organisation under the control of the Executive Board.

The responsibilities of the Central Office include but not be limited to responsibility for all operational activities relating to:

- Course catalogue & calendar database
- Trainee application & database
- Trainer services
- Trainee services
- Examinations organisation and results collection
- Diploma delivery
- Fees (collection, redistribution) and grants (files and payment)
- Research projects & mobility
- Quality procedures
- Communication activities
- Qualification procedures
- Alumni follow-up

5 Promotion of the programme

A specific communication strategy is implemented to disseminate information about the Eu2P Master programme to a targeted audience, such audience to be agreed by the Executive Board. The promotion aspects of the communication shall focus on Eu2P stakeholders' reputation and respectability in pharmacovigilance and pharmacoepidemiology training and expertise fields, pharmacovigilance and pharmacoepidemiology experts' needs in European academic, industrial and regulatory bodies.

An external communication plan to promote the Eu2P Master is developed and implemented by the Eu2P Central Office to facilitate access by Trainees. This communication plan includes a good training dissemination and promotion plan carried out through media such as:

- Web-based social networks (LinkedIn, Facebook, Twitter)
- University information centres
- Industry journals for people in the industry
- Mass media journals for patients
- Economic journals for venture capitalists
- Journalism schools for journalists
- Professional-based or training-orientated meetings

Communication is also carried out by the Eu2P Central Office by the development of a public Eu2P website (<http://www.eu2p.org>) run by the Eu2P Central Office as follows:

- A general section, that is regularly updated and that focuses on providing impartial and objective information (qualitative and quantitative) about the Eu2P training programme and relating awards (Eu2P presentation and history, news, presentation & planning of the training courses, contacts).
- A "My Eu2P section", a secure-web access that provides listing and description of training courses, tools for Trainee application: application/registration, grant application, online payment, Trainee admission, specialisation choices, Modules schedule, and qualification information.

6 Trainee's administration

6.1 Application documents and pre-requisites

Applicants are required to complete the application procedure, uploading or sending to the Eu2P Central Office documents and forms available at the Eu2P web page (www.eu2p.org).

The details of the documents and pre-requisites required for entry on the 1st or the 2nd year of the Eu2P Master Programme are described in the Annex 2 of this Diploma agreement.

6.2 Application calendar

The Executive Board defines each year the application calendar to be followed by Eu2P applicants. Only one application session per academic year shall be organised.

6.3 Criteria for admission

6.3.1 Common selection criteria for Trainees

The following criteria are used in the selection of Trainees:

- Strongly convincing letter of motivation,
- All Modules are taught in English so a B2 level according to the "Common European Framework of Reference for Languages" grid or equivalent is the minimum required in this language.⁴
- All Modules are taught using the Eu2P e-learning platform so computer literacy ability is a pre-requisite that must be acknowledged by the applicant.

6.3.2 Additional selection criteria for entry on the 1st year of the Master

The minimum additional admission criteria for the Eu2P Master (in two years) are:

- For Students: Bachelors' degree (180 ECTS credits / 3 years) or equivalent in Health or Life sciences
- For Professionals: Bachelors' degree (180 ECTS credits /3 years) or equivalent in Health or Life sciences.

Additional selection criteria for direct entry on the second year of the Master

The minimum additional admission criteria for entry in the second year of the Eu2P Master are:

- For Students: Master year 1 level (240 ECTS credits / 4 years) or equivalent in Health or Life sciences, including proof of knowledge in basics in statistics, basics in epidemiology and pharmacology or
- For Professionals: Bachelors' degree (180 ECTS credits /3 years) or equivalent in Health or Life sciences and a minimum of three years of relevant professional experience, including proof of knowledge in basics in statistics, basics in epidemiology and pharmacology.

⁴ European Union and Council of Europe, 2004-213 <http://europass.cedefop.europa.eu>

6.4 Selection procedure

The Executive Board members review all complete applications to the Eu2P Master.

The selection process shall take place early enough to allow for timely notification of final decision before courses start.

The Eu2P Central Office sends admission letters by email to applicants selected by the Executive Board.

Trainees are only registered when:

- They have paid annual Master fees or have committed to pay in several instalments. In the latter case, they will need to have paid the first instalment in order to be registered.

Transparency of application, admission and selection procedures are ensured by the publication of:

- The composition of the Executive Board,
- The relevant information and the selection criteria used, and
- Statistical data on the results of the application procedure.

The Eu2P Master programme is open to anyone regardless of age, class, creed, disability, ethnic origin, gender, marital status, nationality, sexual orientation or caring responsibilities. All individuals are selected and treated based on their relative merits and abilities.

The Eu2P Central Office, along with the Eu2P Academic Partners' international offices may help selected Trainees with the visa, permits and insurance procedures.

Disabled applicants are treated according to the same procedures as any other applicant with the added involvement of the Eu2P Academic Partners Disability Offices to assess their needs. The programme may require adaptation for Trainees with disabilities (*e.g.* hearing impairment, visual impairment, mobility difficulties, dyslexia), and the Eu2P Master Consortium shall make all reasonable attempts to accommodate Trainees wherever possible in accordance with the equality and prevention of discrimination legislation applicable in the host country.

6.5 Enrolment of Trainees

Once selected by the Executive Board and payment of the annual Master fees is secured (*cf.* Section 10 on Financial Management), Trainees are enrolled by the Eu2P Central Office.

Registration in each Eu2P Academic Partner is required under this Diploma agreement; to allow such process, the Eu2P Central Office forwards all necessary information for registration to take place.

The registered Trainee is provided with an International Student Identity Card. This card establishes the student status of the registered trainee at an international level.

Additional local students' cards may be issued by any of the Eu2P Academic Partners to the registered Trainee.

6.6 Research project

6.6.1 Research project general rules

During each year of the Eu2P Master Programme, Trainees stay in a host organisation to work on the composition of a research project report related to a specific Eu2P domain, whereby Trainees demonstrate their ability to carry out an integrated defined task, solve it in a set period of time and adequately report the results of the work in a written report followed by an oral presentation. The work is carried out in the premises of a host organisation that may be part of the Eu2P Master consortium or be external to this consortium. In some exceptional cases however, the Trainee may not be physically present at the host institution and shall be supervised on a distant basis.

The Eu2P Central Office is responsible for dealing with any queries from Trainees.

Common Guidelines regarding the selection, writing and assessment of the Eu2P Master research project are regularly updated by the Executive Board and communicated to the Master Trainees.

6.6.2 Research project tasks

The Trainees select a subject matter and work independently with the guidance of an Academic Advisor belonging to the related Domain team and of the host organisation supervisor, named the research project Director. Even though the research project task is related to a specific Domain, the research project should have an inter-disciplinary approach.

The workload mainly consists of performing research, analysis and development on the chosen subject. The methods and results of the research project lead to a written report that also needs to be presented orally.

The research project workload also includes a number of meetings with the research project Director where the research project development and implementation are discussed and followed-up, up to the final writing of the report and the oral defence preparation.

6.6.3 Research project assessment

Overall, the workload of the research project represents about 750 hours of effective individual work on a sandwich-course format and amounts to 30 ECTS credits.

The research project assessment grade is the average grade of three compensable grades as described in the Annex 2 and in Annex 3.

6.6.4 Research project organisation

A research project agreement is established between:

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

In particular, the research project agreement indicates 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 to be followed by the Trainee at the research project placement

6.6.5 Additional specific rules for professionals

Eu2P Master Trainees currently employed complete the same educational requirements relating to the research project. All parties agree that such Trainees can carry out their research project on their current employer's premises.

7 Academic progress and assessment of Trainees

7.1 Examiners

(1) Each Module coordinator appoints the examiners -including him/herself- and assistant examiners for the individual examinations relating to that Module. The Module examination is conducted under the respective coordinator responsibility, according to the assessment rules of the University to which the Module coordinator belongs and in accordance with the rules set in section 7.3.

(2) Only academic persons who hold a Master degree or a comparable degree or a professional expertise in the module related topics can be appointed as an examiner. Such examiners are in charge of a training session related the particular Module on their own authority. Each Academic Partner is responsible for ensuring that staff meets these requirements.

(3) For the research project evaluation, a specific panel of two examiners is appointed by the concerned members of the Eu2P Programme Examination Board.

The research project periods and respective works are assessed according to the rules set in the Annex 2 and in Annex 3.

(4) The examiners are bound to uphold confidentiality.

7.2 The Eu2P Programme External Examiner

A Eu2P Programme External Examiner is appointed by the University of Hertfordshire (UH) to have oversight of the whole programme assessment and ensure that it has been undertaken in a manner which is equitable to the individual Trainee and that the standards of the different Eu2P Academic Partners' awards are maintained.

The Eu2P Programme External Examiner has to:

- Attend all meetings of Programme Examination Board at which confirmation of progression from Year 1 to Year 2 of the programme and of the award of a Master's Degree are made,
- Be consulted about and agree to any proposed major changes to the assessment or programme regulations which directly affect all Trainees,
- Require assurance that the form and content of proposed assessments have been approved by the Modules coordinators,
- Be satisfied that recommendations for awards are consistent and fair,
- Participate in discussions on individual students,
- Compare the performance of Eu2P Trainees with those on Masters programmes elsewhere,
- Approve and moderate the form and content of proposed assessments where appropriate, and have the right to see all relevant examination scripts,
- Sample Research Project assessments in accordance with the Eu2P Standard Operating Procedure: the "Module External Review of Assessment Policy",
- Where appropriate, take part in forms of assessment,
- Ensure that the assessments are conducted in accordance with the regulations for the Modules,
- Report to the Programme Examination Board annually on the conduct of assessments and on issues relating to assessment across all partners.

Full and serious consideration is given by the Programme Examination Board to the comments and recommendations contained within the report of the Programme External Examiner, and the outcomes of the consideration, including actions taken, shall be formally recorded.

The Programme Examination Board ensures that the Eu2P External Examiner is, within a reasonable time, provided with a considered response to his/her comments and recommendations, including information on any actions taken by the Eu2P Consortium.

Each of the Eu2P Academic Partners agrees to cooperate reasonably and timely to support the responsibilities of the Programme External Examiner.

7.3 UH Modules External Examiner

In addition to the Eu2P Programme External Examiner, a specific UH Modules External Examiner is appointed by the University of Hertfordshire (UH) to ensure that the assessment and academic standards in the Modules UH is in charge of, are appropriate and to the standard required by the University of Hertfordshire. Remuneration for the specific UH Modules External Examiner is at the rates paid by the University of Hertfordshire. UH is responsible for the UH Modules External Examiner fee.

In particular, the UH Modules External Examiner has to:

- Approve and moderate the form and content of proposed assessments where appropriate, and have the right to see all relevant examination scripts,
- Sample major UH Modules assessments,
- Where appropriate, take part in forms of assessment,
- Be consulted about any proposed changes to the assessment regulations which directly affect Trainees currently on the Modules,
- Have the right to recommend changes to the marks awarded by the internal Modules examiners,
- Ensure that the assessments are conducted in accordance with the regulations for the Modules;
- Report to UH annually on the conduct of assessments and on issues relating to assessment and academic standards in the UH Modules.

UH agrees to cooperate reasonably and timely to support the responsibilities of the UH Modules External Examiner.

7.4 Assessment, grading system and pass requirements for the Master assessment process

7.4.1 General rules of assessment

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 works flank the course of study and have to be completed within the standard period of study.

The Trainee has to defend his/her Master year one or year two research project within the deadline fixed in the Eu2P calendar defined each year by the Executive Board.

All Module-specific assessments and research project reports/oral presentations have to be conducted in English.

The grade for each Module assessment is determined by the respective Module coordinator, based on his/her local grading system. All Eu2P Academic Partners responsible for modules need to have marks agreed and approved at their respective institution.

Grades for each of the Modules of the Master year 1 and year 2 are then converted into the Eu2P ECTS grading system according to a specific table approved each year by the Eu2P Executive Board (cf. Annex 2).

Module coordinators collect all the grades granted in their related Module assessment and forward them to the Eu2P Central Office for compilation per Trainee, which are transmitted to the Programme Examination Board.

The Programme Examination Board reviews once a year the assessment process in accordance with the deadline fixed by the annual Eu2P calendar.

Following the Programme Examination Board review, Trainees are informed by the Eu2P Central Office of progression and award outcomes.

The Programme Examination Board decides the method of notification, giving due consideration to data protection requirements relevant in Europe and each national jurisdiction.

7.4.2 Specific additional rules for the research project assessment

Specific rules for the research project assessment are defined in the Annex 2.

7.4.3 Master year 1 final grade

Trainees satisfy the requirements for the Eu2P Master year 1 assessment process when they have obtained at least a pass assessment for each of the Modules as well as for the Master year 1 research project (See section 7.5 in case of failed Module or research project examinations.)

The successful first year Trainees are then allowed to enter the 2nd year of the Master.

7.4.4 Full Master grade

The Université de Bordeaux as coordinator collects via the Eu2P Central Office the results from the Eu2P Academic Partners and certifies to the Eu2P Programme Examination Board the outcome of the assessments of each candidate.

Trainees satisfy the requirements for the Eu2P Master assessment process when they have obtained at least a pass assessment for each of the Modules they are registered on, as well as for the Master year 2 research project.

The Trainee is awarded a Master degree "with distinction" if s/he has met all following requirements (see Grade equivalency table in Annex 2).

- The Trainee must have achieved a grade A in at least 80% of their modules.
- The Trainee must have passed all the assessments only with grades A and/or B
- The Trainee must have passed all the assessments without any retake
- The Trainee must have achieved at least a grade A in the Master year 2 research project.

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 achieved a Grade B or above in at least 80% of their modules.
- The Trainee must have achieved at least a grade B in the Master Year 2 Research Project.

Standard period of study

- 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),
- The annual standard period may be extended to two academic years. The annual standard period may be extended by the Programme Examination Board taking into account exceptional circumstances duly evidenced by the Trainee (e.g. long illness...).
- In any case, the maximal duration of registration for each of the Master year 1 and the Master year 2 curriculum should not exceed three academic years.

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

7.5 Referral and re-enrolment on Modules

7.5.1 Modules assessment failure

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.

Re-enrolment is defined as the opportunity for a Trainee to repeat a module that was previously failed at first and second attempt.

The trainee may also wish to drop this failed Module and enrol into a different Module in order to complement the Master Curriculum.

In case of re-enrolment, the Trainee will have to pay fees for this new Module enrolment at the student rate.

Details on the referral and re-enrolment regulations are set out in the Annex 3.

7.5.2 Research project assessment

Should a Trainee's research project work (year 1 and/or year 2) be given an F grade in accordance with Eu2P Master common grading, the Trainee may be advised once to revise and resubmit or write another report. Such re-assessment possibilities should, as a regular rule, take place within the common calendar deadline set up in the annual Eu2P calendar.

Details on the re-assessment regulations are set out in the Annex 3.

8 Trainees' rights and responsibilities

Each Trainee is provided by the Eu2P Central Office with a Eu2P Trainee's set of Regulations drawn up by the Consortium and listing the rights and responsibilities of Trainees with reference to the academic component as well as the administrative requirements and the services available. The Trainee Regulations – Master Trainee's code of rights and responsibilities- that constitute the Annex 3 to this Agreement must be endorsed by the Trainee.

The procedure concerning Trainees' complaints and appeals is detailed in the Regulations; as a general rule, complaints relating to a specific Module are treated according to the local Module-coordinating university regulations.

8.1 Complaints

- The Trainee wishing to complain about a specific training, service or facility provided by a given Eu2P Academic Partner must invoke the complaint procedure of that institution.
- The Trainee wishing to complain about the Trainee's selection and /or overall organisation of the Master must address her/his complaint to the Executive Board.
- In the event that a Trainee has his or her request dismissed by the Executive Board then the Trainee may, in limited circumstances, make representations to the Vice-Chancellor or nominee at the Université de Bordeaux.
- A Trainee may have access to the United-Kingdom Office of Independent Adjudicator (OIA) wherein the Trainee may request review of the complaint made within the Eu2P Consortium. In the event a Trainee does have access to the OIA, all Academic Partners, and as many as may be appropriate all Associated Partners, agree to cooperate with the process implemented by the OIA.

8.2 Appeals

- The Trainee wishing to appeal against a decision relating to the assessment process within the remit of a specific module must invoke the appeals procedure of the given Eu2P Academic Partner 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 must submit the request in writing to the Chair of the Executive Board.
- In the event that a Trainee has his or her request dismissed by the Executive board then the Trainee may, in limited circumstances, make representations to the Vice-Chancellor or nominee at the Université de Bordeaux.
- A Trainee may have access to the United-Kingdom Office of Independent Adjudicator (OIA) wherein the Trainee may request review of the complaint made within the Eu2P Consortium. In the event a Trainee does have access to the OIA, all Academic Partners, and as many as may be appropriate all Associated Partners, agree to cooperate with the process implemented by the OIA.

9 Mutual recognition within the consortium and the final degree

9.1 Master degree award

Modules following the requirements of Annex 1 and completed under the control of a Eu2P Academic Partner are automatically and fully recognised by all other Eu2P Academic Partners. Provided the terms of this Diploma agreement have been adhered to by all parties, each of the Eu2P Academic Partners agree to recognize the decision made by each of them about the Modules completion and assessment.

Decisions relating to assessment and completion are communicated to all Eu2P Academic Partners with the help of the Eu2P Central Office and of the Eu2P Programme Examination Board.

The Trainees admitted into the Eu2P Master and having successfully completed the Master assessment requirements shall be awarded a joint Master degree from the awarding Eu2P Academic Partners.

Such a single 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 awarding Eu2P Academic Partners.

It is the individual obligation of each of the awarding Eu2P Academic Partners to ensure that the Eu2P Master is awarded and recognised in its respective country by their relevant accreditation bodies.

The joint diploma is printed and issued by the Université de Bordeaux. It is signed by the co-awarding Eu2P Academic Partners Presidents / Rectors and when necessary, by local authorities.

The template of the joint Master degree is annexed to this Agreement as the Annex 5.

In the event that the award of the joint diploma by all Eu2P Academic Partners is not made possible, it is agreed by all the Parties that the Eu2P Academic Partners that are entitled to do so, award and issue the joint Eu2P Master degree to the successful Trainees.

Along the joint Eu2P Master degree, a Eu2P diploma supplement giving all details on the curriculum, the Eu2P consortium partnership & training collaborations is printed and issued by the Université de Bordeaux and shall be signed by all Eu2P Academic Partners and include their logos.

9.2 European Diploma Supplement

A European Diploma Supplement (DS) in English is delivered to successful Eu2P Trainees to improve international transparency and facilitate the academic and professional recognition of qualifications. The DS corresponds to the standard European document according to standards agreed by the European Commission, the Council of Europe and UNESCO (now part of the Europass tools- <https://europa.eu/europass/en/learn-europe/diploma-supplement>). It is issued alongside the Master degree diploma to provide a detailed description of the qualification. 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 a joint award issued by the Eu2P Consortium.

10 Financial Management

10.1 Master Financial management

The Eu2P Master Financial statement, called the Annex 1 to this Agreement, is an annually revised document describing the financial management principles and rules related to Eu2P Master activities.

This document is established in the respect of the following Eu2P values:

- To behave as a non-profit organization,
- To be transparent regarding the programme costs and incomes fluctuations,
- To make sure fair and coherent incomes distribution is performed between the Academic Partners and Eu2P Central Office,
- To reach and maintain programme self-sustainability,
- To propose discounts to Trainees associated to the Eu2P Master Consortium members and Associated Partners,
- To offer grants partially covering fees amount to Trainees based on academic merit and research interest.

This document is the basis to annually define:

- How to share Eu2P funding and incomes to cover costs related to the Eu2P expenses of the Eu2P Academic Partners and Eu2P Central Office
- The tuition fees' amounts for the Master Year 1 and Master Year 2
- The grant offer partially covering fees amount for Master Year 1 and Year 2 Trainees and
- The discounts offer for Eu2P Academic and Associated Partners.

10.2 Tuition fees

The Executive Board determines annual tuition fees and may revise them for each new academic cohort.

Annual fees are paid to the Eu2P Coordinating institution through the Eu2P Central Office. The Eu2P Central Office makes the necessary arrangements with each Eu2P Academic Partner Student office to regularize every Trainee's situation.

The Coordinating institution manages and distributes fees according to the principles included in the Annex 1 and to the decisions taken accordingly by the Executive Board.

No additional national/ local tuition and academic fees are charged by any of the Eu2P Academic Partners to the Trainees.

Costs of study, living and travelling are at Trainees' own responsibility.

Each year, the Eu2P Central Office sends to each of the Eu2P Academic Partners a copy of the annual financial report concerning the distribution of the fees.

10.3 Financial support

The Eu2P Master Consortium members use reasonable endeavours to raise funds to run the Eu2P Master degree and to seek financial support for Trainees participating to the Eu2P Master.

The Eu2P Master Consortium members find the means to accompany the Master programme in particular by applying, when possible, for public grants to allow Trainees enrolled in the Master course to complete their training in good conditions. They also make reasonable efforts to be able to offer some partial Eu2P grants on a performance-based system.

11 Services

11.1 Trainee services

Eu2P Academic Partners each agree to provide all reasonable assistance to Trainees helping them with incoming procedures such as finding housing, having access to language courses, libraries, canteens, study rooms and computer facilities or providing help to in-coming Trainees with formalities such as permits of stay (See above section 4.2).

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

Eu2P Academic Partners are encouraged to provide research project placements in line with the Trainee's pedagogical project, in welcoming such Trainee(s) in their premises and providing them with the resources for them to be successful in their research.

11.2 Insurance obligations

Concerning social security & health insurance, Trainees enrolled in the Eu2P Master are informed by the Eu2P Central Office that they are required to follow the rules in force at the hosting institution for the research project and subscribe to a personal insurance.

Trainees can be advised to subscribe an insurance policy to cover medical expenses, maternity, illness or death, transportation back to the applicant home country in case of a serious accident, as well as to cover any consequence of civil liability.

Each Eu2P Academic Partner undertakes to provide appropriate information to Trainees for their registration in the national health system or for the provision of other kinds of health insurance that may be required either before their arrival or once they have registered at the hosting institution.

11.3 Prevention and security

The hosting organization provides the Trainee while on his/her research project at its premises with detailed information about the specific risks existing in the work environment in which s/he operates and carries out his/her functions and shall provide all necessary documentation about the prevention and emergency security measures and provisions in force in relation to his/her activities, in conformity with the legislative norms and regulations in force in the country of the hosting institution.

12 Quality assurance

The Eu2P Master Programme aims at achieving high academic standards, which is supported by robust quality assurance (QA) procedures:

- All Eu2P Academic Partners have overall responsibility for the academic standards and quality of the Programme delivered under this Agreement; this responsibility is exercised and overseen through the Executive Board.
- All Eu2P Academic Partners recognise the equivalence of each Academic Partner's QA procedures. When the Trainee studies under the responsibility of a Module coordinator, the relevant institutional QA protocols of this Module coordinator apply.
- Each Eu2P Academic Partner agrees to cooperate with the quality assurance requirements, validation processes of the other parties, each party covering its own expenses in doing so.

This mutual and cross recognition is based on the following rationale:

- All Eu2P Academic Partners are located in European countries who have signed up to the Bologna Agreement,
- All Eu2P Academic Partners have Master Degree awarding powers,
- All Eu2P Academic Partners have been chosen because of their expertise in the subject.

Moreover, the Eu2P Partners develop and update Quality Guidelines and Standard Operating Procedures that cover the quality items 1 – 7 as described in the ENQA report on "Standards and Guidelines for Quality Assurance in the European Higher Education Area (ESG) 2015" [© European Association for Quality Assurance in Higher Education, 2015, Brussels, Belgium].

In the absence of Eu2P specific quality processes and procedures agreed upon by all Academic Partners, their respective local rules apply.

A cross partner review of Assessments is undertaken by the Eu2P Programme External Examiner (See above section 7.2).

Monitoring of post-graduation career and graduate rate, together with the External Examiners' annual report shall be analysed by the Executive Board with the help of the Eu2P Central Office and used for the Eu2P curriculum improvement.

13 Intellectual Property Rights

13.1 Intellectual property policy within the Consortium

13.1.1 Ownership and use of intellectual property brought in the programme

Any member of the Eu2P Master Consortium may bring in and disclose to other Eu2P Master Consortium members information, including data and know-how that it holds prior to, on or after the accession to this Diploma agreement, as well as copyrights or other intellectual and industrial property rights pertaining to such information. Such information may be disclosed only in so far as it is necessary to implement the Eu2P Master programme.

This is described as "Background" and it is expressly agreed that each member is and will remain the exclusive owner of its own Background and its participation to the Eu2P Master Consortium does not affect such ownership rights in its Background.

Access rights to Background are granted on a non-exclusive, royalty free basis among the Eu2P Master Consortium members, but only for the purposes of and within the framework of the Eu2P training activities.

Any other type of use is a priori forbidden and must be discussed specifically among the concerned parties. Such access rights shall be granted on a non-exclusive basis under fair and reasonable conditions and negotiated between the parties involved as they see fit.

13.1.2 Ownership of intellectual property created under the programme

As a result of the implementation of the Eu2P programme, any member of the Eu2P Master Consortium may generate data, know-how and other information, including rights related to copyrights or other intellectual and industrial property rights.

This is described as "Foreground": Foreground shall belong to the member who generated it under the Eu2P Master Consortium training collaboration.

The Foreground that results from the collaboration contemplated hereunder (typically the training material accessible on the Eu2P e-learning platform) shall belong to all of the Eu2P Master Consortium members.

Access rights to Foreground are granted on a non-exclusive, royalty free basis among the Eu2P Master Consortium members, but only for the purposes of and within the framework of the Eu2P training activities.

Any other type of use is a priori forbidden and must be discussed specifically among the concerned parties. Such Access rights shall be granted on a non-exclusive basis under fair and reasonable conditions and negotiated between the parties involved as they see fit.

13.2 Intellectual property policy in the study framework

13.2.1 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 must 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.

13.2.2 Dissemination of results by Eu2P Academic partners

13.2.2.1 *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.

13.2.2.2 *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.

14 Confidentiality

No confidential information disclosed by any of the Eu2P Master Consortium members (Disclosing Party) to another Master Consortium member (Recipient Party) under this Agreement may be disclosed by the Recipient Party to any third party other than in those circumstances permitted below or used for any purpose other than as set out below.

No Confidential Information of the Disclosing Party may be used by the Recipient Party for any purpose other than the performance of the Recipient Member's obligations or the exercise of the Recipient Member's rights under this Agreement.

"Confidential Information" shall mean know-how, data and other information (written or oral) provided in pursuance of this agreement or concerning the business and affairs of a party to this agreement. Confidential Information does not include information that:

- Is, at the time of communication, in the public domain
- After the communication, becomes part of the public domain by publication or other lawful means
- Is obtained from a third party not in breach of any obligation of confidentiality; or
- Is known by the Recipient Party prior to the date of the communication; or
- Is required to be disclosed pursuant to any applicable law or judicial or governmental order; or
- Was lawfully in the Recipient Party's possession before receipt and/or was independently developed by any student, employee, and/or agent of the Recipient Party who had no access to the Disclosing Party's Confidential Information and where the independent development can be proven.

The provisions of this Clause 14 survive the expiry or earlier termination (for whatever reason) of this Agreement, or the termination of the participation of a Party, for a period of five (5) years from such expiry or termination, or such longer period as agreed between the Parties.

15 Liabilities of the participants

For the carrying out of the Eu2P Master programme as detailed in the Annex 2, none of the Master Consortium members are, without prior written consent of the other members, entitled to perform any of its obligations through any other institution or entity or otherwise delegate any of its obligations hereunder.

Each Master Consortium member complies with all applicable laws, statutes, and regulations of a governmental nature relating to the operation of the Eu2P Master programme under this Diploma agreement.

Each Master Consortium member is solely liable towards the other Master Consortium members and toward third parties for loss, destruction, damage or injury resulting directly from its own actions in the execution of this Diploma agreement. In no event shall a Master Consortium member be liable to any other member, whether in contract or tort, for any incidental, indirect, consequential, or unforeseeable loss, destruction, damage or injury (including, without limitation, loss of profits or revenue).

Except with respect to a Master Consortium member's breach of its confidentiality obligations or in case of a violation of intellectual property, to the maximum extent permitted under applicable law, a party's liability for breach of contract however arising, out of or in connection with this agreement shall be capped to twenty-five thousand (€25,000) euros.

Each Master Consortium member is fully responsible for the performance of any part of its share of the Diploma agreement and for the requirements of insurance and social security for its personnel, involved herein.

However, neither Master Consortium member is liable for failure to perform its obligations under this agreement if such failure results from circumstances, which are beyond the member's reasonable control.

No member of the Eu2P Master Consortium shall have any liability to another member for any costs, expenses or other liabilities incurred by a member of the Eu2P Master Consortium in relation to the performance of the Master programme activities. For the avoidance of doubt, there is no joint and several liabilities under this Agreement.

The Master Consortium members remain independent of one another and nothing in this Diploma agreement is construed or interpreted, by implication or otherwise, to form a partnership, agency, joint venture or other formal business association.

The Master Consortium members undertake to cooperate with any of the other members in relation to the compliance of such member with the requirement of any public security local laws (in particular as regards the provision of such information as may be requested). For the avoidance of doubt, each member shall be solely liable for its compliance with the requirement of any public security local laws.

16 Duration and Termination

16.1 Duration and termination

This Diploma agreement enters into force from July 1st 2024.

This Diploma agreement remains into force until June 30th 2028 and may then be renewed upon written agreement of all of the Parties for subsequent terms of 48 months.

Any Party wishing to withdraw from the Diploma agreement and terminate its participation in it must notify the other Parties in writing through the Executive Board with a notice of one year before each yearly Master application calendar.

All the Eu2P Academic Partners, including the departing one(s), agree to bear the responsibility for the teaching, supervision, guidance and other services required for the successful completion of studies of the Trainees admitted to the related programme, having been admitted prior to notice to terminate the relevant Diploma agreement, including but not limited to for the Trainees admitted on a part-time basis.

Departing members (whether as Eu2P Academic Partner or as an Associated Partner) do not affect the validity of this Agreement between the remaining Eu2P Master Consortium members unless the Executive Board decides otherwise.

The Executive Board in this case decides on the re-organisation of tasks and responsibilities regarding the Modules and research projects organisation.

16.2 Changes to the Diploma agreement terms

Any Eu2P Master Consortium members wishing to make changes to the Diploma agreement must notify the other Parties in writing through the Executive Board: any change to the Diploma agreement shall require a written agreement, validated by a unanimous decision reached by at least all the Academic Partners in the Executive Board before such change can be considered as agreed to be implemented. The changes shall be formalised through an amendment then signed by the Eu2P Coordinating institution legal representative.

17 New Partners

17.1 New Academic Partners

New Higher Education Institutions may be incorporated into the Master Consortium to participate to the Eu2P Master Agreement as a Eu2P Academic Partner upon decision of the Executive Board as long as they satisfy requirements above included in section 12. Such membership must be validly ratified through an amendment to this Agreement signed by the Coordinating Institution representative, duly authorised to do so by the Executive Board. All relevant terms deriving from this Diploma agreement must directly apply to the new Academic Partner.

The Executive Board must in this case decide on the re-organisation of tasks and responsibilities regarding the Modules and research projects organisation: in such case the *Annexes 1 and 2* must in particular be accordingly updated.

17.2 New Associated Partners

New Private or Public organisations may be incorporated into the Consortium as a Eu2P Associated Partner upon decision of the Executive Board. Such membership must be validly ratified by way of an Accession form to this Agreement signed by the Coordinating Institution representative, duly authorised to do so by the Executive Board. This form must detail the terms of the engagement, in particular as regards the activities related to this Diploma agreement. A template of the Accession form is annexed to the Eu2P Master Agreement (*Annex 4*). All relevant terms deriving from this Diploma agreement must directly apply to the new Eu2P Associated Partner.

17.3 Additional category of new partners: Course Provide Partners

New other partners, distinct from Academic or Associated ones, that may participate in the training and tutoring activities under the pedagogical responsibility of one or several Eu2P Academic Partner(s) may be incorporated into the Consortium as a Course Provider Partner upon decision of the Executive Board. Such membership would need to be validly ratified by way of an accession form to this Agreement signed by the Coordinating Institution representative, duly authorised to do so by the Executive Board.

18 Application of law and dispute resolution

If any dispute arises between any of the Eu2P Master Consortium members, they shall in good faith attempt to negotiate a settlement between them and if unsuccessful through the intermediary of the Executive Board.

If still unsuccessful, they shall in good faith attempt a resolution through an alternative dispute resolution procedure commissioned by the Executive Board.

Should the disagreement persist and no amicable agreement is reached within a period of sixty (60) days, the matter shall be referred to the Courts having jurisdiction in the country where the defendant has its registered office. Each member of the Eu2P Master Consortium has the right to apply to any court of competent jurisdiction for injunctive relief, including injunctions, and any such request shall not be deemed incompatible with this dispute amicable resolution proceeding

This Agreement is governed by and interpreted in accordance with the law of France.

19 Signatures

This Agreement may be entered into by the Eu2P Master Consortium members on separate counterparts, each of which so executed and delivered shall be an original, but all the counterparts shall together constitute one and the same instrument.

This Agreement is drafted in English but can be translated for local and information purpose.

As witness the Eu2P Master Consortium members have caused this Diploma agreement, together with the *Annexes 1 to 5*, to be duly signed by the undersigned authorised representatives as follows:

Authorised to sign on behalf of:

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM (EMC)

Name: Prof. dr. Stefan Sleijfer

Title: Dean of the Board

Date:

Signature with stamp

Authorised to sign on behalf of:

UNIVERSITA DEGLI STUDI DELLA CAMPANIA LUIGI VANVITELLI (UNICAMPANIA)

Name: Prof. Giovanni Francesco NICOLETTI

Title: Rector

Date:

Signature with stamp:

Authorised to sign on behalf of:

UNIVERSITAT AUTÒNOMA DE BARCELONA (UAB)

Name: Dra. Margarita Arboix Arzo

Title: Rector

Date:

Signature with stamp:

Authorised to sign on behalf of:

THE COORDINATOR UNIVERSITÉ DE BORDEAUX (UB)

Name: Prof. Dean Lewis

Title: President

Date:

Signature with stamp:

Authorised to sign on behalf of:

UNIVERSITEIT UTRECHT (UU)

Name: Prof. dr. I.W.C.E. Arends

Title: Dean of the Faculty of Science

Date:

Signature with stamp:

Authorised to sign on behalf of:

UNIVERSITY OF HERTFORDSHIRE HIGHER EDUCATION CORPORATION (UH)

Name: Prof. Quintin McKellar

Title: Vice-Chancellor

Date:

Signature with stamp:

Authorised to sign on behalf of:

BAYER AG (BAYER)

Name: Montse Soriano Gabarró

Title: Head Partnerships and Integrated Evidence Generation Office

Date:

Signature with stamp:

Authorised to sign on behalf of:

CYTEL

Name:

Title:

Date:

Signature with stamp:

Authorised to sign on behalf of:

Jazz Pharmaceuticals

Name: Rajbinder Bhogal

Title: Sr. Director, R&D Business Strategy & Operations

Date:

Signature with stamp:

Authorised to sign on behalf of:

SANOFI-AVENTIS RECHERCHE & DEVELOPPEMENT (Sanofi)

Name: Catherine BAILLIS

Title: VP & Head, Epidemiology and Benefit-Risk

Date:

Signature with stamp:

Authorised to sign on behalf of:

TAKEDA

Name: Véronique Kugener

Title: Senior Vice-President

Date:

Signature with stamp: