



AGREEMENT FOR JOINT CERTIFICATES IN PHARMACOVIGILANCE AND PHARMAEOPIDEMOLOGY

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Agreement for joint Certificates in Pharmacovigilance and Pharmacoepidemiology (Eu2P Certificates)

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 (Cerdanya del Vallès), Spain hereby represented by its Rector 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

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

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,

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 XXXXXXX

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,

AND

The International Society of Pharmacovigilance (ISoP) whose administrative offices are at 140 Emmanuel Road, London SW120HS, United Kingdom, represented by Angela Caro,

Acting as a Eu2P Course Provider Partner,

The Eu2P Academic Partners, the Eu2P Associated Partners and the Eu2P Course Provider Partners forming altogether the Eu2P Certificates 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 a Certificates agreement detailing this new course organisation set up, that entered into force on July 1st 2016, and which has since been renewed, also integrating new partners.

The Eu2P Academic Partners have kept jointly delivering and awarding the Eu2P joint Certificates in Pharmacovigilance and Pharmacoepidemiology.

The Eu2P Associated Partners also agreed to enter into the Certificates agreement as they may, under the pedagogical responsibility of the Eu2P Academic Partners, be involved in the operational activities relating to the training, administrative, legal, communication and financial activities of the Eu2P Consortium activities.

New external public or private bodies are also welcome to participate to the Certificates programme as "Associated or Course Provider Partner" by way of signing an Accession Form that would detail the terms of such engagement.

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 updated Certificates agreement.

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.

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

Annex 1: Financial aspects

The financial aspects of the Eu2P Certificates programme are provided in this agreement *Annex 1*.

Annex 2: Eu2P Certificates curriculum

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

The specific common Eu2P policies that were originally drawn up through the initial development of the Eu2P Certificates under the IMI JU umbrella are updated where needed and still utilised by the Parties as defined in this agreement, to implement the organisation of the Eu2P Certificates.

Annex 3: Trainees codes of rights and responsibilities

In relation to the Trainees, the *Annex 3* gathers the Certificates 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 Certificates Consortium and an external public or private body that wishes to be part of the Eu2P Certificates Consortium as an additional Associated Partner.

Annex 5: Accession Form for Course Provider Partner

This is a template for a legally binding document to be signed between the Eu2P Certificates Consortium and an individual or a public or private body that wishes to be part of the Eu2P Certificates Consortium as a Course Provider Partner.

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 Certificates Consortium and an external public or private body that joins the Eu2P Certificates Consortium as an Associated Partner. A template of an Accession Form is annexed to the present Certificates 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 Certificates programme.

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

“Annex 3” means the Certificates 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 a template for a legally binding document signed between the Eu2P Certificates Consortium and an individual or external public or private body that wishes to be part of the Eu2P Certificates Consortium as a Course Provider Partner. A template is annexed to the present Certificates Agreement. It constitutes the Annex 5.

“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 Consortium” or “Consortium” means the gathering of all Academic Partners, Associated Partners and Course Provider Partners involved in the Eu2P programme (European training and research programme in Pharmacovigilance and Pharmacoepidemiology), 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.

“Eu2P Certificates Consortium” means the gathering of all Academic Partners, Associated Partners and Course Provider Partners involved in the Eu2P Certificates 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.

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

“Eu2P Master Consortium” means the gathering of all Academic Partners, Associated Partners and Course Provider Partners involved in the Eu2P Master 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.

“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 workload.

“Eu2P Memorandum of Understanding” or “Eu2P MoU” is the general agreement signed between the members of the Eu2P Consortium for a 5 years duration and effective on July 1st 2016, that gives the new framework of collaboration to implement concrete training and research activities, by way of additional agreements such as this Certificates 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 Partners, Associated Partner(s) and Course Provider Partner(s) having signed the present Certificates Agreement.

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

“Programme Examination Board” means the board set up to ensure that the Certificates assessment process is conducted in accordance with Eu2P own regulations and with each University Module Coordinator local rules. The Board will approve grade translation, progression and award.

“Student” means a Trainee enrolled in the Eu2P Certificates 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 Certificates 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 et L 613-2 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 deliberation of UB Board of Director dated December 13, 2021 delegating power to the President of the University,
- Having regard to the deliberation 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 Master 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 Certificates. 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) and the Course Provider Partners

The Academic Partners shall perform and complete their share of the Eu2P Certificates programme in accordance with the requirements and Modules coordination share set out in the Annex 2. The Course Provider Partners participate in the preparation, delivery, tutoring and assessment of the Eu2P Certificate programme under the responsibility of one or several of the Academic Partners, as set out in the Annex 2.

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

- The delivery and promotion of the Eu2P Certificates programme
- The performing and supervision of all necessary accreditation steps (through local or national accreditation procedures) in order to jointly award the Certificate diplomas.
- The management of the funds collected and distributed by the Coordinating institution
- Regarding the Trainees:
 - Academic admission and registration
 - Advice on insurance obligations such as detailed in section 11.2

Each Course Provider Partner shall organise and implement its share in the Eu2P Certificates programme activities, and specifically:

- The delivery and promotion of the Eu2P Certificates programme in agreement with the Academic Partner(s) it is related to
- The management of the funds collected and distributed by the Coordinating institution
- Regarding the Trainees:
 - Tutoring and assessment in respect to the training activities the Course Provider Partner is in charge of.

Financial aspects relating to the management, share and use of the Certificates activities derived income between the Academic Partners and the Course Provider 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 Certificates Consortium members upon decision of the Executive Board, and without the need to renegotiate the whole Eu2P Certificates Agreement.

Each Academic Partner and each Course Provider Partner shall be responsible for its own training cost deriving from the Certificates programme implementation.

4.3 The Associated Partners

The description of the commitments and benefits for Associated Partners to be part of the Eu2P Certificates Consortium 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 Certificates Consortium members upon decision of the Executive Board, and without the need to renegotiate the whole Eu2P Certificates 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 Certificates, the Executive Board shall be responsible for its organisation and the collaboration within the Eu2P 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 Certificates registration features e.g., tuition fees,
- To deal with all financial aspects of the Eu2P Certificates programme, including financial relationships between the Eu2P partners
- 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 Certificates 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.

The member representing the Coordinating organisation shall act as the chairman 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 Programme 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.
- Representatives 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 representatives 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-month's prior notice.

(6) Decisions of the Executive Board relating to the Certificates agreement implementation

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 Course Provider Partners have voting rights except for any decision relating to Master Trainees' selection, grading equivalence table, academic quality and award of academic diplomas.
- 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 and the Course Provider Partner.

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

4.4.2 The Domain Boards

(1) One Domain Board shall be established for Certificates relating to each one of the Eu2P Domains.

(2) Each Domain Board tasks shall include:

- To check, in case of difficulty, the applications to the Eu2P Certificates depending of that Domain which have not been treated first by the Eu2P Central Office,
- According to the general educational outline defined by the Executive Board, to organise the consistency of the Modules general organization within such domain,
- To report to the Executive Board on the selection process within one month following each Certificate application session.

(3) Each Domain Board is comprised of:

- The Domain director
- The related Modules coordinators.

The chairman will be the Domain director.

A deputy shall be appointed by the relevant Eu2P Partners institutions for each of the members of the Board. Such deputy must belong to the same organisation than the one of the main member. Notice of a permanent change affecting a member of a Domain Board shall be given at least two months in advance to the chairman.

Changes in the name of a member will not affect the validity of the composition of a given Domain Board.

(4) Decisions of the Domain Boards are normally taken by consensus. In the event that efforts to reach consensus fail, the Domain 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 vote.

(5) Frequency of meetings

During each Certificates application session: each Domain Board shall meet once to select the related Certificates candidates.

Additional meetings may be convened by each Domain Board chairman with at least a one-month notice.

(6) Organisations of meetings

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

Meetings are closed to the public. Members of each Domain Board, their deputies, the examiners and assistant examiners shall observe confidentiality for the meeting's proceedings.

In order for a Domain Board meeting to be quorate there shall be present or duly represented 75% of its members.

When a Domain Board meeting shall be inquorate, the chairman shall reconvene the Board members at a date no later than 14 calendar days from the date of the original meeting.

4.4.3 The Eu2P Programme Examination Board

(1) A joint Eu2P Programme Examination Board (the "Programme Examination Board") is established for the Eu2P training programmes. The Programme Examination Board shall ensure that the 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 define and update the Study regulations
- To define and update the assessment regulations, including the modalities to be fulfilled by Trainees for completing the Eu2P Certificates Programme
- To receive the approved Modules assessment results from the relevant Domain Directors
- To consider the assessment results achieved by Trainees, and to confirm the award of a Certificate
- To define and update the Eu2P External Examiner policy (cf. Section 7.2)
- 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 the award of a Certificate. 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 Certificates, the Eu2P Central Office takes charge of the management and coordination of the overall Eu2P Certificates 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, Certificate trainees' selection & overall database
- Trainer services
- Trainee services
- Examinations organisation and results collection
- Diploma delivery
- Fees (collection, redistribution)
- 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 Certificates 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 Certificates 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, online payment, Trainee admission, 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 a Eu2P Certificate are described in the Annex 2 of this Certificates agreement.

6.2 Application calendar

The Executive Board defines each year the application calendar to be followed by Eu2P applicants. Calls for application shall be organized throughout the year according to the Eu2P calendar that will be defined each year by the Executive Board. Potential Trainees will be informed of the calendar on the Eu2P website.

6.3 Criteria for admission

6.3.1 Common selection criteria for Trainees

The following criteria are used in the selection of Trainees:

- 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
- Most 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 Depending on the Module pre-requisites

- Compliance with a prior university degree level, a relevant professional experience or the prior and successful completion of a given Eu2P Module, as provided in the Annex 2.

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

6.4 Selection procedure

Each Domain Board shall review all complete applications received for its Module-related Certificates.

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 to applicants selected by the relevant Domain Boards.

Trainees are only registered when:

- They have paid for the corresponding fees, or have committed to pay in several instalments along the duration of the course. In the latter case, they will need to have paid the first instalment before the starting date of the course in order to be registered.

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

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

The Eu2P Certificates 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.

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 Certificates Consortium shall make all reasonable attempts to accommodate Trainees wherever possible.

6.5 Enrolment of Trainees

Once selected by the Executive Board and payment of the 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 Certificates agreement; to allow such process, the Eu2P Central Office forwards all necessary information for registration to take place.

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 Module 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 those 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) The examiners are bound to uphold confidentiality.

7.2 The Eu2P Programme External Examiner

The Eu2P Programme External Examiner is appointed by the University of Hertfordshire (UH) within the Eu2P Master programme and shall provide useful comments and recommendations for the Certificates programme.

The annual Programme External Examiner report will be carefully considered by the Eu2P Examination Board concerning the Certificates assessment process.

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 UH 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 Certificates assessment process

7.4.1 General rules of assessment

The Eu2P Certificates assessment process encompasses grade-based and pass / fail assessment in the corresponding Module(s).

All Module-specific assessments 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 are then converted into the Eu2P ECTS grading system according to a specific table approved each year by the Eu2P Examination Board (cf. Annex 2).

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

The Examination Board shall review the assessment process after each "Modules assessment session" and confirm the award of a Eu2P Certificate to the successful ones within 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 Standard period of study

- The standard period of study for one Certificate will be set up in advance by the Module-related coordinator and according to the Eu2P Calendar defined each year by the Executive Board. Trainees will be informed of such period of study on applying for that Certificate.

As a general rule:

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

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

7.5 Referral and re-enrolment on Modules

Referral is defined as a reassessment opportunity for Trainees who have been unsuccessful at their first attempt (that is, students who have received an F grade). Trainees who are successful in referred assessments will be awarded a capped module grade of 50%, a C Pass Grade.

A Trainee has definitely failed the Certificate assessment process when he/she fails to earn any ECTS credit points in the last permissible repeat of a module, making it impossible to earn the number of ECTS credits required for the given Module.

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

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.

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 – Certificate 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 Certificates programme 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 Certificates Consortium and the Certificate award

Modules Certificates 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 Certificates and having successfully completed the assessment requirements for each Certificate shall be awarded a joint Certificate from the Eu2P Academic Partners with specific reference to the number of ECTS credits being validated by the Eu2P Academic Partners.

Such a single joint Certificate is recognised in each of the issuing Eu2P Academic Partners countries following completion of all recognition processes in each of countries involved.

The Eu2P joint Certificate award is made under the individual legal responsibility of the awarding Eu2P Academic Partners.

It is the individual obligation of each Eu2P Academic Partner to ensure that the Eu2P Certificate is awarded and recognised in its respective country by their relevant accreditation bodies if such accreditation level needed by their local regulations. In case the formal recognition is not achieved in time by any of the issuing Academic Partners, such Partner will in any case recognise the Certificate and offer exemptions for comparable Modules in their own local programmes.

The joint Certificate is printed and issued by the Université de Bordeaux. It is signed by the Examination Board Chairman and includes the logos of all Eu2P Academic Partners.

The title of the Certificate is the following: "Certificate in (Domain Name) + (Module name) + number of ECTS credits validated".

10 Financial Management

10.1 Certificates Financial management

The Eu2P Certificates Financial statement, called the Annex 1 to this Agreement, is an annually revised document describing the financial management principles and rules related to Eu2P Certificates 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, the Eu2P Course Provider Partners and Eu2P Central Office,
- To reach and maintain programme self-sustainability,
- To propose discounts to Trainees associated to the Eu2P Academic Partners and Associated Partners.

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, the Eu2P Course Provider Partners and Eu2P Central Office
- The tuition fees' amount for the Certificates,
- The discounts offer for Eu2P Academic Partners and Associated Partners.

10.2 Tuition fees

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

Tuition 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 and to the Eu2P Course Provider Partners a copy of the annual financial report concerning the distribution of the fees.

10.3 Financial support

The Eu2P Certificates Consortium members uses reasonable endeavours to raise funds to run the Eu2P Certificates programme.

11 Insurance obligations

Concerning social security & health insurance, Trainees enrolled in the Eu2P Certificates programme are informed by the Eu2P Central Office that they are required to subscribe to a personal insurance covering any consequences of health problems, accident or civil liability.

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.

12 Quality assurance

The Eu2P Certificates 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 Masters 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 within the Certificates Consortium

13.1 Ownership and use of intellectual property brought in the programme

Any member of the Eu2P Certificates Consortium may bring in and disclose to other Eu2P Certificates 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 Certificates 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 Certificates 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 Certificates 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 Ownership of intellectual property created under the programme

As a result of the implementation of the Eu2P programme, any member of the Eu2P Certificates 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 Certificates 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 Certificates Consortium members.

Access rights to Foreground are granted on a non-exclusive, royalty free basis among the Eu2P Certificates 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.

14 Confidentiality

No confidential information disclosed by any of the Eu2P Certificates Consortium members (Disclosing Party) to another Certificates 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 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 Member 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 Member's possession before receipt and/or was independently developed by any student, employee, and/or agent of the Recipient Participant who had no access to the Disclosing Participant'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 member, for a period of five (5) years from such expiry or termination, or such longer period as agreed between the members.

15 Liabilities of the participants

For the carrying out of the Eu2P Certificates programme as detailed in the Annex 2, none of the Certificates 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 Certificates Consortium member complies with all applicable laws, statutes, and regulations of a governmental nature relating to the operation of the Eu2P Certificates programme under this Diploma agreement.

Each Certificates Consortium member is solely liable towards the other Certificates 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 Certificates 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 Certificates 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 Certificates Consortium member is fully responsible for the performance of any part of its share of the Certificates agreement and for the requirements of insurance and social security for its personnel, involved herein.

However, neither Certificates 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 Certificates Consortium shall have any liability to another member for any costs, expenses or other liabilities incurred by a member of the Eu2P Certificates Consortium in relation to the performance of the Certificates programme activities. For the avoidance of doubt, there is no joint and several liabilities under this Agreement.

The Certificates 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 Certificate 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 six months before the suggested changes go into effect.

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, having been admitted prior to notice to terminate the relevant Diploma agreement.

Departing members (whether as Eu2P Academic Partner, Course Provider Partner or as Associated Partner) does not affect the validity of this Agreement between the remaining Eu2P Certificates 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 organisation.

16.2 Changes to the Diploma agreement terms

Any Eu2P Certificates 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 at least by 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 Academic, Course Provider or Associated Partners

17.1 New Academic Partners

New Higher Education Institutions may be incorporated into the Certificates Consortium to participate to the Eu2P Certificates 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 Certificate Agreement (*Annex 4*). All relevant terms deriving from this Diploma agreement must directly apply to the new Eu2P Associated Partner.

17.3 New Course Provider Partners

Individuals, or new private or public organisations may be incorporated into the Consortium as a Eu2P Course Provider 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 Certificate Agreement (*Annex 5*). All relevant terms deriving from this Diploma agreement must directly apply to the new Eu2P Course Provider Partner.

18 Application of law and dispute resolution

If any dispute arises between any of the Eu2P Certificates 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 Certificates 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 Certificates 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 Certificates 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: