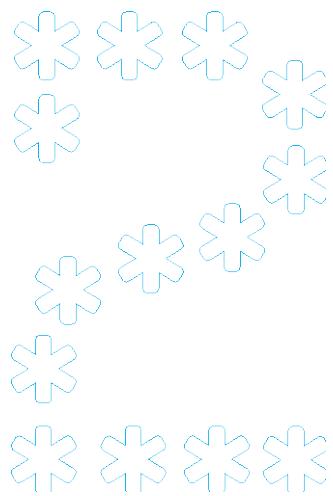




EUROPEAN PROGRAMME IN
PHARMACOVIGILANCE AND
PHARMA~~C~~OEPI~~E~~MI~~O~~LOGY



AGREEMENT FOR SHORT COURSES IN PHARMACOVIGILANCE AND PHARMA~~C~~OEPI~~E~~MI~~O~~LOGY

1	Description of the Programme	4
Definitions		6
2	Legal Framework	8
2.1	French regulations	8
2.2	Dutch Regulations	8
2.3	English Regulations	8
2.4	Spanish Regulations	8
2.5	Italian Regulations	8
2.6	Eu2P Conventions	9
3	Cooperation aspects	10
3.1	Coordinating institution	10
3.2	The Academic Partners (including the Coordinating institution) and the Course Provider Partners	10
3.3	The Associated Partners	10
3.4	The Boards	11
3.4.1	<i>The Executive Board</i>	11
3.4.2	<i>The Domain Boards</i>	12
3.5	The Eu2P Central Office	13
4	Promotion of the programme	14
5	Trainee's administration	15
6	Assessment of Trainees	15
7	Trainees' rights and responsibilities	15
8	Financial Management	15
8.1	Short Courses Financial management	15
8.2	Tuition fees	16
8.3	Financial support	16
9	Quality assurance	16
10	Intellectual Property Rights within the Consortium	17
10.1	Ownership and use of intellectual property brought in the programme	17
10.2	Ownership of intellectual property created under the programme	17
11	Confidentiality	18
12	Liabilities of the participants	19
13	Duration and Termination	20
13.1	Duration and termination	20
13.1	Changes to the Diploma agreement terms	20
14	New Academic, Course Provider or Associated Partners	21
14.1	New Academic Partners	21
14.2	New Associated Partners	21
14.3	New Course Provider Partners	21
15	Application of law and dispute resolution	22
16	Signatures	23

Agreement for Short Courses in Pharmacovigilance and Pharmacoepidemiology
(Eu2P Short Courses)

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,

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 Course Provider Partners and the Eu2P Associated Partners forming altogether the Eu2P Short Courses 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 Short Courses 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 Short Courses in Pharmacovigilance and Pharmacoepidemiology.

The Eu2P Associated Partners also agreed to enter into the Short Courses 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 Short Courses 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 Short Courses agreement.

Four annexes are attached to complete the Short Courses Agreement and form an integral part thereof.

Annex 1: Financial aspects

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

Annex 2: Eu2P Short Courses curriculum

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

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 3: Accession Form

This is a template of a legally binding document signed between the Eu2P Short Courses Consortium and an external public or private body that wishes to be part of the Eu2P Short Courses Consortium as an additional Associated Partner.

Annex 4: Accession Form for Course Provider Partner

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

2 Definitions

Any word(s) or expression(s) appearing in this Short Courses 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 3” means a legally binding document signed between the Eu2P Short Courses Consortium and an external public or private body that joins the Eu2P Short Courses Consortium as an Associated Partner. A template of an Accession Form is annexed to the present Short Courses Agreement. It constitutes the Annex 3.

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

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

“Annex 4: means a template for a legally binding document to be signed between the Eu2P Short Courses Consortium and an individual, or a public or private body that wishes to be part of the Eu2P Short Courses Consortium as a Course Provider Partner.

“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.

“Course Provider Partner” means an individual or 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).

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

“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 the training offer, training issues, selection procedures, research mobility, administration, promotion, quality assurance and enhancement, development strategy, financial and legal matters.

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

“Trainee” means the person enrolled in the Eu2P Short Courses 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 UBx 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 la 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 Certificates Agreement

4 Cooperation aspects

4.1 Coordinating institution

The Université de Bordeaux acts as the Academic Coordinating institution of the Eu2P Consortium regarding the delivery of the Eu2P Short Courses. 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 Short Courses programme in accordance with the requirements and Modules coordination share set out in the Annex 2. The Course Provider Partners participate in the preparation and delivery of the Eu2P Short Courses programme under the responsibility of one or several of the Academic Partners, as set out in the Annex 2.

Each Academic Partner and Course Provider Partner shall organise and implement the Eu2P Short Courses programme activities in its own institution, and specifically:

- The implementation and promotion of the Eu2P Short Courses programme
- The management of the funds collected and distributed by the Coordinating Institution.

Financial aspects relating to the management, share and use of the Short Courses 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 Short Courses Consortium members upon decision of the Executive Board, and without the need to renegotiate the whole Eu2P Short Courses Agreement. Each Academic Partner and each Course Provider Partner shall be responsible for its own training cost deriving from the Short Courses programme implementation.

4.3 The Associated Partners

The description of the commitments and benefits for Associated Partners to be part of the Eu2P Short Courses 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 Short Courses Consortium members upon decision of the Executive Board, and without the need to renegotiate the whole Eu2P Short Courses Agreement.

4.4 The Boards

4.4.1 The 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 Short Courses, the Executive Board shall be responsible for its organisation and the collaboration within the Eu2P Consortium. The related Executive Board tasks shall include:

- To identify learning pathways according to level type and training needs,
- To define the Eu2P Short Courses registration,
- To deal with all financial aspects of the Eu2P Short Courses programme, including financial relationships between the Eu2P partners
- To define the modalities to be fulfilled by Trainees for completing the Eu2P Short Courses Programme
- To overall define the course planning
- To annually define the Eu2P calendar
- To involve additional lecturers

(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 University of Hertfordshire 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 Short Courses 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.

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 has been established for Certificates relating to each one of the Eu2P Domains by the Eu2P Certificates agreement.

(2) As regards the Eu2P Short Courses, each Domain Board tasks shall include:

- According to the general educational outline defined by the Executive Board, to organise the consistency of the Modules general organization within such domain, thus to define and deliver the Short Courses material related to those Modules.

(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. 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

Each Domain Board shall meet once a term.

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.

4.5 The Eu2P Central Office

The Eu2P Central Office based in the Université de Bordeaux premises takes charge of the management and coordination of the overall Eu2P Short Courses 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
- Fees (collection, redistribution)
- Quality procedures
- Communication activities
- Qualification procedures

5 Promotion of the programme

A specific communication strategy is implemented to disseminate information about the Eu2P Short Courses 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 Short Courses 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, Short Courses schedule, and qualification information.

6 Trainee's administration

The Trainee can register to one or several Short Courses anytime during the academic year. The Trainee selects the Short Course(s), s/he is interested in, by browsing the Short Courses catalogue.

Once satisfied with his/her choice:

- s/he confirms the course selection
- s/he logins with his/her "My Eu2P" account (create one if needed) to provide billing information
- s/he pays the tuitions fees online or by bank transfer, cheque and get his/her invoice.
- s/he receives his/her Eu2P platform credentials to access the Short Courses.

Short Course registration entitles the Trainee to study online for a period of one year or until certification attempt.

7 Assessment of Trainees

The course is assessed through an on-line examination consisting in randomised multiple-choice questions covering all followed learning activities. The assessment is conducted under the academic supervision of the related Domain Board.

A final result of at least 80% of good answers is expected to be awarded the joint award called "Certificate of Achievement in Pharmacovigilance and Pharmacoepidemiology". The joint Certificate is printed and issued by the Eu2P Central Office. It includes the logos of all Eu2P Academic Partners and is signed by the Chairperson of the Executive Board as a means of authentication.

8 Trainees' rights and responsibilities

Each Trainee is subject to

- the Eu2P Terms of Sales
- the Eu2P e-learning platform Terms of Use
- the Eu2P Privacy and Security policies. In particular, the privacy and confidentiality of the Trainees' records shall be preserved as outlined in the Eu2P privacy and security policy and in the privacy policies applicable in each Eu2P University according to the General Data Protection Regulation (GDPR) (EU 2016/679) as well as to all relevant local laws.

9 Financial Management

9.1 Short Courses Financial management

The Eu2P Short Courses Financial statement, called the Annex 1 to this Agreement, is an annually revised document describing the financial management principles and rules related to Eu2P Short Courses 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, Associated Partners and Course Provider 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 Academic Partners, the Eu2P Course Provider Partners and Eu2P Central Office

- The tuition fees' amounts for the Short Courses
- The discounts offer for Eu2P Academic Partners, Associated Partners and Course Provider Partners.

9.2 Tuition fees

The Executive Board determines tuition fees and may revise them for each next academic year. Tuition fees are paid to the Eu2P Coordinating Institution either on-line or through the Eu2P Central Office.

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.

9.3 Financial support

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

10 Quality assurance

The Eu2P Short Courses 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.

11 Intellectual Property Rights within the Consortium

11.1 Ownership and use of intellectual property brought in the programme

Any member of the Eu2P Short Courses Consortium may bring in and disclose to other Eu2P Short Courses 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 Short Courses 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 Short Courses 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 Short Courses 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.

11.2 Ownership of intellectual property created under the programme

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

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

12 Confidentiality

No confidential information disclosed by any of the Eu2P Short Courses Consortium members (Disclosing Member) to another Short Courses Consortium member (Recipient Member) under this Agreement may be disclosed by the Recipient Member 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 Member may be used by the Recipient Member 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:

The provisions of this Clause do not apply to Confidential Information which:

- 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 12 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.

13 Liabilities of the participants

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

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

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

The Short Courses 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 Short Courses 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.

14 Duration and Termination

14.1 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 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 an Associated Partner) does not affect the validity of this Agreement between the remaining Eu2P Short Courses 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 Short Courses organisation.

14.1 Changes to the Diploma agreement terms

Any Eu2P Short Courses 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 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.

15 New Academic, Course Provider or Associated Partners

15.1 New Academic Partners

New Higher Education Institutions may be incorporated into the Short Courses Consortium to participate to the Eu2P Short Courses Agreement as a Eu2P Academic Partner upon decision of the Executive Board as long as they satisfy requirements above included in section 10. 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.

15.2 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 Short Courses Agreement (Annex 3). All relevant terms deriving from this Diploma agreement must directly apply to the new Eu2P Associated Partner.

15.3 New Course Provider Partners

New individuals, or 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 Short Courses Agreement (Annex 4). All relevant terms deriving from this Diploma agreement must directly apply to the new Eu2P Course Provider Partner.

16 Application of law and dispute resolution

If any dispute arises between any of the Eu2P Short Courses 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 Short Courses 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.

17 Signatures

This Agreement may be entered into by the Eu2P Short Courses 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 Short Courses Consortium members have caused this Diploma agreement, together with the Annexes 1 to 4, 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: