

# Privacy Policy

## Introduction

This present Privacy Policy applies to all services provided by the PharmaTrain Federation or any contact with a PharmaTrain Federation representative.

In this document:

- “We”, “Us”, “The Federation”, refer to the PharmaTrain as a Federation with its Representatives and Executives
- “The Platform”, “My PharmaTrain”, refer to the private part of the PharmaTrain Website on pharmatrain.eu to which only Members can access
- “The Website”, “Public Website”, “PharmaTrain Website” refer to the publicly available website on pharmatrain.eu to which everyone can access
- “Visitor” refers to anyone who is consulting the PharmaTrain Website
- “User” refers to anyone who has an account and use services provided by the My PharmaTrain Platform
- “Partner” refers to any organisation to which PharmaTrain collaborates with for Funding, Communication, Events, or Projects
- “Member(s)” refers to any organisation or person recognised as a PharmaTrain Member
- “PharmaTrain Initiative” refers to any Project, Working Group, Task Force or Event managed by the Federation and/or its Members
- “External Initiative” refers to any Project, Working Group, Task Force or Event in which PharmaTrain is involved and to which Members can participate
- “Participant” refers to anyone who has joined a PharmaTrain or External Initiative.

The PharmaTrain Federation acts as a data controller and is committed to protect data of its members, visitors, users and partners.

## Type of Collected Data

1. **Account Data** – Login, Password, e-Mail
2. **Profile Data** – Name, Surname, Organisation, Position, Address, Zip Code, City, Country, Phone, e-mail
3. **Billing & Payment Data** –
  - a. **Billing:** Name, Surname, Organisation, Position, Address, Zip Code, City, Country, Phone, e-mail, VAT Number
  - b. **Payment:** Date of Payment, Due Amounts
4. **Preferences & Consent Data** – Authorisations for Newsletter, Authorisation for PharmaTrain Initiatives information, Authorisation of Consultation and Review of Courses, Authorisation for Initiative Participation & Publication, Authorisation for Cookies Use
5. **Services Related Data** – PharmaTrain Initiative Affiliation Data, PharmaTrain Initiative Activity Data, Courses Providers Public Data, Courses Public Data, Courses Assessment Related Data<sup>1</sup>
6. **Usage Data** – Google Analytics on Public Website and My PharmaTrain Platform
7. **Correspondence Data** – Email Exchanges, Exchanges through My PharmaTrain Platform, Telephone Call & Web Conferences

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<sup>1</sup> See Annexe 1: Course Questionnaire for the exhaustive list of collected data

## Use of Collected Data

1. **Account Data** – Your account email address is used for any technical support related to the use of the My PharmaTrain Platform, and communications related to services provided through it. None of those data are publicly displayed or shared.
2. **Profile Data** –
  - a. While PharmaTrain Membership is active: Those data are used by the Federation to process membership administration or membership services and to communicate for membership administration.
  - b. In case of application to join a PharmaTrain or External Initiative: The Name, Surname, Organisation, Position and e-mail address will be shared with the Leaders of the initiative for application review. Once accepted, those data will be shared with the rest of the PharmaTrain or External Initiative Participants:
    - i. For a PharmaTrain Initiative: Data will not be published on the PharmaTrain Website or shared to Non-Members participants unless stated otherwise. In case they would be shared and displayed publicly, it will not be made without participant consent and only the Name, Surname, Organisation and Position will be shared or displayed. Each participant will have the right to change his mind and ask PharmaTrain for a full removal of publicly displayed data.
    - ii. For an External Initiative: All Data will be shared and processed within the rules defined by the External Initiative’s owners or leaders. PharmaTrain will not be held responsible for misuse of any provided data within the framework of External Initiatives as it will not assume the Data Controller function. However, PharmaTrain will try to make sure that the External Initiative is GDPR Compliant within the limits of the possibilities and available data, and will properly inform each Members on how data will be processed within the External Initiative before they apply to join it.
3. **Billing & Payment Data** –
  - a. Those data are exclusively used for the invoicing process and budgeting purpose.
  - b. They are shared exclusively with an External Contractor who process the Accounting for PharmaTrain.
  - c. Name, Surname, Organisation, Position, Address, Zip Code, City, Country, Phone, e-mail and VAT Number will never be publicly displayed or shared to other Members.
  - d. Name, Surname, Organisation, Due Amount and Date of Payment could be shared with the Executive Committee for reporting purpose.
  - e. Date of Payment and Due Amount could be anonymously published on the website in Budgets and Annual reports.
4. **Preferences & Consent Data** – Preferences & Consent information will be used to define data uses for services and communication.
  - a. Authorisations for Newsletter and Authorisation for PharmaTrain Initiatives Information: Those data are used to set the preferences in terms of communication between the Federation and its Members. They will also be compiled anonymously to issue statistics that might be shared in reports.
  - b. Authorisation of Consultation and Review of Course Data: This consent is mandatory to submit any Assessment and to be granted the PharmaTrain Recognition.

- c. Authorisation for Initiative Participation & Publication: This consent is mandatory to join any External or PharmaTrain Initiative. The participant will always be informed on what kind of data could be shared to other Initiative's Participants or publicly displayed.
5. **Services Related Data** – Data gathered by the Federation within the framework of its provided services could be used anonymously for reporting and statistics purpose.
  - a. PharmaTrain Initiative Affiliation Data are used to provide services related and specific to the initiatives depending on each Member's affiliations.
  - b. PharmaTrain Initiative Activity Data are used to produce the outcome of the Initiative, activity administration, reporting and manage initiative resources.
  - c. Course Providers Data are used to create a public profile displayed on the PharmaTrain Website for each Course Providers.
  - d. Courses Public Data are used to create a course information sheet on the PharmaTrain Website for each PharmaTrain Recognised Course.
  - e. Courses Assessment Related Data are composed of information on Course Content, Detailed Descriptions, Objectives, Methodology, Administration, Involved Resources and Pedagogy. They are made available to the PharmaTrain Assessors Team to perform Assessment of Courses and award the Recognition. Those data aren't made available to other Members or publicly displayed.
6. **Usage Data** – Google Analytics will be running to gather usage information on each page of PharmaTrain Website and Platform. The Federation will use those data to identify issues, improve online services and monitor the website's performances. Those data will stay anonymous and will not be linked to any account on the PharmaTrain Platform. Gathered data could include but are not limited to: IP address, screen resolution, time spent per page, issues when loading a page, access recurrence.
8. **Correspondence Data** – Those data will be used to process and coordinate the different services provided by the Federation and for administration purpose.

## How to Access Data

1. **Account, Profile and Billing Data** can be accessed and edited at any time in the Account & Profile sections of the My PharmaTrain Platform.
2. **Payment Data & Information** can be requested by email at [administration@pharmatrain.eu](mailto:administration@pharmatrain.eu)
3. **Preferences Data** can be accessed and edited at any time in the Account & Profile sections of the My PharmaTrain Platform.
4. **Given Consent** is recorded upon acceptance to access the related service, it is made accessible within the related service section of the Platform.
5. **Service Related Data**
  - a. That are publicly displayed on the PharmaTrain Website can be accessed and edited at any time in the service related section of the My PharmaTrain Platform, with the exception of publicly displayed Assessment Related Data for the Recognition.
  - b. That aren't publicly displayed on the PharmaTrain Website and ARE NOT Courses Assessment Related Data can be accessed in the service related section of the My PharmaTrain Platform and could be edited depending on the related service and technical restrictions.
  - c. That aren't publicly displayed on the PharmaTrain Website and ARE Courses Assessment Related Data can be accessed in the service related section of the My PharmaTrain Platform but cannot be edited. They can only be updated every 1 or 3 years during the Re-Assessment process.

6. **Usage Data** cannot be accessed at all time due to technical complexity of providing such a service. However, they can be requested by email at [administration@pharmatrain.eu](mailto:administration@pharmatrain.eu)
7. **Correspondence Data**
  - a. Email Exchanges are not made accessible by the Federation, it is up to the recipients included in the conversation to make sure that the exchanges are recorded and made accessible.
  - b. Exchanges through the My PharmaTrain Platform tools are recorded and accessible in the related service section of the Platform. They cannot be edited or removed.
  - c. Telephone Calls or Web Conferences organised by the Federation can be made available to the participants either by email or within the My PharmaTrain Platform in the related service section, or publicly on the Website.

## Security

1. We use cookies on our website. Any visitor is warned that cookies are in use when browsing the Website or Platform
2. Passwords are encrypted, there is no way to recover them. They can however be recovered by setting a new password, using the account associated email.
3. The pharmatrain.eu domain is covered by an SSL Certificate. It protects exchanges of data between Visitors and the Website, the Platform, or any other online service provided by the Federation. Attention: It doesn't cover services provided by Partners websites, such as the E-Learning Modules.

## Partner or External Services

The PharmaTrain Website and Platform could provide services from partners or external organisation. The present policy will not be applicable anymore when accessing those services as the Federation has no control over data usage when a visitor or user access those services. We will not be held responsible for any misuse of data within the framework of those services. The visitor or user will be warned when accessing such service from the PharmaTrain Website or Platform.

## Initiatives Outcomes

Any outcomes produced by a PharmaTrain Initiative could be used and published at PharmaTrain's own discretion. Outcomes produced by an External Initiative could be used and published at the Initiative Leader's own discretion. Possible outcomes include but are not limited to: Reports, Support Documents, Reviewed Regulations, e-Learning Modules, Guidelines.



# ANNEXE 1: PharmaTrain Questionnaire

## PharmaTrain Centre Recognition

### Assessment Questionnaire

To be completed by the applicant

I herewith confirm that the information provided in this Questionnaire is correct and complete.

Affiliation:

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Signature

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Place and Date

## **Cross Project Shared Course Quality Standards**

### **A formalised and transparent QA/QC policy**

- University accreditation OR a suitable system for approving, monitoring and reviewing the training offered.
- A system for quality assurance of teaching staff.
- Regular review of the QA/QC process

### **A set of documented criteria for individual modules, courses or course programmes**

- Defined and transparent admission criteria.
- A predefined set of teaching objectives, leading to defined learning outcomes.
- Adequate facilities, infrastructure, leadership and competences
- Assessment of the students' achievement according the learning outcomes
- A system for collecting, assessing and addressing feedback
- Adequate reference materials

### **Principles**

- Trainees are supported to acquire the necessary knowledge and skills
- Course structures encourage exchange and multidisciplinary
- Equality principles
- Teaching methods are appropriate to the goals of the course
- Transparency is observed regarding potential conflicts of interest

## PharmaTrain “Centre” and “Centre of Excellence” Assessment and Re-assessment Questionnaire

(for Re-assessment please highlight the areas that have changed)

### 1. General Information

1.1 Title of Course: \_\_\_\_\_

1.2 (Main) University organising the Course: \_\_\_\_\_

1.3 Address of Secretariat of Course

1.3.1 Telephone number: \_\_\_\_\_

1.3.2 Tax number: \_\_\_\_\_

1.3.3 E-mail address: \_\_\_\_\_

1.3.4 Website (if available): \_\_\_\_\_

1.4 Names of:

1.4.1 Course Director: \_\_\_\_\_

1.4.2 Course Coordinator: \_\_\_\_\_

1.4.3 Course Quality Officer: \_\_\_\_\_

1.4.4 Secretary/Assistant: \_\_\_\_\_

1.5 Type of Course and Degree (please mark right answer)

1.5.1 Base Diploma Course DiMD

yes       no      Degree: \_\_\_\_\_

1.5.2 Extended Master Programme MMD

yes       no      Degree: \_\_\_\_\_

1.5.3 Integrated Master Programme MMD

yes       no      Degree: \_\_\_\_\_

1.6 Year of Foundation of the Course: \_\_\_\_\_

1.7 Language of the Course: \_\_\_\_\_

**2. PharmaTrain QA Questionnaire/Check-list for Shared Quality Standards Assessment**

**2.1 Cross Project Shared Course Quality Standards**  
(please indicate what is in place)

**A formalised and documented QA/QC policy that includes the following:** % in place (0-100%)

- 2.1.1 University accreditation OR a suitable system for approving, monitoring and reviewing the training offered. \_\_\_\_\_
- 2.1.2 Quality assurance of teaching staff. \_\_\_\_\_
- 2.1.3 Regular review of the QA/QC process and demonstration that the training is further developed in light of this review. \_\_\_\_\_

**A set of documented criteria for individual modules, courses or course programmes that include the following:** % in place (0-100%)

- 2.1.4 Defined and transparent admission criteria. \_\_\_\_\_
- 2.1.5 A predefined set of teaching objectives, leading to defined learning outcomes. \_\_\_\_\_
- 2.1.6 The facilities, infrastructure, leadership and competences available for the support of student learning. \_\_\_\_\_
- 2.1.7 Assessment of the students' achievement in accordance with the agreed learning outcomes of the training offered \_\_\_\_\_
- 2.1.8 A system for collecting, assessing and addressing feedback from learners, teachers, technical/administrative staff and programme/course/module managers. \_\_\_\_\_
- 2.1.9 Availability of appropriate and regularly reviewed reference material (e.g. published articles, links, book chapters, scripts, etc.) \_\_\_\_\_

**2.2 Modules**

(2.2.1-2.2.3 requires 100% adherence)

- 2.2.1 Does the programme cover all items mentioned in the PharmaTrain Syllabus 2010?  
\_\_\_\_\_
- 2.2.2 Is the PharmaTrain Modular Structure in place? (comprising the 6 Modules of the Base Diploma Course)  
\_\_\_\_\_
- 2.2.3 Are Learning Outcomes which refer to PharmaTrain Syllabus 2010 V1.0 in place?  
\_\_\_\_\_
- 2.2.4 Are the modules distributed over 1, 2 or more years?  
\_\_\_\_\_



2.2.5 How many hours of teaching does the full course contain? \_\_\_\_\_

2.2.6 How is this distributed?

Pre-F2F Module activity \_\_\_\_\_

Didactic lectures: \_\_\_\_\_

Workshops: \_\_\_\_\_

Group discussions/Case Studies: \_\_\_\_\_

Post F2F Module assignments: \_\_\_\_\_

Other (please specify): \_\_\_\_\_

\_\_\_\_\_

2.2.7 Is distance learning or homework scheduled in the course?

yes  no

2.2.8 Is the course taught (please mark right answer)

all in one place?

rotating to several places in the same city, in the same country or in different countries?

2.2.9 Assessed Assignments

Please state if / which assignments – which are also compulsory for the (Base) Diploma Course – are in place? Assignments account for 2 ECTS (a min. 25 learning hours) and relate to the learning outcomes of a given Module.

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

2.2.10 Are they assessed as part of each Module for the Certification (a document)?

yes  no

## 2.3 Time

2.3.1 How many hours are spent on teaching of:

Introductory course?	_____	hours
Drug discovery and development planning?	_____	hours
Non-clinical testing?	_____	hours
Pharmaceutical development?	_____	hours
Early clinical development?	_____	hours
Clinical trials?	_____	hours
Regulatory affairs?	_____	hours
Drug safety?	_____	hours
Pharmacovigilance?	_____	hours
Healthcare marketplace?	_____	hours
Economics of healthcare?	_____	hours

## 2.4 Teachers

2.4.1 How many teachers are participating in the programme? \_\_\_\_\_

2.4.2 How many are from:

Academia? \_\_\_\_\_

Industry? \_\_\_\_\_

CROs? \_\_\_\_\_

Regulatory Authority? \_\_\_\_\_

Other organisations? (Please specify) \_\_\_\_\_

\_\_\_\_\_

## 2.5 Course material

2.5.1 Is course material (please mark right answer)

- Paper-based
- E-learning tools
- Both

## 2.6 Students

- 2.6.1 What has been the average number of students registering each year?  
the full Course? \_\_\_\_\_  
individual Modules ? \_\_\_\_\_  
the integrated examinations? \_\_\_\_\_
- 2.6.2 Which percentage of applications for participation to Courses/Modules have been accepted? \_\_\_\_\_
- 2.6.3 What are the requirements to register for the course and the examinations?  
(Please mark right answer):  
 Physicians only  
 Physicians and biomedical sciences degree only  
 Plus other scientists? (Please specify) \_\_\_\_\_  
\_\_\_\_\_
- 2.6.4 What is the average ratio of physicians versus non-physicians? \_\_\_\_\_

## 2.7 Integrated Examination

(Theoretical part for Specialist title to be combined with documentation of work experience)

- 2.7.1 Are examinations conducted (Please mark right answer)  
 Once a year  
 Twice a year  
 Other frequency (Please state) \_\_\_\_\_  
\_\_\_\_\_
- 2.7.2 Are the examinations (Please mark right answer)  
 Written only  
 Oral only  
 Both written and oral
- 2.7.3 Does the written examination include (Please mark right answers):  
Multiple Choice Questions (MCQs):  
 yes       no  
If yes, how many MCQs are asked at each session? \_\_\_\_\_
- In the choices given is only one correct or several ones?  
 Only one       several
- Short questions essays?  
 yes       no
- Short dissertation?  
 yes       no

2.7.4 Who writes and updates the MCQs? A specific Committee?

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2.7.5 What is the duration (in minutes or hours) of

The written examination?

The oral examination?

Is attendance to the courses compulsory for sitting the examination?

yes       no

If yes, how much of the course must be completed (in percentage)? \_\_\_\_\_

Are there any assessments during the course?

yes       no

## 2.8 Recognition

2.8.1 Do you want your course recognised by (please mark the right answer)

Your National Health Authorities?       yes       no

Your National Academy of Medicine?       yes       no

Your Regulatory Authorities?       yes       no

Employers?       yes       no

2.8.2 Is your course already recognised by any of these organisations or others?  
Please comment:

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## 2.9 Fees (in Euro)

2.9.1 What is the fee to be paid for attendance to?

The full course?

Per module?

The integrated examination?

2.9.2 Is a fee requested when awarding a diploma, certificate, or award?

yes       no

## 2.10 Marketing

2.10.1 Do you communicate and promote your course by using the PharmaTrain Brand "Mastering Medicines Development"?

yes       no

2.10.2 Have you implemented the PharmaTrain Identifier on your website?

yes       no