EUPATI Open Classroom

MODULE 1. CLINICAL AND NON-CLINICAL DEVELOPMENT

EUPATI

Introduction and summary

The importance of patient involvement in medicines R&D is commonly acknowledged and offers benefits for all involved parties. Patients should have access to knowledge and experiences that enable effective participation. EUPATI training responds to the need for educated patients in the current medicines R&D system and allows patients to develop their capacity to collaborate and engage with other stakeholders as equal partners.

This module is composed of two of the modules available in the EUPATI Open Classroom, the Non-clinical Development module and the Clinical Development module

The module **Non-Clinical Development** explains in detail non-clinical studies, the pre-requisites for clinical studies in humans and the purpose and relevance of animal testing, it also gives an overview of the steps in the development of the substance and the final medicine product and elaborates on the concepts of pharmacogenetics and genomics.

The **Clinical Development** module is designed to provide an overview of clinical trials. It describes the basic concepts of clinical trials as well as the types of studies in early clinical development, it also highlights the rights and obligations of trial participants, as well as the history of ethics in clinical research and the basic concepts of statistical methods.
This module also elaborates on the types of data and principles of data collection, as well as how to interpret and disseminate the results.

Learning and Assessment

The objective of EUPATI is to provide appropriate academic and rigorous training, yet presented in a way that enables concrete and applicable learning outcomes for the patient community, leading to measurable impact in medicines development.
Each on-demand training unit has a short multiple choice assessment that is available to learners wanting to receive a certificate for the training unit.

Training is delivered through the **EUPATI Open Classroom**, a Moodle workplace learning management system that includes instructional text content, infographics, videos and case studies. The learner has also access to an online **toolbox and glossary.**

The **Toolbox** is an online library on the A-Z of medicines research and development (R&D) and patient involvement. The purpose of the Toolbox is to provide access to well-structured, comprehensive, scientifically reliable, and user-friendly educational materials for patients on a variety of topics in these areas. The information is not medicine- or disease-specific, but is applicable to the majority of diseases and/or medicines.

The **Glossary** is integrated into the content and allows learners to read keyword descriptions as they go through the learning process.

Learning is **modular, flexible and on-demand**, supported by the EUPATI team. The Trainees can access learning materials at their own pace and convenience. Once they finish a course or module, the certificates is generated automatically after successfully completed assessment.

The **assessments** are made for each course and are problem-based multiple-choice questions. Assessments are used to determine the competency of the established learning outcomes for each course in the module.

During the course, learners are encouraged to:

- Make connections between what they have learned and their personal and professional situation.
- Think of opportunities to apply the training in their personal and professional life.

Learning and assessment strategies

EUPATI Open Classroom uses the following learning strategies to effectively deliver educational content to trainees in a digital environment:

- **Asynchronous Learning**: Trainees can access learning materials at their own pace and convenience. They can read course materials including lectures and infographics, watch videos, listen to audios and complete assignments without being constrained by a specific schedule.

- **Microlearning**: Breaking down complex content on medicines R&D into small, easily digestible units allows trainees to absorb information more effectively. The content is separated into different pages with short text lessons that are combined with images, infographics, and videos.

- **Gamification**: Open Classroom uses badges after the completion of each module. Learners get rewards for completing their profile or finishing modules which can boost their engagement and progress. They can also share these badges on LinkedIn and get public recognition of their learning.

- **Self-assessment and feedback**: The online modules include self-assessment quizzes at the end of each course. This module includes 6 courses, therefore, to obtain the certificate for this module it is necessary to complete 6 quizzes. Along the lines of microlearning, Open Classroom encourages frequent, small-quantity assessments that help learners calibrate their understanding of the material. Immediate feedback on their performance helps learners identify areas for improvement and reinforces their understanding of the content.

- **Multimedia integration**: The modules offer multimedia elements, such as videos, images, infographics, to enhance the presentation of content and meet different learning styles. User-friendly content is available on different devices such as desktops, tablets and cell phones.

- **Real-world application**: Incorporating real-world examples and case studies as part of the content helps learners understand how the knowledge they acquire can be applied in practical life situations.

- **Accessibility and Inclusion**: The content meets the accessibility features to ensure that learners with disabilities can fully participate in the learning process.

Curriculum

The module of Non-clinical Development is composed of 3 courses and the Clinical Development module of 7.

Completion of all **10 courses** is mandatory to obtain the **module Clinical and Non-Clinical Development**

Courses	Hours*
Non-Clinical Development	
Requirements for Non-clinical Studies and the Purpose and Relevance of Animal Testing	3
Development of Medicines Substance and Final Medicines Product	2
Role of Pharmacogenetics / Pharmacogenomics in the Development of Medicines	3
Clinical Development	
Clinical Trials and Trial Management	6
Early Clinical Development	3
Trial Participants' Rights & Obligations	4
Ethics	5
Statistics	4
Documentation & Management	4
Interpretation and Dissemination of Results	6
Total	**40 hours**

*This is an estimate based on the volume of content, although the actual hours required vary on an individual basis.

Learning Outcomes per course

The learning outcomes of the different courses of the Non-Clinical Development module are:

Non-clinical Development	
Courses	**Learning Outcomes**
Requirements for Non-clinical Studies and the Purpose and Relevance of Animal Testing	• Describe the need and requirements for non-clinical studies prior to clinical studies in humans and the purpose and relevance of animal testing.
Development of Medicines Substance and Final Medicines Product	• Outline the steps in the development of a medicines substance and final medicines product (including chemical and biotechnology-derived products).
Role of Pharmacogenetics / Pharmacogenomics in the Development of Medicines	• Discuss the techniques that are emerging in specific product development or disease areas. • Understand the role of pharmacogenetics/pharmacogenomics in the development of medicines. • State the ethical challenges.
Clinical Development	
Courses	**Learning Outcomes**
Clinical Trials and Trial Management	• Describe basic clinical trial concepts, types and benefits of different clinical trial designs and their practical implications including decisions to alter or end the trial before termination including the role that patients can play.
Early Clinical Development	• Understand the principles of pharmacology, methods of measuring and; • Describe the types of studies in early clinical development (Phase I and Phase II studies).
Trial Participants' Rights & Obligations	• Describe trial participants' roles and rights and how they are protected.

COURSES	LEARNING OUTCOMES
Ethics	• Describe the history of ethics in clinical research and the concepts and values of ethics for research involving humans. • Explain how ethics evaluations are conducted internationally, nationally and locally. • Describe the potential roles of patients at each level.
Statistics	• Understand the basic concepts and statistical methods used in clinical research. • Describe the purpose of the statistical analysis plan (SAP).
Documentation & Management	• Describe types of data and the principles of data collecting and management in clinical trials. • Outline the principles and key elements of overall clinical trial quality management and the stakeholders involved.
Interpretation and Dissemination of Results	• Describe the elements of clinical trial results including how to avoid bias, fraud, misconduct and ethics violations during trial and reporting of results. • Describe how to perform critically reading.