



Project CONSCIOUS II

Curriculum Development Of Human Clinical Trials For The Next Generation Of Phd Students And Early Career Researchers In The Medical, Science, Pharmacy And Health Professions

Project CONSCIOUS

- The Curriculum Development of Human Clinical Trials for the Next Generation Biomedical Students (2018-1-HU01-KA203-047811)
- Project period: September 1, 2018 – August 31, 2021
- **purpose:** to tackle the skills gaps and mismatches related to European-level Clinical Trial Professionals through curriculum development and preparation of **e-learning material** for the career development of biomedical undergraduate students.
- **objectives:** e-Learning course on ‘Introduction to Clinical Trials’; open education and innovative practice in a digital area by making e-Learning material available for the Next Generation Biomedical Students regardless of geography
- **target population:** undergraduate students
- <http://conscious.novaims.unl.pt/login/index.php>

Project CONSCIOUS II

- Curriculum Development Of Human Clinical Trials For The Next Generation Of Phd Students And Early Career Researchers In The Medical, Science, Pharmacy And Health Professions (2021-1-CZ01-KA220-HED-000023177)
- Project period: November 1, 2021 – October 31, 2024
- **purpose:** to create a curriculum on training the clinical trialist of the future and provide them the skills to design, conduct, and manage multicenter clinical trials, to provide tools to become clinical trial leaders
- **objectives:** clinical trial curriculum, curriculum focused on interdisciplinary training curriculum; dissemination of the finished curriculum through HEI and partnerships; standardize curriculum; reinforcement the existing cooperation in the field of clinical trials
- **target population:** PhD students, early career researchers

Project CONSCIOUS II

- Consortium leader: MU

- Partners:

University of Pécs

NOVA University Lisbon

University of Paris

University College Cork

University of Szeged

- Experienced team members

- Associated partner - ECRIN



Project CONSCIOUS II – PR1, PR2

1. Clinical Trials Design
2. Trial methodology
3. Trial Management
4. Quality and regulatory affairs and sources of regulatory information
5. Pharmacovigilance and study medication
6. Data management and statistical analysis
7. Early phase trials
8. Pediatric clinical trials
9. Medical devices
10. Leadership for PIs, team management and networking skills in research
11. Scientific publishing and open research
12. Teaching the teachers

Project CONSCIOUS II – PR 4

The screenshot shows a Moodle course overview page. The course title is "Conscious II - Curriculum Development of Human Clinical Trials for the Next Generation". The user is identified as "Katerina Nebeska". The left sidebar contains a navigation menu with items: Dashboard, Site home, Calendar, Private files, My courses, CHAPTER 01-Clinical Trial Design, CHAPTER 02-Trial Methodology Research, CHAPTER 04-Quality and Regulatory, CHAPTER 07 - Early phase trials, CHAPTER 08-Paediatric Clinical Trials, and Add a block. The main content area is titled "Course overview" and displays a grid of course sections. Each section includes a representative image, the chapter title, and a progress bar. The progress for the first three chapters is 0% complete, while the fourth chapter, "CHAPTER 08 - Paediatric Clinical Trials", is 28% complete.

Chapter	Image Description	Progress
CHAPTER 01 - Clinical Trial Design	Hand pointing at a hexagonal grid of icons	0% complete
CHAPTER 02 - Trial Methodology Research	Hand holding a stethoscope over a blue background with hexagons	0% complete
CHAPTER 04 - Quality and regulatory affairs and ...	Yellow gavel on a stack of papers with a "REGULATIONS" sign	0% complete
CHAPTER 07 - Early phase trials	Document titled "INFORMED CONSENT"	0% complete
CHAPTER 08 - Paediatric Clinical Trials	Two healthcare professionals looking at a tablet with a teddy bear	28% complete

CHAPTER 04 - Quality and regulatory affairs and sources of regulatory information

Dashboard / My courses / CHAPTER 04 - Quality and Regulatory

Your progress

Open Close

CHAPTER 4- Quality and Regulatory Affairs and sources of regulatory information

1 Introduction to the chapter

2 Regulatory framework

2.1 Regulatory authorities

2.2 European legislation, recommendations, and guidelines a)

QUIZ 1

2.2 European legislation, recommendations, and guidelines (b)

3.3 Trials registration vs. patient registries

Discussion board 5

4 Quality

4.1 Quality – Concept of quality in clinical research

4.2 Quality management system, risk-based management

Discussion board 6

4.2.1 Planning

4.2.2 Quality assurance (QA) and Quality control (QC)

4.2.3 Quality improvement

Discussion board 7

4.3 International quality guidelines for clinical trials

QUIZ 5

5 Conclusion

Discussion board 7

Discussion board 7

A non-compliance was detected by the monitor during the monitor's visit. How to solve it?

Firstly, watch the YouTube video "CAPA Case Study".

What do you agree/disagree with? Do you have any suggestions or comments? Discuss the described solution of non-compliance on the discussion board, together with the following task:

Suggest a plan by yourself for: "the lab tests for the 2nd visit are not complete for 3 study participants". That information is not sufficient to construct a single CAPA plan, it offers several possible root causes, as well as the evaluation severity of that non-compliance can differ according to the type of test missing. Discuss your suggested solution on the discussion board. How many root causes can we get? Explore the discussion board.

Curriculum Development of Human Clinical Trials for the Next Generation

Kateřina Nebeská

CHAPTER 08 - Paediatric Clinical Trials

Dashboard / My courses / CHAPTER 08-Paediatric Clinical Trials

Your progress

Open Close

CHAPTER 08 - Paediatric Clinical Trials

1 Introduction to the chapter

2 Paediatric regulatory framework

In the EU, the role of the regulatory body exerts a network of national agencies, coordinated by the European Medicines Agency and the European Commission.

In the past, market forces alone were not a sufficient incentive for adequate research and development of paediatric medicines. Paediatric development has depended to a considerable extent on the pharmaceutical company's product strategy with respect to the adult population. For many companies, adults represent the most economically attractive market. The consequence of this was and still is a low number of conducted paediatric clinical studies, a lack of data supporting paediatric indication and the frequent use of medication in off-label mode. In 1997, the European Commission organized a round table of experts to discuss paediatric medicines at the EMA. The experts identified the need to strengthen the legislation, in particular by introducing a system of incentives. In 1998, the Commission supported the need for international discussion on the conduct of clinical trials in children in the context of the International Conference on Harmonisation (ICH). In 2000, the harmonized tripartite E11 ICH guideline "Clinical investigation of medicinal products in the paediatric population" was finalized and subsequently became a European guideline in 2001. ICH guideline was later amended with an integrated Addendum known as **ICH E11(R1) guideline (2017)**. (!) ICH E11 serves as an international quality standard for paediatric clinical trials. The goal of this guidance is to encourage and facilitate the timely development of paediatric medicine products worldwide.

Curriculum Development of Human Clinical Trials for the Next Generation

Kateřina Nebeská

3 Ethics of paediatric clinical trials

3.1 Informed consent and agreement/assent

Discussion Board 1 - PRACTICAL EXERCISE

Discussion Board 1 - PRACTICAL EXERCISE

Enpr-EMA's working group on ethics has also developed a document called [Assent / Informed Consent Guidance for Paediatric Clinical Trials with Medicinal Products in Europe](#).⁽¹⁾

- This document is intended to be used as an overview tool of the contents for assent/informed consent forms for all stakeholders, such as patients, sponsors and investigators.
- You can find two tables in this document, first with general information for informed consent and assent/agreements and second with trial-specific information for informed consent and assent/agreements.
- In both tables, there are separate columns for each age category (0<2, 2<6, 6<10, 10<18) and legal representative as well accompanied by 3-level recommendation symbols for all age groups.
- Review these tables to get a basic overview of what information the informed consent and assent/agreements should contain and what should not be missing from it.

Practical exercise

Open the [Enpr-EMA Toolkit table](#) to find out information about your country. Go to the discussion board and write down your selected country, the legal age of consent, mandatory / suggested age ranges defined for assent and the number of required signatories.

However, we should first specify the difference between the terms "informed consent", "agreement", "assent", and dissent. Please see the explanation of the terms in Table 3.

Project CONSCIOUS II

Project Identification: 2021-1-CZ01-KA220-HED-000023177

Investor/Program/Project type: European Union - Erasmus+ Key Action 2: Cooperation for innovation and the exchange of good practices; Strategic Partnerships in the field of education, training and youth

Curriculum Development of Human Clinical Trials for the Next Generation of PhD Students and Early Career Researchers in the Medical, Science, Pharmacy and Health Professions

CHAPTER 4 QUALITY AND REGULATORY AFFAIRS AND SOURCES OF REGULATORY INFORMATION

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Reviewers: ECRIN representatives – Marta del Alamo, Christine Kubiak

Date first created: 06/06/2022

Last revision: 23/07/2022

Content

- 1 Introduction to the chapter
- 2 Regulatory framework
 - 2.1 Regulatory authorities
 - 2.2 European legislation, recommendations, and guidelines
 - 2.3 Compliance with legislation: practical aspects for investigators
 - 2.3.1 Planning, authorisation procedure, before the trial initiation
 - 2.3.2 During the clinical trial
 - 2.3.3 After the termination of the clinical trial
 - 2.4 Databases of regulatory information
- 3 Databases of clinical trials
 - 3.1 European databases
 - 3.1.1 EudraCT and EU Clinical Trial Register (EU CTR)
 - 3.1.2 Clinical Trials Information System (CTIS)
 - 3.1.3 Registration of non-interventional studies
 - 3.2 ICTRP, ClinicalTrials.gov, others
 - 3.2.1 International Clinical Trials Registry Platform (ICTRP)
 - 3.2.2 ClinicalTrials.gov
 - 3.3 Trials registration vs. patient registries
- 4 Quality
 - 4.1 Concept of quality in clinical research
 - 4.2 Quality management system, risk-based management
 - 4.3.1 Planning
 - 4.3.2 Quality assurance (QA) and Quality control (QC)
 - 4.3.3 Quality improvement
 - 4.3 International quality guidelines for clinical trials
- 5 Conclusion

Time required to complete this chapter

Core content:	55m
Additional/advanced content (yellow boxes):	20m
Activities/practical exercises (blue framed boxes):	1h 15m
Total time:	2h 30m

Pilot teaching

- COIL
- PhD students, ECR, teachers
- January 9, 2024 – April 2, 2024
- Zoom lessons/90 minutes
- The individual home preparation/preclass reading
- Each participant attending $\geq 60\%$ of the online sessions can get a certificate of completion of this course
- Registration for the online lessons will be opened in September and closed by November

CONSCIOUS II

Curriculum Development of Human Clinical Trials

What is the pilot teaching about?

The pilot teaching is an integral part of the CONSCIOUS II project.

The pilot teaching overarches and connects all project results and provides a space to validate the knowledge gained and develop key competencies to design, conduct, manage, evaluate, and publish investigator-initiated trials.



Co-funded by the Erasmus+ Programme of the European Union

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Who is the target population?

- Ph.D. students in medicine, pharmacy, health sciences
- early-career researchers
- investigators/sponsors planning an academic clinical trial
- teachers and lecturers of the theory of the clinical trial
- persons starting to work in clinical trials

Why should I apply for pilot lessons?

- you can acquire a better understanding of the topics.
- you can work with international students, teachers, and researchers.
- you can learn how to work in virtual teams.
- you can improve your language skills.



Schedule and topics of the pilot teaching:

- January 9, 2024 Course opening
- January 16, 2024 Clinical Trial Designs
- January 23, 2024 Early Phase Trials
- January 30, 2024 Pediatric Clinical Trials
- February 6, 2024 Quality and regulatory affairs
- February 13, 2024 Trial Management
- February 20, 2024 Data management and statistical analysis
- February 27, 2024 Pharmacovigilance and study medication
- March 5, 2024 Trial Methodology
- March 12, 2024 Medical Devices
- March 19, 2024 Leadership for PIs
- March 26, 2024 Open research and scientific publishing
- April 2, 2024 Teaching the teachers

Practical info:

Is registration needed?
Yes, will start in September 2023. End date for registration is November 30, 2023.

How to register?
Registration will be available on the project websites.

Is the pilot teaching a lecture? Or is it interactive?
Pilot teaching is going to be interactive - blended classroom.

Can I get a certificate?
Yes, for attending more than 60% of the online sessions.

Is there a fee?
No, all materials and pilot lessons are free of charge.

Where to find more info?
www.conscious2.eu or contact representatives of the partners.

every Tuesday
from 6 PM to 7.30 PM (CET)
via Zoom

www.conscious2.eu

Project CONSCIOUS II <http://consciousii.novaims.unl.pt/login/index.php>

<http://conscious2.eu/>

CONSCIOUS II
Curriculum Development of Human Clinical Trials

What is the project about?
The CONSCIOUS II project is an educational project focusing on the field of clinical trials. It aims to develop the skills necessary to conduct high-quality academic clinical trials as well as the skills to effectively disseminate the results obtained.

Co-funded by the Erasmus+ Programme of the European Union

2021-1-CZ01-KA220-HED-000023177

Who is the target population? Curriculum in

Building key competencies clinical trialists of the future: CONSCIOUS curriculum projects

Logos: MASARYK UNIVERSITY, UCC, NOVVA

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CORRESPONDENCE

Training clinical programs

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Klinická farmakologie a farmacie

Rozvoj klíčových kompetencí v oblasti klinického výzkumu: CONSCIOUS curriculum projects

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Oblast nekomerčních klinických studií zaznamenává v posledních letech významný vzestup hlavně v kontextu precision medicine a individualizované léčby. Nekomerční studie totiž poskytují prostor pro výzkum otázek přiléhavějších klinické praxi a nabízí příležitost pro využití inovativních designů klinických studií. Nekomerční klinické studie ale současně kladou vyšší nároky na hlavní zkoušející a členy jejich týmů, neboť tyto svou pozici ve studii rozšiřují o koordinační a manažerskou roli zadavatele.

Klíčová slova: nekomerční klinické studie, vysokoškolské vzdělávání, biomedicínské obory, kurikulum, problémová vyuuka.

Building key competencies in clinical research: CONSCIOUS curriculum projects

The field of non-commercial clinical trials has experienced significant expansion in recent years, especially in the context of precision medicine and individualized treatment. Indeed, non-commercial trials provide a venue for research on questions relevant to clinical practice and offer the opportunity to use innovative clinical trial designs. At the same time, however, non-commercial clinical trials place greater demands on principal investigators and their team members as they extend their position in the study to include the coordination and management role of the sponsor. On the other hand, training in the organization and theory of clinical trials at medical and pharmaceutical faculties in the Czech Republic is limited. It is typically included in pharmacology as part of an introduction to the overall process of drug research and development. At the postgraduate level, only some faculties offer comprehensive courses on the organization and interpretation of clinical trials. The ERASMUS+ CONSCIOUS and ERASMUS+ CONSCIOUS II projects can thus help to fill the gap in education in this area, offering a comprehensive, free-of-charge collection of lessons for undergraduate and postgraduate biomedical students, and an open pilot course of twelve on-line lessons with international participation is also planned.



Děkuji za pozornost