







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 MUNI Med









- 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
- <u>http://conscious.novaims.unl.pt/login/index.php</u>











- 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









- 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

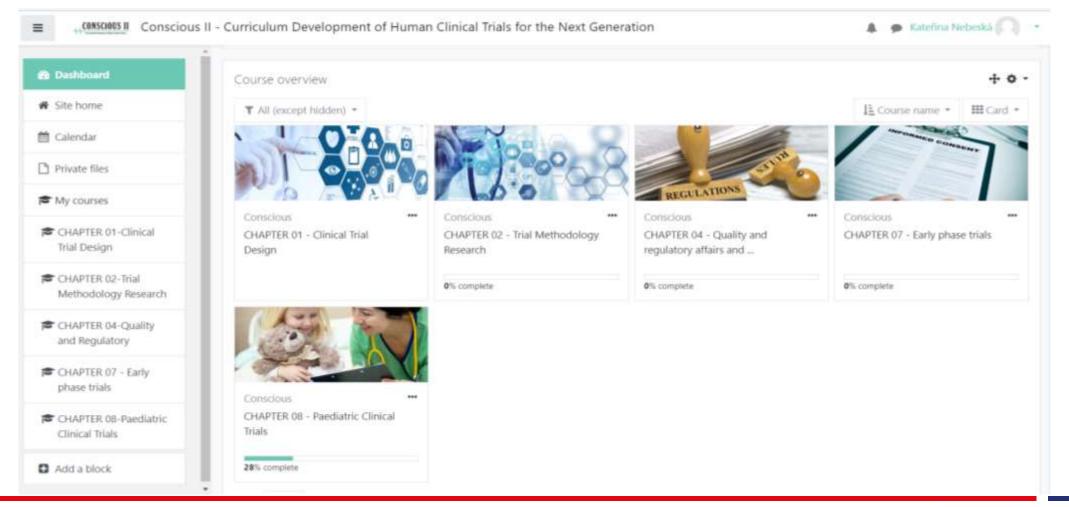








Project CONSCIOUS II – PR 4













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

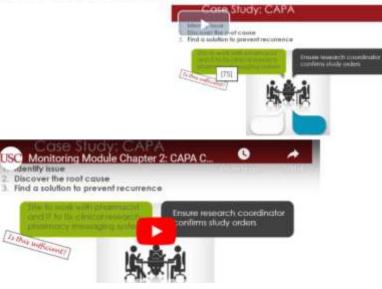
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	Anna tradician O
Open #I Close #I	
CHAPTER 4-Quality and Regulatory Affairs and sources of regulatory information	F
1 Introduction to the chapter	F
2 Regulatory framework	P
2.1 Regulatory authorities	Þ
2.2 European legislation, recommendations, and guidelines a)	E.
QUIZ 1	*
2.2 European legislation, recommendations, and guidelines (b)	Þ
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	b.

Olscussion 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.

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- Curriculum Development of Human Clinical Trials for the Next Generation 🔒 🙍 Katerina Neteská 🎧 🔹	Curriculum Development of Human Clinical Trials for the Next Generation	
CHAPTER 08 - Paediatric Clinical Trials	3 Ethics of paediatric clinical trials	
Debboard / My courses / CHAPTER OF Paediatric Cirrical Titals	3.1 Informed consent and agreement/assent	
Your progress ()	Discussion Board 1 - PRACTICAL EXERCISE	
Open MI Close MI	Discussion Board 1 - FRACTICAL EXERCISE	
CHAPTER 08 - Paediatric Clinical Trials	Enpr-EMA's working group on ethics has also developed a document called Research Informati Content Condence for Readiates Clinical Trian	
1 Introduction to the chapter	 This document is intended to be used as an overview tool of the contents for assent/informed consent forms for all stakeholders, such as 	
2 Paediatric regulatory framework 💌	 You can find two tables in this document, first with general information for informed consent and assent/agreements and second with trial- 	
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.	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	
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	 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. 	
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	Practical exercise Open the interactive totals 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.	
and subsequently became a European guideline in 2001. ICH guideline was later amended with an integrated Addendum known as ICH E11(R1) guideline (2017) . (1) 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 gaediatric medicine products worldwide.	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.	





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

Authors: Zora Čechová, Jitka Rychlíčková, Kateřina Nebeská, Lenka Součková Masaryk University, Brno, Czech Republic

Reviewers: ECRIN representatives - Marta del Alamo, Christine Kubiak

Date first created: 06/06/2022 23/07/2022 Last revision:



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:

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2h 30m

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... towards patient-oriented medicine!



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 ≥ 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



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.



CONSCIOUS II

Curriculum Development of Human Clinical Trials

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 Trial Methodology March 5, 2024 March 12, 2024 Medical Devices March 19, 2024 Leadership for PIs March 76, 7024 Open research and scientific publishing Teaching the teachers April 2, 2024

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? where considus? ou 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







Děkuji za pozornost