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

www.czecrin.cz

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

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

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Curriculum Development of Human Clinical Trials
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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

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- 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

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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

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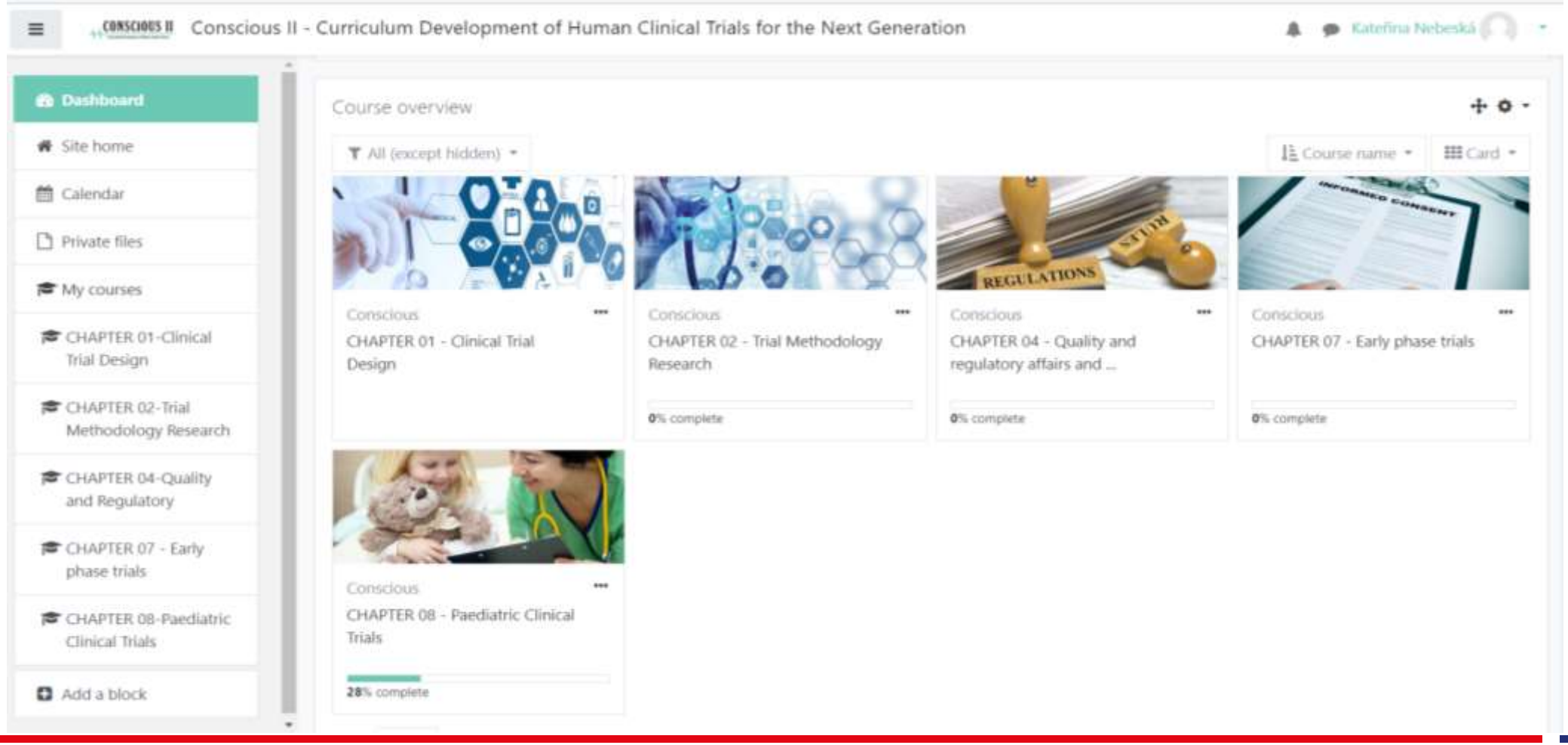
Project CONSCIOUS II – PR 4



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

Dashboard / My courses / CHAPTER 04-Quality and Regulatory

Your progress

Open all Close all

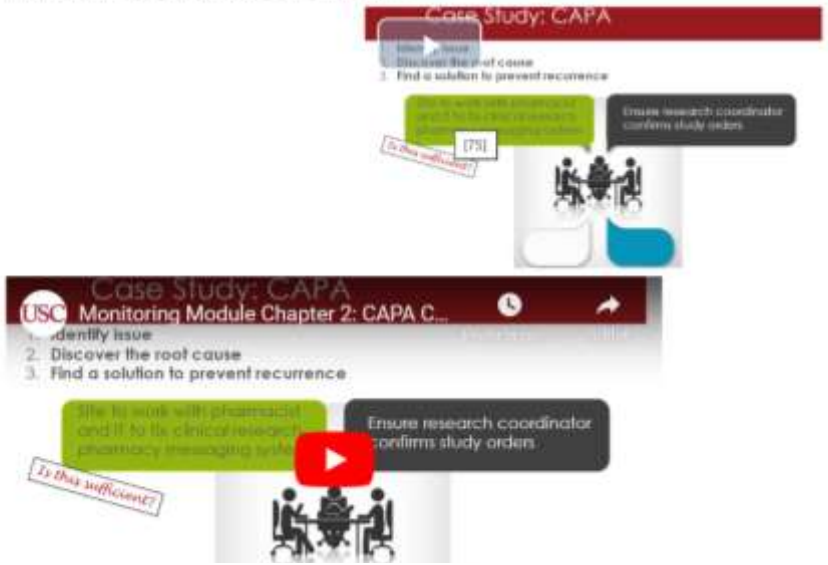
- CHAPTER 4-Quality and Regulatory Affairs and sources of regulatory information
- 1 Introduction to the chapter
- 2 Regulatory framework
- 2.1 Regulatory authorities
- 2.2 European legislation, recommendations, and guidelines a)
- QUIZ 1
- 2.2 European legislation, recommendations, and guidelines (b)
- 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

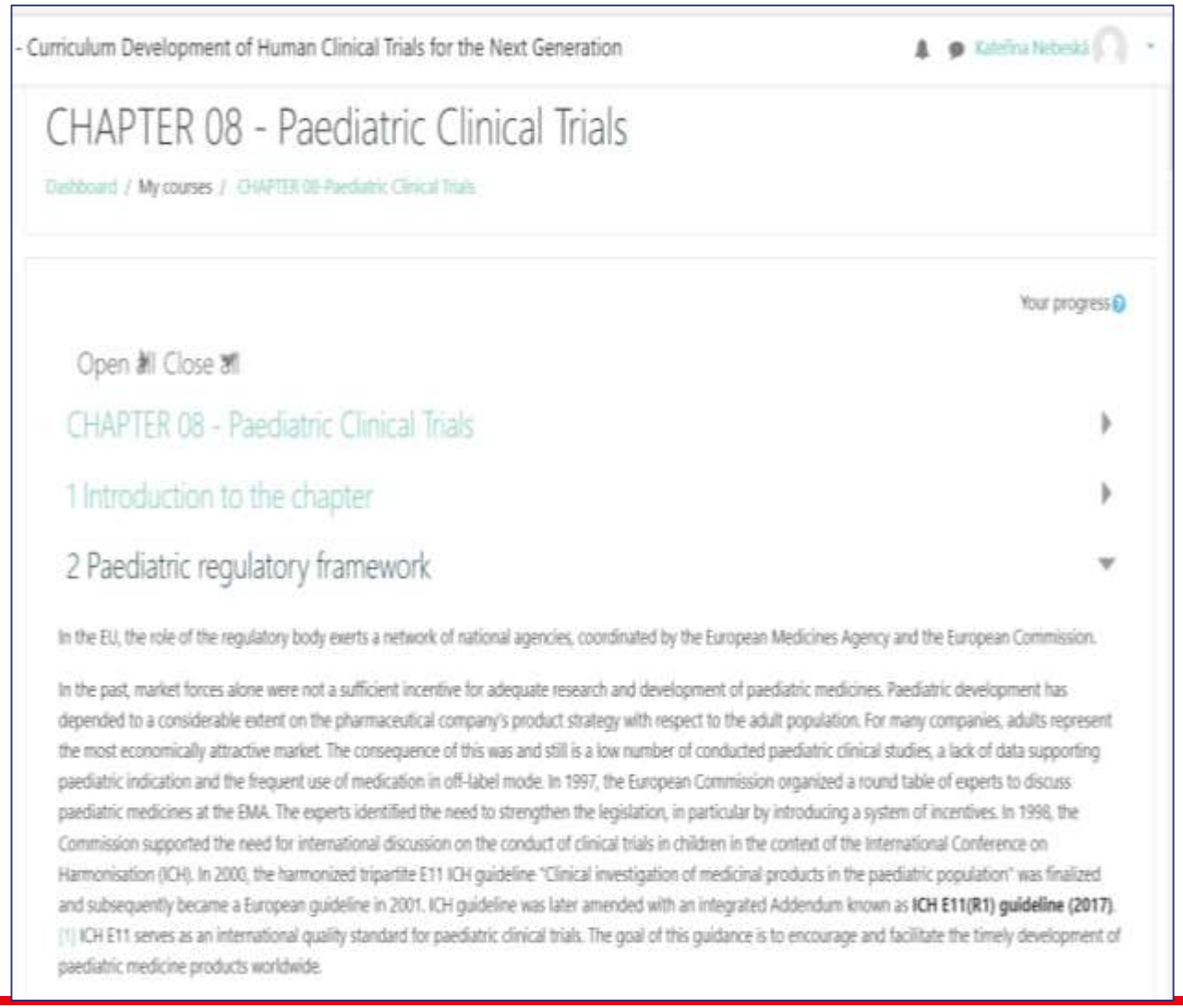
A non-compliance was detected by the monitor during the monitor's visit. How to solve it?

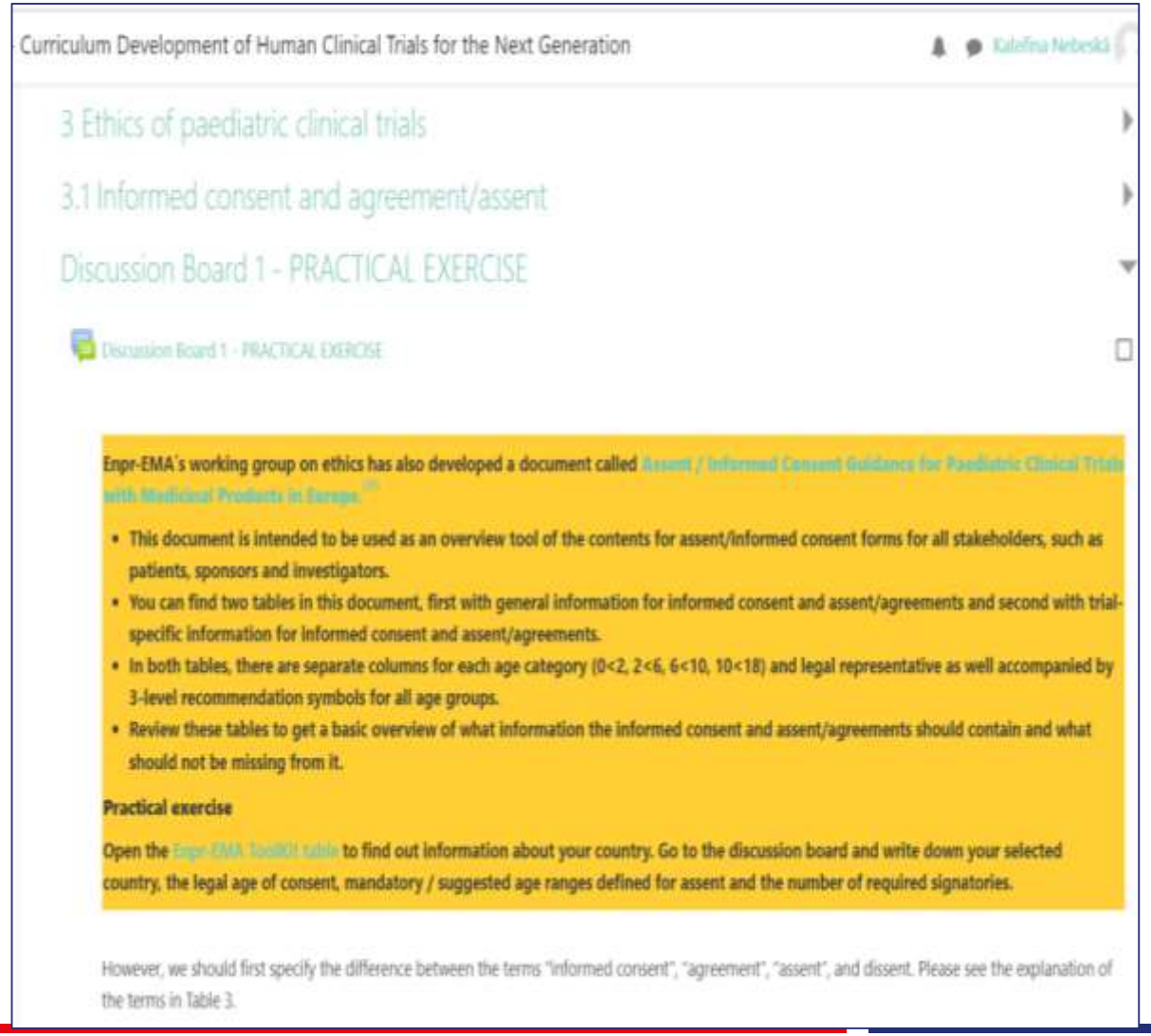
Firstly, watch the YouTube video "CAPA Case Study".



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.





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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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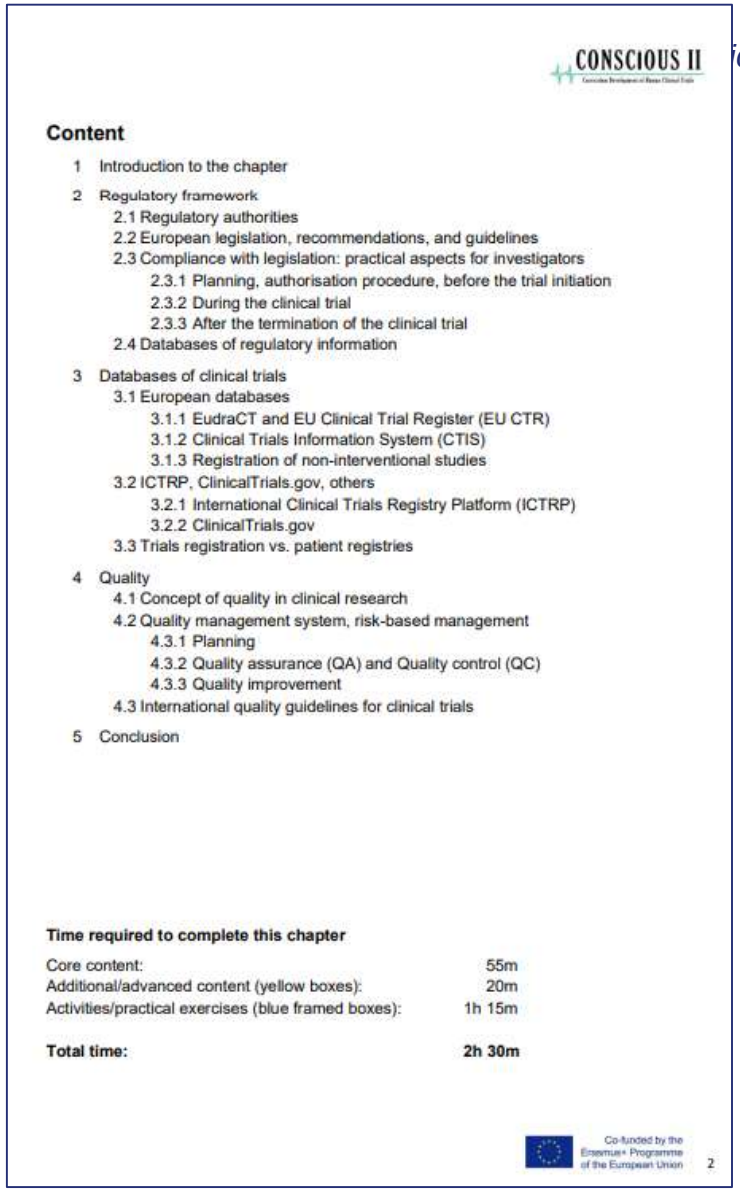

CONSCIOUS II

Content

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**

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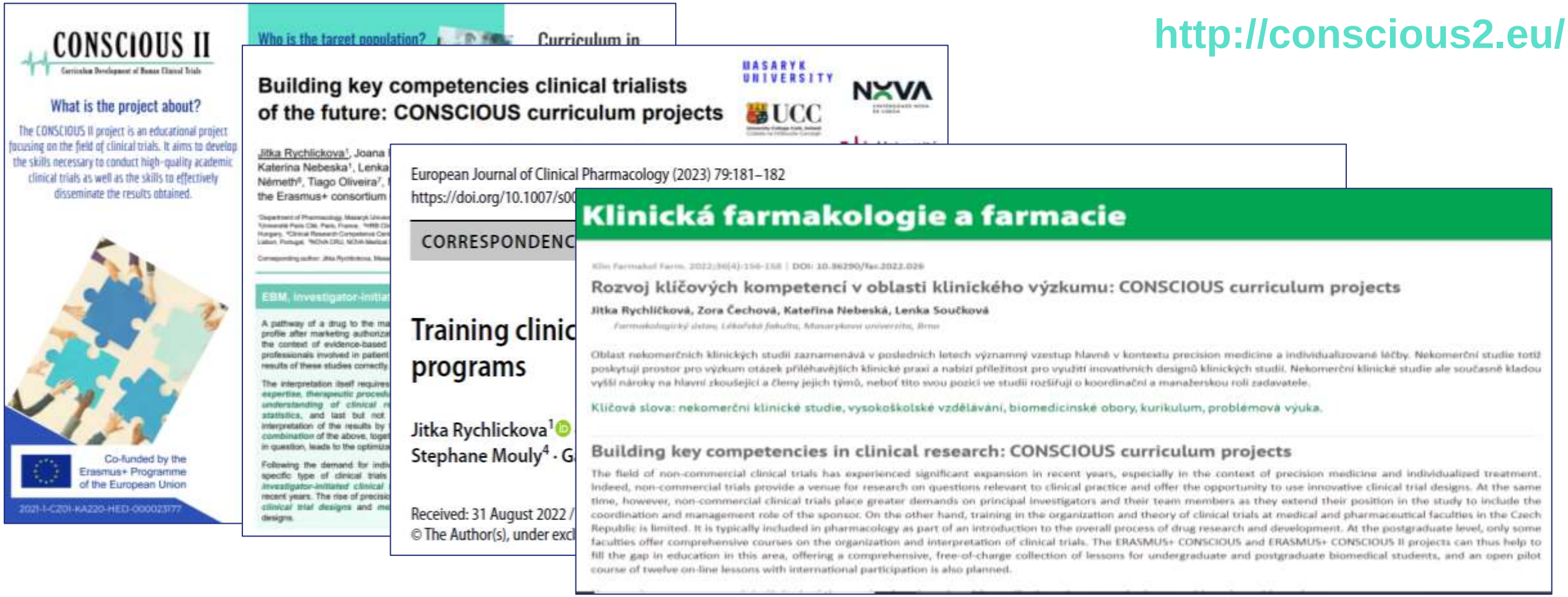
Pilot teaching

- 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

Project CONSCIOUS II

http://consciousii.novaims.unl.pt/login/index.php

http://conscious2.eu/



Děkuji za pozornost