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CONSCIOUS
Curriculum Development of Human Clinical Trials

CONSCIOUS II
Curriculum Development of Human Clinical Trials

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

CONSCIOUS – educational projects in CT

Clinical trials – A neglected part of the curriculum

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Training for investigators

- *ICH GCP Section 4.1 "Investigator´s Qualifications and Agreements* - key to ensure that appropriate qualified staff are available to conduct the trial

- The Principal Investigators (PI) have the responsibility to first verify and confirm that their team members are qualified and trained to discharge their roles in the study

- Only 6 MSc Clinical Trials in Europe

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- ERASMUS+ funded projects
- An educational project
- International cooperation of 5/6 European partner universities:

- University of Pécs
- Masaryk University
- NOVA University Lisbon
- University of Paris
- University College Cork
- (University of Szeged)

– ECRIN associated partner

CONSCIOUS (2018-1-HU01-KA203-047811)

– Finished project, still freely available online, designed for pregradual biomedical students

CONSCIOUS II (2021-1-CZ01-KA220-HED-000023177)

– Ongoing project, designed for investigators, junior researchers, PhD students

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Curriculum Development of Human Clinical Trials for the Next Generation Biomedical Students

- **Target** - Biomedical students - pregradual level
- **Aim** - to supplement the curriculum of undergraduate biomedical (medical, pharmacy,…) students within the field of clinical trials
- **Output** - e-learning materials, teacher´s guides

E-learning materials are freely available.

Chapters:

1. Clinical research
2. Why clinical trials are the gold standard
3. Case study: Tuskegee Syphilis
4. Ethics in clinical trials
5. Informed Consent
6. Equipoise; Forming a research question and defining the outcome
7. Clinical Trial Phases
8. Phase III Trial Design RCT
9. Protocol and CRF
10. Trial Management
11. The numbers…sample size, why it´s important; interpreting the results
12. Medical devices and advanced therapies
13. Critical Appraisal of RCT
14. Adverse events and reporting responsibilities

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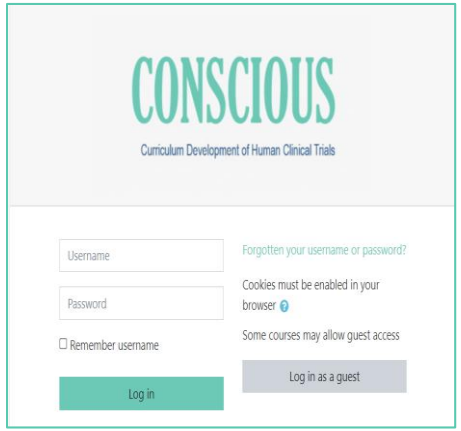
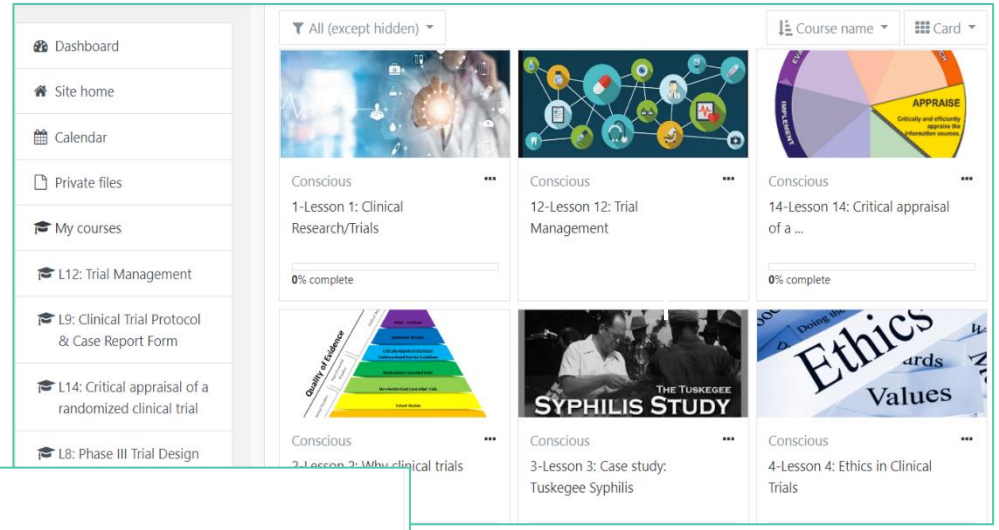
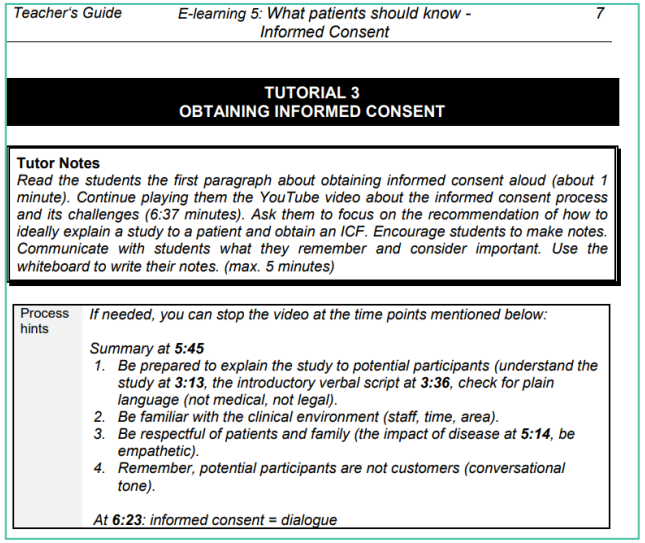
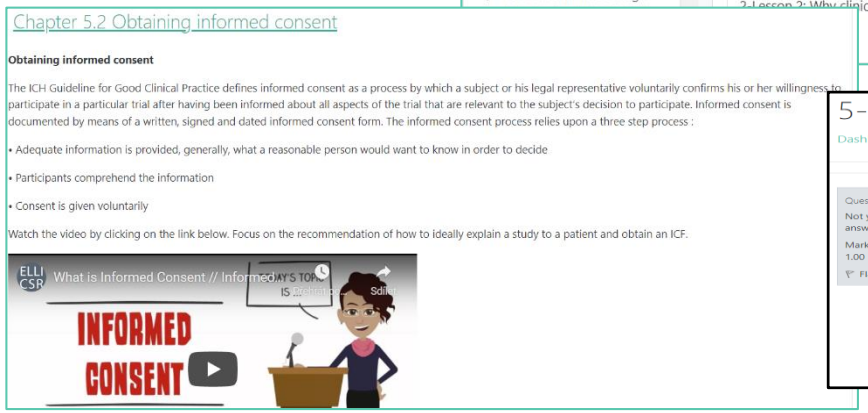
CONSCIOUS I e-learning materials

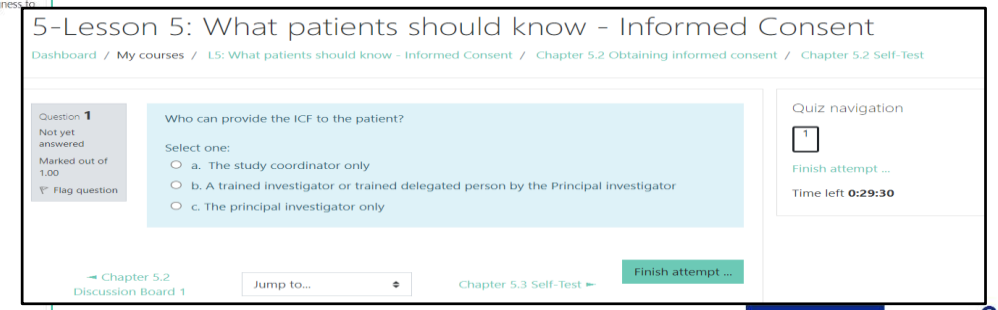
[Conscious - Curriculum Development of Human Clinical Trials: Log in to the site (unl.pt)]











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Quizzzzz…

1. When should an ICF be signed?

Select one:

- a. After patient randomisation into the clinical trial
- b. Prior to any study-specific intervention
- c. Whenever during the clinical trial

1. Is approval from an Ethics Committee needed before obtaining an ICF from the patient?

Select one:

- a. Yes
- b. No

1. What is the age limit in the EEA when a parents' signature is not needed for participation in a CT?

Select one:

- a. 16 years
- b. 18 years
- c. The age limit differs in European countries

1. The consent form serves several purposes, including:

Select one:

- a. Documenting the subject's voluntary agreement to participate
- b. All of the above
- c. Providing a "take home" reminder of the elements of the clinical investigation
- d. Helping to ensure that the subject receives the required information

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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

- **Target** – PhD students and junior researchers in the medical, science, pharmacy and health professions
- **Aim** – 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
- **Output** – e-learning materials, pilot teaching

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- PR1: Training materials – Lifecycle of the trial curriculum

1. Clinical Trials Design **UCC**
2. Trial Methodology **UCC**
3. Trial Management **UNL**
4. Quality and regulatory affairs and sources of regulatory information **MU**
5. Pharmacovigilance and study medication **UCC + MU**
6. Datamanagementand statistical analysis **UP**
7. Early phase trials **USZ**
8. Pediatric clinical trials **MU**
9. Medical devices **USZ**

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- PR2: Training materials – transferable interdisciplinary training

1. Leadership for PIs **UdP**
2. Open research and scientific publishing **UdP**
3. Teaching the teachers: innova tive pedagogical methods in health research education

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Next steps, contacts…

- 1st transnational meeting, 26-27th May 2022, Cork, Ireland
- **Timeline** – first lessons published on project´s platform

- **Project website**: http://conscious2.eu/
  - Outlines of chapters
  - Information about published lessons
  - Events, newsletters,..
- **Project´s coordinator** – Jitka Rychlíčková rychlickova@med.muni.cz

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Thank you for your attention

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