

M U N I
M E D



Co-funded by the
Erasmus+ Programme
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CONSCIOUS – educational projects in CT

Clinical trials – A neglected part of the curriculum

Kateřina Nebeská, Jitka Rychlíčková, Zora Čechová, Lenka Součková

Supported by the national budget through RI CZECRIN (LM2018128) and from ERASMUS+ CONSCIOUS (2018-1-HU01-KA203-047811), CONSCIOUS II (2021-1-CZ01-KA220-HED-000023177)

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



CONSCIOUS, CONSCIOUS II

- 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



- **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

CONSCIOUS | e-learning materials



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

CONSCIOUS
Curriculum Development of Human Clinical Trials

Username [Forgotten your username or password?](#)

Password [Cookies must be enabled in your browser](#)

Remember username [Some courses may allow guest access](#)

Dashboard

Site home

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My courses

L12: Trial Management

L9: Clinical Trial Protocol & Case Report Form

L14: Critical appraisal of a randomized clinical trial

L8: Phase III Trial Design

All (except hidden)

Course name

Card

Conscious
1-Lesson 1: Clinical Research/Trials
0% complete

Conscious
12-Lesson 12: Trial Management

Conscious
14-Lesson 14: Critical appraisal of a ...
0% complete

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2-Lesson 2: Why clinical trials

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3-Lesson 3: Case study: Tuskegee Syphilis

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4-Lesson 4: Ethics in Clinical Trials

Teacher's Guide

E-learning 5: What patients should know - Informed Consent

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**TUTORIAL 3
OBTAINING INFORMED CONSENT**

Tutor Notes
Read the students the first paragraph about obtaining informed consent aloud (about 1 minute). Continue playing them the YouTube video about the informed consent process and its challenges (6:37 minutes). Ask them to focus on the recommendation of how to ideally explain a study to a patient and obtain an ICF. Encourage students to make notes. Communicate with students what they remember and consider important. Use the whiteboard to write their notes. (max. 5 minutes)

Process hints
If needed, you can stop the video at the time points mentioned below:
Summary at 5:45
1. Be prepared to explain the study to potential participants (understand the study at 3:13, the introductory verbal script at 3:36, check for plain language (not medical, not legal).
2. Be familiar with the clinical environment (staff, time, area).
3. Be respectful of patients and family (the impact of disease at 5:14, be empathetic).
4. Remember, potential participants are not customers (conversational tone).
At 6:23: informed consent = dialogue

Chapter 5.2 Obtaining informed consent

Obtaining informed consent

The ICH Guideline for Good Clinical Practice defines informed consent as a process by which a subject or his legal representative voluntarily confirms his or her willingness to participate in a particular trial after having been informed about all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form. The informed consent process relies upon a three step process:

- Adequate information is provided, generally, what a reasonable person would want to know in order to decide.
- Participants comprehend the information
- Consent is given voluntarily

Watch the video by clicking on the link below. Focus on the recommendation of how to ideally explain a study to a patient and obtain an ICF.



5-Lesson 5: What patients should know - Informed Consent

Dashboard / My courses / L5: What patients should know - Informed Consent / Chapter 5.2 Obtaining informed consent / Chapter 5.2 Self-Test

Question 1
Not yet answered
Marked out of 1.00
Flag question

Who can provide the ICF to the patient?

Select one:

a. The study coordinator only

b. A trained investigator or trained delegated person by the Principal investigator

c. The principal investigator only

Quiz navigation

Finish attempt ...

Time left: 0:29:30

Chapter 5.2 Discussion Board 1

Jump to...

Chapter 5.3 Self-Test



Quizzzzzz...

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

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

- **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

– 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**

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

- PR2: Training materials
 - transferable interdisciplinary training

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

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



Thank you for your attention

nebeska@med.muni.cz