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

Jitka Rychlickova[1], Joana R. Batuca[2], Viktória Nagy[3], Frances Shiely[4], Zora Cechova[1], Katerina Nebeska[1], Lenka Souckova[1], Stephane Mouly[3], Gábor L. Kovács[5], Annamária Németh[6], Tiago Oliveira[7], Marco Painho[7], Sara Maia[8] and Emília C. Monteiro[2], on behalf of the Erasmus+ consortium CONSCIOUS II

[1]Department of Pharmacology, Masaryk University, Brno, Czech Republic, [2]PtCRIN, NOVA Medical School Universidade Nova de Lisboa, Lisbon, Portugal, [3]Université Paris Cité, Paris, France, [4]HRB Clinical Research Facility and School of Public Health, University College Cork, Cork, Ireland, [5]University of Pécs, Pécs, Hungary, [6]Clinical Research Competence Center, University of Szeged, Szeged, Hungary, [7]NOVA Information Management School, Universidade Nova de Lisboa, Lisbon, Portugal, [8]NOVA CRU, NOVA Medical School Universidade Nova de Lisboa, Lisbon, Portugal

Corresponding author: Jitka Rychlickova, Masaryk University – email address: rychlickova@med.muni.cz

EBM, investigator-initiated trials

A pathway of a drug to the market or refinement of its therapeutic and safety profile after marketing authorization passes through a wide range of studies. In the context of evidence-based medicine (EBM), physicians, as well as other professionals involved in patient care, need to be able to interpret and apply the results of these studies correctly.

The interpretation itself requires a broad understanding not only of the ***field of expertise***, ***therapeutic procedures***, and their ***conditions of choice*** but also an ***understanding of clinical research theory***, ***clinical trial designs*** and ***statistics***, and last but not least, the ability to ***critically evaluate*** the interpretation of the results by the authors of the publication is desirable. The ***combination*** of the above, together with consideration of the needs of the patient in question, leads to the optimization of treatment, which is the central aim.

Following the demand for individualized treatment and precision medicine, a specific type of clinical trials - ***academic clinical trials*** (also known as ***investigator-initiated clinical trials***) - has become increasingly important in recent years. The rise of precision medicine is also reflected in the ***adaptation of clinical trial designs*** and ***methodologies*** and the use of innovative study designs.

Education and training clinical trial teams of the future

These types of clinical research should therefore be seen as relevant not only in shifting the quality and individualization of patient treatment, but also in the context of the ***need to train experts designing and conducting*** their own (academic) studies.

Clinical research is only very ***marginally*** subject to ***undergraduate medical*** and biomedical training in Europe; ***post-graduate education*** is mostly ***not compulsory*** for investigators performing and taking responsibility for clinical trials in most EU countries. Thus, the lack of adequate education and training in clinical research and the increasing demand for competent professionals, on the other hand, have made it necessary to build efficient curricula to train clinical researchers of the future. And this is the space in which two ERASMUS+ projects have been applied:

- Curriculum Development of Human Clinical Trials for the Next Generation Biomedical Students (***CONSCIOUS***);
- 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 (***CONSCIOUS II***).

The CONSCIOUS project

Timelines: started 09/2018, finished 08/2021

Target population:

- **undergraduate** biomedical students

Results:

- ***14 lessons*** available covering clinical research in general, fundamental knowledge sufficient for conducting clinical trials
- All lessons available on the ***training platform*** for self-study or for lecturer-led lessons
- ***Teachers' guides*** accompanying each lesson (didactic, professional support)

CONSCIOUS
Curriculum Development of Human Clinical Trials

Who prepared the project results?

- Developed by the ***consortium*** led by the University of Pécs; consortium members University College Cork, Paris Cité University, Masaryk University, and NOVA University Lisbon.
- ECRIN as an Associated partner.

More information and access to the training platform available here:
http://conscious.novaims.unl.pt/login/index.php

The CONSCIOUS II project

Timelines: started 11/2021, planned till 10/2024

Target population:

- PhD students in health sciences, pharmacy, medicine
- Early-career researchers
- Investigators planning an academic clinical trial
- Teachers and lecturers of the theory of clinical trials
- People starting to work in clinical trials

What to expect?

- ***12 e-learning*** highly practice-based and -oriented ***lessons*** classified into three categories:
- A ***training platform*** with interactive elements overarching all e-learning materials
- ***Pilot teaching lessons*** – planned from 11/2023 to 05/2024

CONSCIOUS II
Curriculum Development of Human Clinical Trials

Who works on the project results?

- Developed by the ***consortium*** led by the Masaryk University; consortium members University College Cork, Paris Cité University, University of Pécs, University of Szeged and NOVA University Lisbon
- ECRIN as an Associated partner.

More information and access to the training platform available on the ***project websites*** http://conscious2.eu/ and by contacting the project manager: Jitka Rychlickova rychlickova@med.muni.cz

Main topics of the e-learning lessons:

Planning and organizing clinical trials

1. Clinical trial 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 – standardizing and analyzing data

Specific types of clinical trials and their specifics

7. Early phase trials
8. Pediatric clinical trials
9. Medical devices clinical trials

Transdisciplinary program

10. Leadership, team management and networking skills in research
11. Scientific publishing and open research
12. Teaching the teachers

Where to find out more?

Project websites

Multiplier event in Paris, France May 12, 2023

The next ***upcoming Multiplier events*** in Hungary (11/2023), the Czech Republic (05/2024), and Portugal (10/2024)

This work was supported by the *Erasmus+ Programme of the Europe Union*
(2018-1-HU01-KA203-047811 and 2021-1-CZ01-KA220-HED-000023177).

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