CONSCIOUS II

Curriculum Development of Human Clinical Trials

PILOT TEACHING PROGRAMME 2024

Calling all Future Trialists!

Unleash your potential and embark on a transformative journey in clinical research! Join our cutting-edge CONSCIOUS II course, tailored for PhD students, early-phase researchers, aspiring trialists, and visionary educators.

Explore the trial design, conduct high-quality trials, master data management, and publish groundbreaking results. Shape the future of healthcare through evidence-based medicine. Enrol now to become a trailblazer in investigator-initiated clinical trials! Don't miss this golden opportunity!

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March 26	Open research and scientific publishing
April 2	Teaching the teachers

Jitka Rychlíčková, project manager
Masaryk University, Czech Republic

This session will kick off a pilot course aimed at training skills useful for successful clinical trial conduction. The entire session is designed to give you a better idea of what exciting things to expect during the upcoming course. Individual lecturers will introduce themselves to you, we will unveil the innovative and efficient format of education implemented in this course for you to get the maximum knowledge and skills possible, we will also introduce the character of tasks that will be tackling together. We introduce you to the training platform and its possibilities. Last but not least, there will be space for your questions.

The course aims to provide you with a space to practice your skills, discuss burning issues with the lecturers, and build collaboration with your colleagues near or far. So let's dive into this enriching course together and learn together.

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Frances Shiely
University College Cork, Ireland

What do you do when you want to test a product or a therapy? You conduct a clinical trial. This chapter will introduce you to the process of designing a clinical trial. It will take you through the need for equipoise when developing your research question. From there you will work with the SPIRIT guidelines to design your trial. There are many different types of trials. In some you want to just show your new drug/therapy is equivalent, sometimes you want to show it's superior and sometimes you want to show that it is not inferior. There are many reasons for this and we will take you through them all. We will talk about cluster randomised trials too and how they differ from individually randomised trials. Finally we will talk about pragmatic trials, trials conducted in the real world setting.

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Annamária Németh
University of Szeged, Hungary

How do the phases of clinical trials differ from each other? What are the specialities of early phase clinical trials? What do researchers need to keep in mind when they plan the trial design of early phase trials? These are some of the questions that are addressed in this chapter. Moreover, you can also get an insight into the difficulties of determining the first human dose, dose concepts, the roles and tasks of study participants, planning endpoints of trials. Through practical examples and case studies appering in this lesson you can also get a taste of recent trends in early phase trials.

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Kateřina Nebeská
Masaryk University, Czech Republic

In what ways do pediatric clinical trials differ from clinical trials for adult populations, specifically in regard to study design, ethical considerations, and patient recruitment? We'll start by exploring the paediatric regulatory framework then we´ll learn how to write informed consent form that are appropriate for children and how to navigate the specific requirements in different EU countries. Next, we'll talk about the challenges that come with conducting paediatric clinical trials, and we'll explore how involving patients and parents in the process can ease some of those challenges and lead to more successful trials.

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Zora Čechová
Masaryk University, Czech Republic

Are regulatory authorities friends or enemies? And how do you feel about the legislation? In the pilot teaching, we will use practical tasks to navigate you through this seemingly complicated network of regulations and guidelines. We will focus on different types of clinical studies with various products and take your experience too. Additionally, we will discuss where, when, and why it is essential to register your study and its results. Lastly, together we will explore the quality and quality management system from the investigator's point of view and gain insight into the risk assessment process and CAPA in real practice.

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Joana Batuca, Sara Maia
Universidade NOVA de Lisboa, Portugal

Do you know that successful clinical trials are almost all about management? Why clinical trials of whatever size and complexity, requires efficient trial management? Many clinical trials fail to deliver because of the lack of a structured, practical, businesslike approach to trial management. In this chapter we will introduce you to the most important aspect of managing a clinical trial from the implementation phase to the end of trial. We will discuss legal requirements and who is responsible for the trial management. Additionally, we will discuss the importance of oversight and monitoring the progress of the trial to ensure rights and safety of the participants and guaranteeing high-quality data. We will share some tips and tools to help you to overcome operational challenges.

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Gábor Kovács
University of Pécs, Hungary

In the world of medical research, data management (DM), and statistical analysis are crucial for maintaining the quality, integrity, and compliance of information. Our course facilitate to understand the basic needs for data collection is handled seamlessly, enabling you to focus on what matters most – achieving successful outcomes. In the pilot teaching, we will delve into the FAIR Principles and the global standards they encompass, which are essential for successful data handling as well as data analysis. By understanding and implementing these principles, you will be well-equipped to navigate the world of medical research data management. Let's dive in and discover how effective data handling/statistical concepts can enhance the quality of our medical research/study/trial and lead you to a successful outcomes.

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Frances Shiely,
University College Cork, Ireland

Lenka Součková, Jitka Rychlíčková
Masaryk University, Czech Republic

Join us for the seventh topic of our pilot course, where we dive into the intriguing world of study medication and its safety. Don't miss the chance to get hands-on experience in evaluating adverse effects in clinical trials, including training on proper and timely reporting. This discipline is challenging in itself, with various restrictions and regulations. However, the ever-changing legislation adds another layer of complexity, disrupting long-established practices. Based on real clinical trial data, you'll navigate every aspect from A to Z, following the up-to-date rules. In the second part of the lesson, we'll discuss your ideas on selecting IMPs and AMPs for your clinical study and explore the intricacies of designing labels for them. Walk away with a clear vision for your own clinical trial or, at the very least, an understanding of what needs to be set up and how.

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Frances Shiely
University College Cork, Ireland

What is trial methodology research? Simply put, it's research on research. This can be qualitative or quantitative. Trial methodology is all about making trials more efficient. In this chapter we will talk about trial methodology research as an embedded feature of clinical trials training. We will discuss priority setting exercises in this area and talk about key unresolved methodological challenges, such as recruitment and retention. Finally, we introduce SWATs (Studies Within A Trial), their key features and why there should always be a SWAT embedded in your trial.

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Annamária Németh, Éva Takács
University of Szeged, Hungary

How do medical device investigations differ from drug trials? Is there a need to do clinical investigations for all new medical devices? How should a researcher plan clinical investigations and what supporting documents are needed? Among other questions these will be discussed in this pilot lesson. First, you can get an insight into the legal environment of medical device developments and also understand all stakeholders of this process. Then we will talk about clinical evaluations and clinical investigations. Practical examples and case studies from academia will help you navigate through the complex issues raised in this chapter.

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Viktória Nagy
Université Paris Cité, France

Do you know how to manage a team, how to set up a CTU and a CRU, how to fund your research project and promote it? This interdisciplinary chapter will introduce to you the pros and cons of management techniques (command and control, engage and create, econ 101, Agile etc.) and leadership styles (from the autocratic to servant leadership), regulations, on establishing gender balance in team, on CTU and CRU management including staff recruitment and the role of the PI, on European, industrial and private funding schemes and grant proposal submission, on the role of European Learned Societies and Scientific Networks, on pitching to sponsors and policymakers. You'll evolve in a problem-based learning, practical setting – so after you're class, you'll be able not just to explain abstract notions but to do all these things and be a leader in the scientific space!

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Viktória Nagy
Université Paris Cité, France

Do you know how to write a scientifically and linguistically accurate article? Would you like to get published? Are you curious about the new era of publications? This chapter will introduce to you publication standards (APA, STROBE, CONSORT, PRISMA, Cochrane collaboration, MOOSE, STARD, EASE guidelines), you'll get an overview of scientific journals, online publication possibilities, the submission and peer-to-peer review process, the ethical guidelines and the legal framework, and you'll get some practical tips about language use, table and graph creation etc., and finally you'll get familiar with the legal, ethical and practical considerations of Open Science and Open Publishing, Science 2.0 and crowdsourcing.The intended learning outcome of the class is for you to come away with the draft of a publishable product.

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Viktória Nagy
Université Paris Cité, France

If you're a researcher, most probably you'll be one day a teacher! Are you fed up with simple powerpoint presentations? Do you want your students to show up to class, remain active and take away applicable skills? You'll learn in this class about the pros and cons of passive and active pedagogies (lectures vs. problem-based, project and challenge-based learning, flipped classrooms and blended learning), innovative teaching formats, and you'll be able to use digital tools (zoom, Wooclap, Wooflash etc.) to make your classes interactive. Other than that, you'll be able to create adapted content for the learners of the 21st century with adapted evaluations, accompany your students and finally, the cherry on the cake, to design a MOOC.