BMC Medical Education

RESEARCH

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Enhancing pragmatic competence in investigator-initiated clinical trials: structure and evaluation of the CONSCIOUS II training programme

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Abstract

Introduction Investigator-initiated trials (IITs) bridge the gap between applied clinical research and everyday clinical practice. However, they require the skilled multidisciplinary teams from different backgrounds but all with clinical trial training to ensure trials are designed, conducted and reported according to best practice and regulatory standards. The availability of trainings to fulfil these needs is limited. The CONSCIOUS II project facilitated to expand the supply of such programmes. The objective is to describe the curriculum designed for PhD students and early-career researchers, and evaluate participants' perceptions and feedback after completion of the training.

Methods The curriculum was developed according to key principles that underpin building of competencies relevant to quality IITs and transdisciplinary skills. A multidisciplinary team created the curriculum, elaborated a comprehensive set of study materials, including the training platform. This team also conducted an international, collaborative pilot course. The effectiveness of the educational materials for the target audience was assessed through questionnaires administered after the pilot course. Additionally, all learning materials, including the video recordings of the pilot course, were externally evaluated.

Results A 12-chapter thoroughly revised curriculum was developed for asynchronous preparation and served as a pre-class reading for a 3-month pilot course. The chapters, along with supplementary materials, and recordings of the pilot course are freely accessible on the CONSCIOUS II training platform. This platform facilitates the dissemination and implementation in the existing curricula. The feedback from both the pilot course participants and the stakeholders was uniformly positive across all survey aspects.

Conclusion This remote programme which combines asynchronous and synchronous components with international and interprofessional collaboration effectively addresses the gap in developing core competencies for

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the 21st -century clinical researchers. The implementation of this curriculum has the potential to improve the quality of IITs.

Keywords Investigator-initiated trials, Curriculum, Early-career researchers, Practice-oriented

Introduction

Investigator-initiated trials (IITs) are essential for patient-centered research, bridging the knowledge gap between clinical trials and real-world scenarios [1–4]. These studies, typically driven by clinical practice or academia interest, address the challenges and needs of everyday practice, often focusing on underserved populations or therapeutic specific areas. In a wider context, IITs contribute significantly to improving clinical practices. Their value lies in providing unbiased evaluations free from commercial interests, which helps in developing accurate clinical guidelines, formulating population-specific policies and repurposing existing drugs [1–4]. This approach enables the adoption of impartial and sustainable health policies, offering both direct and indirect benefits to patients and enhance the efficiency of the healthcare system. However, for such medical research, it is necessary to educate the trial leaders of the future [3]. In IITs, the role of the principal investigator (PI) extends beyond orientation in the field and critical evaluation of available literature to design quality trials. They typically assume the role of the sponsor and take responsibility for the coordination and management of the entire study through their parent organization [5].

Education in clinical research is not systematic compared to medical education and often relies on the mentor-mentee relationship or experience gained as a sub-investigator [4, 6–8]. Unfortunately, mentoring in IITs is constrained by dramatic changes in the clinical trial landscape, regulatory framework, and ever-evolving quality demands. Repetitive, one-size-fits-all training like the GCP certificate, a standard mandatory qualification requirement for PIs and any staff of the team in a clinical trial, is often perceived as a necessity with little added value due to its generality and didacticism [7]. There is a general consensus on the ideal direction for developing clinical investigator training: it should be individualized and flexible, based on real-world applications of GCP guidelines and real-world problems. Training should take into account the diverse experiences of participants and focus on building practical skills, including non-traditional training modalities [3, 7, 9, 10]. At the same time, it is important to reflect that for many investigators, research is somewhat secondary to their own clinical work, and therefore, the goal should be to maximize the content-, time-, and cost-effectiveness of training [9]. The format of the training is also important, especially with innovative approaches (e.g., learning by doing, peer-to-peer training) significantly enhancing training effectiveness [7].

The CONSCIOUS II project facilitates a practice-oriented, and pragmatic learning program applying innovative teaching methods to the widest possible academic and non-academic stakeholders community. The curriculum provides support for designing, implementing, conducting, managing and reporting IITs. A broad consortium of partners with extensive expertise in IITs management, clinical research methodology and IITs design, data science, clinical pharmacology, teaching, and research in medical education formulated the CONSCIOUS II curriculum. This dynamic set of skills enabled the creation of a unique curriculum in terms of content and format. The objective of this paper was to (1) describe the developed curriculum, (2) summarize participant's perceptions after completion, and (3) review stakeholders' feedback.

Methods

Curriculum design

The development of the CONSCIOUS II curriculum began with the conceptualization of key principles and ideas based on the project objectives and the target population. This included a careful selection of chapter topics focused on building general competencies applicable to all clinical trials, specific types of clinical trials, and transdisciplinary skills. The primary target population includes PhD students, early-career researchers as potential IITs PIs or members of project or study teams, as well as teachers and lecturers. At first, an outline was created for each chapter with an executive summary, aims, learning outcomes, and complementarity of the new materials with those already available from the previous CONSCIOUS project [11]. These outlines now accompany each chapter, providing a clear framework and context. The second step was to define the structure of each chapter: core content, additional/advanced content (explanatory, expanding information, providing further context), and the activities (exercises, case reports, discussion boards, quizzes to practice theoretical knowledge or skills). The third step focused on the teaching methods implemented in the chapters, the requirements for the training platform to support interactivity and communication between participants, and the techniques used in the pilot course. The next step was implementing the graphic design, including promotional materials (leaflets and interview videos with the primary authors). In

addition, the individual chapters and video-recordings of the pilot lessons are licensed under CC-BY-SA 4.0.

All materials underwent multiple revisions. The first outputs were outlines. The outlines were first discussed within the consortium. A revised version was submitted to European Clinical Research Infrastructure Network (ECRIN) experts for review [12]. Based on the comments, the first official version of each chapter outline was issued. The chapter was then prepared according to this proposal. It went through the same review procedure. Once the chapter was completed, the outline was modified where necessary. This revised material served as training material for the participants of the pilot course. After the pilot course, the chapters and outlines were again revised and aligned.

An educational platform was created to consolidate all materials in one place, enhance the digital competencies of the target population, and facilitate the implementation of the curriculum into existing programs. Moreover, such a platform preserves the interactivity of the content, allows interaction between participants with each other or between lecturers and participants (discussion boards) regardless of their geographical location.

The pilot course

The pilot course was designed as an international, interdisciplinary, and collaborative course. The course was intended as a flipped classroom where participants were required to independently review the core content of the relevant chapter and complete the exercises in the week preceding the session. This independent preparation was followed by an online lesson, led by the chapter's primary author. Each online lesson was recorded and an edited version– excluding parts of the teamwork in breakout rooms, time for technical problem solving– became a project output, serving both learning material, and a teacher's guide. The participants obtained a certificate upon fulfilling the conditions of attending more than 60% of lessons and being present more than 60% of the overall time of the lesson.

Curriculum evaluation, stakeholders' feedback

The curriculum evaluation took place at two levels– feedback from participants of the pilot course (i.e., the target population) and feedback from stakeholders (i.e., the knowledgeable population– experienced clinical trialist, university teachers guaranteeing subjects on drug development and clinical research, IITs project managers, national agencies', clinical research organizations', and ECRIN representatives; nobody was involved in preparation of the curriculum). An online questionnaire consisting of 32 and 20 questions, respectively, was developed for both groups. The paticipant questionnaire was divided into five sections– (1) Participant Profile, (2) General Satisfaction, (3) Platform, (4) Pilot Teaching, and (5) Course Improvement; the stakeholder questionnaire was similar but modified in the first (Stakeholder Profile) and fourth sections (Pilot Teaching Records). A five-point Likert-type scale was used for the questions in Sects. 2, 3, and 4 (with range: 1 as "strongly disagree" to 5 "strongly agree"). Two questions were open-ended. The questionnaire was distributed to the pilot course participants immediately after the course, followed by two reminders and a total of 8 weeks to complete it. The stakeholders recieved the questionnaire approx. 3 months later, after all materials and pilot lessons recordings had been completed and uploaded to the training platform, with one-follow-up reminder issued. As a result, participants' feedback covered both asynchronous and synchronous components of the curriculum, while stakeholders' feedback reflected all asynchronous parts, i.e. including video-recordings of synchronous sessions.

Another type of feedback was obtained during three face-to-face dissemination meetings [13–15]. In these meetings, participants were given a general overview of the project and the curriculum. They were then asked to share their views via a questionnaire on the extent to which a similarly focused curriculum was available or established at their institution, its need, and the appropriateness of the chosen topics and format. The answers are scored on a five-point Likert-type scale, with 1 as "strongly disagree" to 5 as "strongly agree".

Results

The curriculum consists of 12 multiply revised chapters divided into three thematic clusters, encompassing approximately 70 h of individual training (see Table 1 for details). The learning materials for the asynchronous work are hosted on the Moodle learning platform (version 3.0) and are also available in a printable format on the project websites (www.conscious2.eu) [16]. The platform is freely accessible, protected by credentials provided upon request by the CONSCIOUS II project contact persons. The chapters are visibly structured in core content, additional/advanced content (highligthed in yellow boxes), and activities (interactive elements in the training platform and blue boxes in the printable version). Each chapter is part of a comprehensive package of materials on the topic that includes: the chapter, the outline, an interview video with the primary author, a video-recording from the pilot course session. These packages are available on both the training platform and the project websites (here, except for the video-recordings from the pilot course). To help navigate the curriculum, learning materials, and organization of the pilot lesson, an introductory session preceded the pilot course and was published on the platform.

Table 1 Curriculum structure and time allocation

Thematic cluster	Chapter	Time required to complete the chapter (in hours)			Duration of the pilot lesson recording (in hours)
		Core content	Additional/ advanced content	Activities/ practical exercises	
General competencies	Clinical Trial Design	2.0	3.0	0.5	1.5
	Trial Methodology Research	0.6	1.5	2.75	1.5
	Trial Management	3.0	1.5	0.5	1.4
	Quality and Regulatory Affairs	0.9	0.3	1.25	1.2
	Pharmacovigilance and Study Medication	1.2	0.3	1.0	1.0
	Data Management and Statistical Analysis	1.0	0.5	–	1.5
Specific types of trials	Early Phase Trials	0.8	1.2	0.7	1.3
	Pediatric Clinical Trials	1.0	0.25	1.0	1.4
	Clinical Evaluation and Clinical Investigation of Medical Devices	1.5	0.5	1.5	0.9
Transdisciplinary skills	Leadership for 21st -Century Trialists	4.0	2.0	0.5	1.4
	Scientific Communication	3.0	1.5	0.5	1.5
	Training the Trainers of the 21st Century	3.0	1.5	0.5	1.3
Average time required per chapter part		1.8	3.0	0.9	1.3
Total time required to complete the chapter part		22.0	36.5	10.7	15.9
Time required to complete all the curriculum materials		85.1			

Table 2 Structure of registered participants according to countries

Country	*n*	%
Czech Republic	84	32.6
Ireland	63	24.4
Portugal	63	24.4
United Kingdom	24	9.3
outside Europe*	8	3.1
Netherlands	4	1.6
Hungary	3	1.2
Slovakia	3	1.2
Serbia	2	0.8
Belgium	1	0.4
Spain	1	0.4
Greece	1	0.4
Italy	1	0.4

* Angola, Brazil, Kenya, Malaysia, Peru, South Africa, Taiwan, USA

Table 3 Structure of registered participants according to the position/role

Position/role	*n*	%
PhD student	114	44.2
Early-career researcher	59	22.9
Clinical trial position*	54	20.9
Teacher/lecturer/supervisor	15	5.8
Undergraduate student	9	3.5
Other	7	2.7

* Project Manager, Data Manager, Pharmacovigilance Specialist, Clinical Research Associate, Investigator, Study Coordinator

The pilot course ran from January to April 2024 comprising 12 sessions that corresponded with the 12 chapters, each approximately 90 min long, held at weekly intervals. A total of 258 participants registered for the pilot course (see Table 2 for geographic distribution and Table 3 for the distribution according to the main position/role). Adherence to the flipped classroom format is summarized in Table S1 (see Supplementary materials). During the pilot course lessons, hands-on activities were implemented in breakout rooms, polls, and quiz questions with subsequent discussion, and moderated interviews with experts as activating didactic approaches. In total, 108 certificates were issued to participants who met the attendance and participation criteria.

Forty-eight of the 108 certified pilot course participants (44.4%) provided the feedback (Table S2 and Table S3 provide details on their structure according to nationality, current level of studies and experience in clinical trials before the course). They expressed consistent satisfaction with the course (mean score 4.40 out of 5), ranked the skills acquired as applicable to their professional practice (mean score 4.25 out of 5), and found the content as easy to understand (mean score 4.27 out of 5). The chapters on Clinical Trial Design, Trial Management, and Leadership for 21st -Century Trialists were rated as the most interesting. Conversely, the chapters on Quality and Regulatory Affairs, Data Management and Statistical Analysis, Clinical Evaluation and Clinical Investigation of Medical Devices were identified as the most challenging to understand. The lowest average rating (3.69 out of 5) was for the adequacy of the time required to complete

all platform materials. Participants also strongly agreed that the pilot course helped them to understand the topic better than the pre-class reading alone (4.50/5). Further details from the participant feedback are in Figure S1 (see Supplementary materials).

The curriculum achieved similar ratings in the knowledgeable stakeholder population: overall satisfaction (4.33/5), the expected applicability of skills to professional practice (4.83/5), and the understandability of content (4.50/5). A better rating was achieved in the time estimate for completing all platform materials (4.50/5). Stakeholders suggested a more unified approach to each lesson of the pilot course and the structuring of activities from the familiar to the new and application within breakout rooms, hand in hand with the assignment of a group leader. The stakeholders strongly agreed that the pilot course improved their understanding of the topics better than pre-class reading alone (4.17/5) and anticipated the same for the participants (4.67/5).

Thirty-three people completed the survey as part of multiplier events, 81.8% working at a higher education institution (HEIs). Ten individuals (30.3%) reported that their institution had a multi-year clinical trialist program in place for more than 2 years, and 12 (36.3%) participants' institutions have a multi-week or semester course of the same focus. Sixteen (48.4%) respondents do not have a similar course at their institutions. Respondents agreed on the need for such a curriculum (mean 4.27/5). There was also agreement on the choice of topics, format, and willingness to implement the materials in their teaching (4.39/5, 4.18/5, and 4.09/5, respectively). Furthemore, there was also agreement on whether teachers could benefit from the curriculum (4.64/5).

Discussion

Training future researchers in clinical research is a burning issue, especially in the context of IITs and patient-centered research. A plethora of training courses was identified earlier that vary in terms of target group, overall scope, required background knowledge, and the expertise of the trainers [4, 8–10]. However, Boeynaems et al. conclude that these courses tend to be local, spontaneous, and often reactive activities [10]. The CONSCIOUS II training program primarily targets PhD students and early career researchers, i.e., less experienced researchers today but potential PIs of the future. As the results of our survey show, the availability of courses building skills in designing and conducting clinical trials, as well as interdisciplinary curricula, is limited. In our small sample, almost 50% of HEIs did not offer even short-term training. Fortunately, the situation is improving as at least the CONSCIOUS II consortium partners have already implemented the curriculum in postgraduate programmes and microcredentials.

Bechtel et al. suggest that, unlike experienced investigators, these less experienced trialists may benefit from more comprehensive, time-intensive types of training [7]. Markman et al. and Boeynames et al. also emphasize the time demands since academic research is usually secondary to the primary clinical activities [8, 10]. This is also true for the target audience of this training program. A flipped classroom format was thus chosen for the curriculum, where synchronous online sessions are preceded by individual, time-flexible asynchronous preparation. The combination of asynchronous and synchronous components is also advantageous in the context of achieving learning outcomes– while the individual work is a transferr of knowledge through self-paced learning, is more didactic but encourages deeper exploration and independent problem solving, the synchronous part focuses on practice, building skills, and is essential to reduce misconceptions and refine understanding through direct communication with and insight from the teacher and peers. Despite this arrangement, the time estimate for completing the pre-class materials ranked lowest in the feedback (3.69/5). This might be explained by a combination of the high time density of the course, the inconsistent anticipated length of preparation for each lesson, and, in some cases, being too demanding for the target group. The value of the synchronous part was confirmed by the feedback of both the participants in the pilot course and knowledgeable stakeholders, who strongly agreed that the pilot course helped them to understand the topic better than the pre-class reading alone. The participants were awarded certificates upon course completion. However, the certificate was not contingent on creating and submitting elaborated case studies or practical exercises. Participants did contribute to case studies, by making a short submission in advance of the synchronous session which resulted in a discussion point (learning by doing) rather than final evaluation and certification criteria. Similarly, the course did not conclude with a final test. This is a limitation because the entire evaluation of the course relies on subjective feedback rather than an objective assessment or a pre- and post-course comparison.

The curriculum has several advantages, including a low entry threshold with no prerequisites such as prior clinical research experience or initial level of knowledge. While the lack of validation of initial knowledge, such as in the pilot course, might contribute to the high ratings of content clarity, this aligns with the target group of less-experienced PhD students and early-career researchers. For this group, it can be expected that the variability of knowledge will not be as high as for experienced researchers, for whom the CONSCIOUS II course would probably take on the character of a one-size-fits-all training course. Notably, the curriculum emphasizes

information-seeking skills, offers guidance on where to go for consultation, and presents practical tools. This contributes to the curriculum degree of sustainability, even though it covers the highly variable area of clinical trials. ECRIN is an associate partner of the project, and most of the curriculum content authors are associated with ECRIN. This provides students with valuable contacts on whom to refer to if they become IITs PIs possibly.

A wide range of experts contributed to the curriculum, including project managers, monitors, data managers, regulatory specialists, clinical research methodologists, teachers, and researchers in medical education. This breadth of expertise differentiates the curriculum from purely academic courses, which may lack real-world context. However, all the partners working on the curriculum are based in the European region and work with European legislation daily. This partly limits the transferability of the curriculum to other areas with different regulatory frameworks for clinical research but our funder was the EU and this was the reason for this focus. However, the materials are available to any country in the world where they may add country and regional specific examples to the existing foundation materials.

Transferability was one of the primary considerations in designing the curriculum, consistent with one of the key principles articulated by Clinical Trials Transformation Initiative (CTTI) for improving the quality, conduct and efficiency of clinical trials: the PI must be supported by an effective study team and infrastructure [7]. All curriculum materials are freely available on the training platform, ensuring accessibility and interlinking with existing curricula. Since the pilot sessions usually used pre-class materials, the video-recordings can serve as a teacher's guide. This mitigates any limitations arising from the local trainer's experience and supports the wide implementation of the curriculum. The second idea stemming from the principle cited above is interdisciplinary collaboration. The training platform itself supports this through discussion boards connecting all platform users. It was also supported by the wide dissemination and inclusiveness of the pilot course, with PhD students and early career researchers making up 67.1% and experienced clinical trialists almost 21% of the attendees. On the other hand, not all professionals involved in clinical research need to acquire the same level of competence in clinical trial performance, and this curriculum primarily focuses on potential PIs [10]. The curriculum, or parts of it, can be used as supplementary material for biomedical students, lifelong education, or training programs for patient organizations. It can also serve as a basis for broader courses or degree programmes. The license used, the focus on providing guidance rather than bare facts, the platform supporting adaptability and transferability, the automatic assessments, and the availability of teacher's guides support reuse in areas such as those mentioned above.

The curriculum developed within the CONSCIOUS II project follows previously proposed recommendations for future investigator training [3, 7, 10]. It has the potential to fill a gap in the education of clinical trialists, especially PIs, and thus support the development of quality patient-centered research focused on underserved therapeutic areas and populations, as well as real-world issues.

Conclusion

The CONSCIOUS II project aims to support quality patient-centered research by developing a training program for the PIs of the future. The pragmatic curriculum reflects the previously proposed recommendations for the clinical trialists' education programs, fills the existing gap in this area, and extends the range of voluntary training activities individualized for early-career researchers and PhD students. The subjective perception of the curriculum of both the graduates and the knowledgeable stakeholders is more than positive regarding the content, format, and applicability to clinical trial practice. However, only an objectively measurable change in the PI's skills will demonstrate the actual value of the developed curriculum.

Abbreviations

CTTI	Clinical Trials Transformation Initiative
ECRIN	European Clinical Research Infrastructure Network
HEIs	Higher education institutions
IITs	Investigator-initiated trials
PI	Principal investigator

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12909-025-07054-5.

Supplementary Material 1

Acknowledgements

We wish to acknowledge Annamária Neméth from the University of Szeged, Hungary, for assistance with the chapter and related materials on Early Phase Trials. The authors did not receive support from any organization for the submitted work.

Author contributions

JR, ZC, VN, LS, StM, GLK, JB, SaM, FS– conceptualization, ZC, KN, TO, MP– formal analysis, JR, VN, LS, StM, GLK, CK, ET, MP, ECM, JB, FS - funding acquisition, JR, ZC, VN, KN, LS, StM, GLK, CK, ET, TO, MP, ECM, SaM, JB, FS– investigation, JR, LS, VN, SaM, JB, FS– methodology, JR– project administration, TO, MP– software, JR, ZC, LS, JB, FS– writing– original draft, VN, KN, StM, GLK, CK, ET, ECM, SaM– writing– review and editing.

Funding

Supported by the national budget through MEYS, LRI CZECRIN (LM2023049) and ERASMUS+ (project CONSCIOUS II, 2021-1-CZ01-KA220-HED-000023177).

Data availability

All data generated or analysed during this study are included in this published article and its supplementary information files.

Declarations

Ethics committee approval

The CONSCIOUS II project was approved by the Review Board of the Faculty of Medicine, Masaryk University. Following a request by the project investigator, PharmDr. Jitka Rychlíčková, Ph.D., a certificate has been issued that confirms that the CONSCIOUS II project does not require approval by the Ethics Committee of the Faculty of Medicine, Masaryk University. The certificate is provided to the editor. As a result, it was not necessary for the participants to sign the informed consent form for their involvement in the CONSCIOUS II project activities. Their participation in the pilot course and in the feedback collection was entirely voluntary. The research carried here is in compliance with the Declaration of Helsinki principles.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Received: 8 September 2024 / Accepted: 25 March 2025
Published online: 08 April 2025

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