CZECRIN Annual Research Conference

and

CONSCIOUS II multiplier event

ABSTRACTS COLLECTION

12th September 2024, Brno, Czechia

Masaryk University
Brno 2024

The conference is supported from the state budget through the Ministry of Education and Culture by the project Czech National Node of the European Clinical Research Network (CZECRIN), identification code LM2023049, and from the European Social Fund and the European Regional Development Fund by the project CZECRIN_PRO PACIENTY – Introduction of Innovative modern therapies, reg. number CZ.02.1.01 /0.0/0.0/16_013/0001826.

ISBN 978-80-280-0588-7

Editorial

Dear colleagues,

you hold in your hand the Abstracts collection of CZECRIN Annual Research Conference, and this year also the CONSCIOUS II multiplier event.

It is a great honour for the St. Anne´s University hospital Brno that it can once again organize the national professional event in academic clinical research.

We greatly appreciate all the contributions you have sent us and for which we sincerely thank you and your co-authors. We have prepared a colourful one for you a program rich in educational messages, and sections dedicated to multidisciplinary cooperation.

An integral part are how invited lectures, as well as a number of self-authored contributions. This year's conference will feature a total of 12 invited lectures, all of which will be accompanied by a panel discussion.

Maintaining the quality of the anthology is an important priority for us, as the CZECRIN abstract anthology is, as usual, an indexed MUNI anthology. This year again, the collection consists of abstracts prepared according to the prescribed structure and scope.

The full collection of abstracts will be available for download in electronic form at any time from the CZECRIN website: www.czecrin.cz.

Content

CZECRIN

CZEch Clinical Research Infrastructure Network

CZECRIN is a key large research infrastructure supporting the implementation of academic clinical research in the Czech Republic, which was established by a decision of the Ministry of Education, Youth and Sports (MEYS). Since 21 March 2014, it has also been financed from the funds for targeted support of large research infrastructures, based on the cooperation between Masaryk University (MUNI; host institution) and the St. Anne´s University Hospital in Brno (FNUSA; partner institution).

For the current period, from 2023 to 2026, financial support from the Ministry of Education, Youth, and Sports (LM2023049) has been provided for the solution of the large research infrastructure project. The legal entity and host institution of CZECRIN is MUNI, one of the leading scientific institutions in Central Europe.

LRI CZECRIN was built as a unique infrastructure, involving the network of most major clinical sites with a focus on clinical research and providing knowledge, development, production, and implementation capacities in the field of research and development of drugs and medical devices. CZECRIN set up advanced solutions for the effective provisioning and use of high-quality scientific data, fully implementing the FAIR (Findable, Accessible, Interoperable, and Reusable) principles.

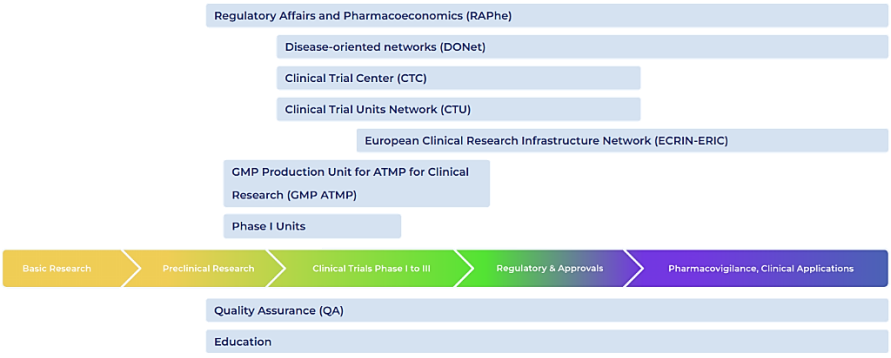

Fig. 1: CZECRIN LIFE CYCLE EXPERTISE

Masaryk University (MU) as one of the leading Central European scientific institutions is the legal entity and the host institution of CZECRIN. Research infrastructures operated by MU are an important pillar of research and innovation systems in the Czech Republic. Their importance is emphasized by participation in 16 research infrastructures listed in the Czech National Roadmap for Large RDI Infrastructures. Nine of these projects are also part of research infrastructures of pan-European interest included in the European Strategy Forum for Research Infrastructures (ESFRI). Eight research infrastructures are in the field of health and nutrition.

St. Anne´s University Hospital Brno, the founding partner, is a university hospital with excellent clinical research capacities concentrated in the International Clinical Research Center (ICRC). FNUSA provides the background for some Disease Oriented Networks, e.g. Stroczech or CZECRIN EPINet, CZECRIN DON NEURODEGEN which are an essential part of CZECRIN and participate in the support of CZECRIN Academy, as an educational infrastructure platform.

Currently, the large CZECRIN research infrastructure is a nationwide and fully functional research infrastructure supporting and implementing academic clinical research in the Czech Republic. It provides unique expertise, research, development, manufacturing and implementation capabilities in the medical sciences.

General University Hospital Prague
Institute of Hematology and Blood Transfusion
Memorial Cancer Institute
National Institute of Mental Health
St. Anne´s University Hospital Brno
Thomayer University Hospital
University Hospital Hradec Králové
University Hospital Královské Vinohrady
University Hospital Motol
University Hospital Ostrava
University Hospital Plzeň Masaryk
University Hospital Brno

Fig. 2: Healthcare providers participated in CZECRIN – Local Hubs

CZECRIN supports national and international cooperation in clinical research for the benefit of patients, citizens and healthcare. All this includes the new comprehensive strategy of CZECRIN with a vision characterised by the motto: "...towards patient-oriented medicine".

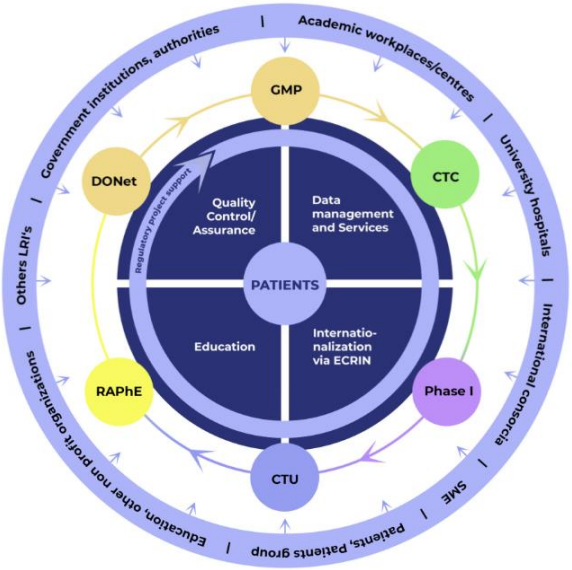

Fig. 3: CZECRIN services in patient-oriented clinical research

As the Czech node of the European Network of Clinical Research Infrastructure, ECRIN-ERIC contributes significantly to the participation of academic institutions in international clinical research projects.

More information: www.czecrin.cz

ECRIN

European Clinical Research Infrastructure Network

The European Clinical Research Infrastructure Network (ECRIN) is a non-profit intergovernmental organisation that supports the conduct of international clinical trials in Europe. Since 2013, ECRIN has had the legal status of a European Research Infrastructure Consortium (ERIC).

Based in Paris, ECRIN works with European correspondents across Europe, national networks of Clinical Trials Units (CTUs), and many European and international stakeholders involved in clinical research.

Member countries:
Czech Republic,
France,
Germany,
Greece,
Hungary,
Ireland,
Italy,
Norway,
Poland,
Portugal,
Greece,
Spain,
Switzerland.
Observer:
Slovakia

Fig. 4: ECRIN member and observer countries

ECRIN offers researchers support in the preparation and implementation of international clinical trials. Areas of support include the preparation of funding applications, protocol evaluation and expert consultation, project management, quality assurance and other services.

ECRIN works with various stakeholders in member and observer countries and in other countries involved in the studies. ECRIN provides targeted support to facilitate the design and conduct of clinical trials.

Transnational clinical trials provide greater access to patients, facilities and medical expertise; they improve methodological standards; enable sharing of costs, tools and procedures; increase the potential for broad implementation of research results; prevent duplication of research.

ECRIN collaborates with national networks of clinical trial units (CTUs) involving European correspondents who communicate with the management team in Paris.

Fig. 5: Setting up ECRIN cooperation with participating countries

ECRIN also cooperates with many European and international entities involved in clinical research.

More information: www.ecrin.org

Organizational and scientific committee

Lenka Součková, PharmD, Ph.D. – chairperson of the committee

Associate prof. Regina Demlová, MD, Ph.D.

Jitka Rychlíčková, PharmD, Ph.D.

Jiří Deml MD

Kateřina Nebeská, MSc.

Markéta Salačová

Petra Pavlů

Programme

INTRODUCTION AND FOREWORD

9:00–9:15

CZECRIN and CREATIC as Solutions for Patient-Centric Clinical Trial Challenges
Lenka Součková, Regina Demlová

SESSION I: Advanced education in clinical trials and clinical pharmacology

9:15–10:50

Trial Methodology Research, Inclusivity in Clinical Trials, the SENSITISE Project
Frances Shiely

Clinical Trialists of the Future: the CONSCIOUS II Project
Jitka Rychlíčková

CONSCIOUS II project Pilot Teaching Outcome
Kateřina Nebeská, Zora Čechová, Lenka Součková, Jitka Rychlíčková

Unified by Diversity: Insights into Pharmacotherapy Education Through an International and Interprofessional Student-Run Clinic
Erik M. Donker, Joost D. Piët, Jitka Rychlíčková, Yoann Cazaubon, Fabrizio De Ponti, Jelle Tichelaar, et al.

Panel Discussion
Jitka Rychlíčková, Kateřina Nebeská, Zora Čechová, Frances Shiely, Joana Batuca, Eric Donker, David Brinkman

SESSION II: Patient-Centered Clinical Research

11:05–12:20

Current Research in Colistin Therapeutic Drug Monitoring – Pre-eliminary Results of Investigator-Initiated Clinical Trial COL-ECMO2022
Jitka Rychlíčková, Pavel Suk

BEATSep
Jan Frič, Marcela Hortová Kohoutková
Stroczech: Insights from Management and Trials in the Czech Stroke Research Network
Veronika Kunešová, Veronika Svobodová, Robert Mikulík

Panel Discussion
Jitka Rychlíčková, Pavel Suk, Jan Frič, Marcela Hortová Kohoutková, Robert Mikulík

SESSION III: Clinical research for or with medical students

13:00–14:00

Scientific publishing and communication
Stéphane Mouly, Viktoria Nagy
Assessing the willingness of future EU healthcare providers (medical and paramedical students) to participate in vaccine trials: A cross-sectional VACCELERATE European study
Zoi Dorothea Pana
Barriers and opportunities to inclusive vaccine trials: Results of the VACCELERATE EU Expert Survey with focus on underrepresented population groups
Zoi Dorothea Pana

Panel Discussion
Zoi Dorothea Pana, Stéphane Mouly

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Timo Schinköthe

Panel Discussion – 20 min
Jana Popova, Timo Schinköthe

Abstracts

CZECRIN and CREATIC as solutions for Patients-Centric Clinical Trial Challenges

Lenka Součková [1,2] & Regina Demlová [2,3]
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CZECRIN, Large Research Infrastructure and the CREATIC, Centre of Excellence represent pivotal advancements in addressing patient-centric challenges in clinical trials. CZECRIN integrates academic, clinical, industry and regulatory body stakeholders to streamline and enhance the clinical trial process in the Czech Republic. It provides a comprehensive platform that fosters collaboration, ensures compliance with regulatory standards, and promotes the adoption of innovative methodologies. By focusing on patient-centricity, CZECRIN enhances recruitment, retention, and overall patient engagement, ensuring that trials are more aligned with patients' needs and experiences.
The CREATIC Centre of Excellence, focused on advanced clinical technologies, complements CZECRIN by offering cutting-edge solutions research and development of ATMP and gene therapies, including their manufacturing, and personalized medicine to address the complexities of modern clinical trials, particularly in tailoring treatments to individual patients. CREATIC leverages a comprehensive range of services and support that are essential for the successful implementation of clinical trials, especially in the field of rare diseases and the development of advanced therapy medicinal products.
This synergy between CZECRIN and CREATIC enables the development of more efficient, patient-centric, personalised clinical trials that are better equipped to address the diverse and evolving needs of patients.
Together, these initiatives embody a holistic approach to overcoming traditional barriers in clinical research, such as low patient engagement, inefficient trial designs, and ATMP and gene therapy manufacturing challenges. By prioritizing patient-centric strategies and integrating innovative

technologies, CZECRIN and CREATIC significantly contribute to the evolution of clinical trials, ultimately improving patient outcomes and accelerating the development of new therapies.

CREATIC has received funding from the European Union's Horizon Europe Coordination and Support Action under the Grant agreement number 101059788.

Supported by the national budget through MEYS, LRI CZECRIN (LM2023049) and from the European Social Fund and the European Regional Development Fund by the project CZECRIN_PRO PACIENTY – introduction of innovative modern therapies, reg. number CZ.02.1.01/0.0/0.0/16_013/0001826.

SESSION I: Advanced education in clinical trials and clinical pharmacology

Trial Methodology – making trials more efficient

Frances Shiely[1]
[1]*University College Cork, Ireland*

The primary objective of trials methodology research is to refine the design, conduct, analysis, and reporting of clinical trials to ensure robust evidence generation and informed decision-making in healthcare. In recent years, significant progress has been made in addressing methodological challenges such as participant recruitment, randomisation procedures, outcome measurement, and statistical analysis.

In this presentation, we will delve into a wide array of research work in trials methodology. For instance, we will explore innovative methods for participant recruitment, such as leveraging social media platforms and patient registries. Additionally, we will examine the repercussions of conducting substandard trials and the implications for methods research. Moreover, we will underscore the significance of involving patients and the public (PPI) in trials methodology research, recognising their invaluable perspectives and contributions. Furthermore, we will spotlight an ongoing European Union project focused on enhancing diversity and inclusivity in trials through training and education initiatives. Lastly, we will delve into emerging trends and areas of interest within trial methodology research, shedding light on evolving methodologies and promising directions for future investigation.

Trials Methodology research continues to evolve rapidly, driven by the imperative to enhance the reliability, efficiency, and ethical integrity of clinical trials. By embracing innovative approaches and addressing methodological challenges, researchers strive to optimise the generation of high-quality evidence to inform clinical practice and improve patient outcomes.

This work was supported by the Erasmus+ Programme of the Europe Union (2023-1-IE02-KA220-HED-000159532).

Clinical Trialists of the Future: the CONSCIOUS II Project

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The three-year CONSCIOUS II project aimed to fill a gap in the training of clinical trialists of the future. The aim of this presentation is to describe the journey of the of the project and the curriculum as its output, helping to make the curriculum visible and accessible to the widest possible range of potential users.
A broadly multidisciplinary team collaborated on curriculum development. The first step was conceptualizing key principles and ideas in relation to the target population. This was followed by creating the outlines providing a clear framework and context. Based on the outlines, the curriculum materials themselves were developed. A parallel step was working on the design and promotional materials. All materials then formed the basis for the flipped classroom pilot course.
A 12-chapter curriculum divided into three thematic clusters and encompassing approximately 70 hours of asynchronous training was created in the CONSCIOUS II project. The chapters, along with additional resources and recordings from the pilot course, are freely available on the CONSCIOUS II training platform which further supports the integration and distribution of the curriculum within existing educational programs.
The CONSCIOUS II curriculum combining asynchronous and synchronous components effectively addresses the gap in developing core competencies for the 21st-century clinical researchers. The implementation of this curriculum has the potential to improve the quality of investigator-initiated trials.

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

CONSCIOUS II project Pilot Teaching Outcome

Kateřina Nebeská[1], Zora Čechová[1,2], Lenka Součková[1,2], Jitka Rychlíčková[1,2]
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The CONSCIOUS II project implemented a flipped classroom approach in the pilot teaching. The objective is to summarize the outcomes and evaluation of the pilot course.
The invitation to the pilot course was widely distributed across all project partners' networks. No prerequisites were applied for the target population of PhD students and early-career researchers. The course was opened to experienced clinical trialists too. The sessions were conducted via Zoom in the evening hours for the European region; the expected length was 90 minutes per session. The pre-class materials were uploaded to the training platform. The online sessions were organized as collaborative, enabling training skills using theoretical knowledge gained earlier. Participants meeting the condition of adherence and active approach were awarded certificates. Two questionnaires were designed for participants and stakeholders to collect feedback. Responses were measured using a five-point Likert-type scale.
The pilot course was conducted from January 9, 2024, to April 2, 2024, as weekly online meetings, including one introductory meeting. A total of 258 participants registered for the pilot course, 108 of whom received a certificate upon course completion (approx. 67% were PhD students and early career researchers). Feedback was received from 44.4% of the certified participants. Participants were consistently satisfied with the course, the applicability of the skills acquired, and the content clarity. Stakeholders provided similar ratings.
The pilot course, in its format and content, effectively built core competencies for quality clinical research. The top-down implementation of this curriculum could enhance the quality of investigator-initiated clinical trials.
Acknowledgement: Supported by the national budget through MEYS, LRI CZECRIN (LM2023049) and the project ERASMUS+CONSCIOUS II (2021-1-CZ01-KA220-HED-000023177)

Unified by Diversity: Insights into Pharmacotherapy Education Through an International and Interprofessional Student-Run Clinic

Erik M. Donker[1], Joost D. Piët[1], Jitka Rychlíčková[2], Yoann Cazaubon[3], Fabrizio De Ponti[4], Jelle Tichelaar[1], et al.

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International guidelines for medication prescribing show considerable variations. These discrepancies arise from factors such as antimicrobial resistance, medicine accessibility and reimbursement policies, as well as cultural and historical prescribing attitudes. The European Association of Clinical Pharmacology and Therapeutics has initiated programs to modernize and harmonize pharmacotherapy education across Europe. Despite these efforts, international differences remain a significant challenge. To explore the educational potential of these variations, we introduced in 2022 the "International and Interprofessional Student-run Clinic", involving medical and pharmacy students from 10 European universities (9 different countries).

Four to six times a year, 2-hour video meetings were held involving students from three to four universities. During each meeting, a student presented a real-life case of a patient on polypharmacy. In 45-minute breakout sessions, students reviewed the patient's medication in groups of students from other countries and/or backgrounds, using the prescribing optimization method and STOPP/START criteria. Teachers rotated among the groups to offer guidance. The last 45 minutes were used for debriefing and discussing the learning outcomes of the meeting.

The video meetings were attended by third-to-final-year medical and pharmacy students (mean n=15). Both students and teachers reported gaining

a lot from each other, including insights into international and interprofessional healthcare perspectives. They also learned the importance of patient-centred, context-dependent decision-making. Moreover, among the observed differences were that in the Netherlands, most hospitals have local prescribing guidelines, leading to specific preferences. In contrast, Italy's hospital prescribing guidelines are mostly regional, with certain medications restricted to specialist prescription by national rules.

The meetings highlighted notable differences in prescribing guidelines, medicine use, and accessibility between the countries. This exposure offered a broader understanding of how healthcare practices and policies differ, emphasizing the need for context-dependent clinical decision-making. Moreover, we learnt that geographical distance no longer needs to be an obstacle to organizing educational events.

SESSION II: Patient-Centered Clinical Research

Current Research in Colistin Therapeutic Drug Monitoring – Pre-eliminary Results of Investigator-Initiated Clinical Trial COL-ECMO2022

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[4]Department of Anaesthesiology and Intensive Care, St. Anne's University Hospital Brno and Faculty of Medicine, Masaryk University, Brno, Czechia

Recap the shortcomings in colistin therapeutic drug monitoring (TDM) and summarize lessons learned from several follow-up projects that address these gaps.
A literature review on colistin TDM. Development of a method for determining colistin/CMS in three matrices. Short-term stability tests of colistin and CMS in the above matrices. Preliminary results of a prospective, non-randomized, single-center phase IV pharmacokinetic clinical trial to assess the effect of ECMO on the pharmacokinetics of colistin and CMS (COL-ECMO2022 trial).
The primary shortcomings in colistin TDM are the lack of a method for routine measurement, insufficient stability data for samples, a limited availability of the population pharmacokinetic models.
A simple LC-MS/MS method for the determination of both substrates has been established and validated in the associated laboratory; it is currently the only facility in the Czech Republic capable of determining colistin and CMS in plasma/serum. The total analysis time is 5 minutes.
Short-term stability data confirming a relationship between colistin/CMS stability and temperature/temperature and concentration provide valuable input for preanalytical sample processing.

Preliminary results of the pharmacokinetic study show a high colistin exposure despite standard dosage use. Colistin AUCSS,24h was 165±128 mg.h/L, cSS corresponds to 6.9±5.3 mg/L. Considering the variable relationship between CMS concentration and achieved colistin concentrations, the determination of colistin itself, especially trough concentration, seems to be crucial; the determination of CMS is not essential.
Real-time TDM appears to be a fundamental condition for the rational use of colistin, and the above data helps with practical implementation.

Acknowledgement: Supported by the national budget through MEYS, LRI CZECRIN (LM2023049).

BEATsep tackles the long-term burden of sepsis

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Sepsis is a life-threatening organ dysfunction resulting from dysregulated immune responses to infection, affecting almost 50 million people yearly. Sepsis is a major global health challenge and a leading cause of death worldwide. Moreover, people surviving sepsis often suffer post-sepsis immunosuppression, a long-lasting state of immune dysfunction predisposing them to infections, autoimmune and non-communicable diseases (NCDs), and long-term reduced fitness.
The molecular mechanisms driving post-sepsis immunosuppression remain largely elusive. Furthermore, predicting which patients will survive or develop immunosuppression is currently impossible.
BEATsep will tackle this challenge by combining the expertise of physicians, clinician scientists, and immunologists in top European institutions. We will, for the first time, longitudinally assess unique immunological and clinical parameters and combine them to: i) gain insight into the long-term immunological consequences of septic shock; ii) identify novel markers to identify patients at risk; and iii) unravel molecular mechanisms driving post-sepsis immunosuppression using AI approaches.
BEATsep will also develop strategies to improve the stratification of acute sepsis survivors and identify patients with a higher risk of sepsis-associated NCDs and comorbidities.
BEATsep will have significant societal, scientific, and economic impacts, as efficient prevention of sepsis-induced comorbidities could save significant amounts within healthcare budgets and potentially improve the quality of life for millions worldwide who suffer from the long-term effects of sepsis.

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No. 101137484.

"Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them." .

Stroczech: Insights from Management and Trial in the Czech Stroke Research Network

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The Czech Stroke Research Network (Stroczech) was established in 2020 to advance stroke research in the Czech Republic by coordinating multicentre clinical trials and observational studies, ensuring evidence-based outcomes that contribute to stroke care improvements. Stroczech operates under the CZECRIN infrastructure *(Czech Clinical Research Infrastructure Network)* and is part of international organizations like ESOTA (*European Stroke Organisation Trials Alliance)* and GAINS *(Global Alliance of Independent Networks focused on Stroke trials)*.

This abstract outlines the management strategies, challenges, and significant achievements of Stroczech, with a focus on clinical trial coordination, data management, and the integration of research outcomes. Key findings from recent network trials are also highlighted.

Stroczech employs a centralized approach to trial management, using standardized protocols, advanced data management systems, and continuous communication with participating centres. The network involves a multidisciplinary team, including neurologists, radiologists, clinical researchers, and study coordinators to ensure efficient study execution and accurate data collection.

Since its inception, Stroczech has coordinated 24 clinical trials and observational studies, enrolling over 8,000 patients (more than 1,500 in prospective studies) across 24 stroke centres in the Czech Republic.

Key achievements include:

- Implementation of standardized study documents in investigator-initiated trials, leading to improve data consistency and trial efficiency.
- Introduction of a centralized data management system, reducing errors and accelerated data analysis.

- Production of 30 publications with impact factors and data that may inform updates to clinical guidelines.
- Establishment and strengthening of international collaboration.

Future directions for the network include stabilization, participation in prospective international clinical projects, the initiation of new own trials, and the implementation of research findings into clinical practice.

Special thanks to all members, collaborators, and partners for their invaluable support in improving stroke care.
Supported by STROCZECH within CZECRIN Large Research Infrastructure (No. LM2023049) funded by the state budget of the Czech Republic.

SESSION III: Clinical research for or with medical students

Scientific publishing and communication

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The objective of this chapter is to provide students with manuscript writing, editing and submitting skills and an understanding of the publishing space, including the traditional platforms of biomedical journals but also the new spaces created by Open Research.

In addition to descriptive e-learning material enriched with videos, links to publications, a normative quiz to test students' acquired knowledge and understanding, and a discussion board, the chapter will adopt an interactive problem-based learning approach, in that students will have to produce articles, spot mistakes, and provide feedback on each other's productions and solve issues linked to the publishing process. This shall equally lead to the creation of a shared database/library that'll allow students to contribute to an ever-growing curriculum and learn from each other in a student-led learning perspective.

Scientific publishing will deal with three major topics that'll allow doctoral students in health sciences to improve their overall publishing skills and hence make it possible for them to successfully promote their research and further scientific cooperation within the European space but also within the international research community when starting their professional careers. it'll focus on writing skills per se, including the explanation of the IMRAD format as defined by the APA, its application to typical study types and standards concerning scientific content, language use and cohesion, including typical mistakes to be avoided. training in publication skills in the broader sense, including a thorough overview of biomedical and medical journals, how to find the right journal, applying for publication, the ethical and legal standards of publishing, the peer-review process, interacting with editors and reviewers, tools for the dissemination of published work, online libraries and other publication platforms. Finally, it is important to focus on new trends in

scientific publishing and the possibilities and horizons they've opened up in terms of transnational digital cooperation, including open access and open research, crowdsourcing and initiatives such as Creative Commons, Open Research Europe and the societal, legal and ethical repercussions they entail. Conclusion Scientific publishing and communication are mandatory to disseminate research findings at the world level and accelerate patient care optimization and individualization in clinical practice.

The authors are sincerely indebted to all members from the CONSCIOUS II ERASMUS+ Consortium

Assessing the willingness of future healthcare providers to participate in vaccine trials: A cross-sectional VACCELERATE European study

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The present study aimed to evaluate the willingness of medical and paramedical students, as future healthcare providers (HCPs), to participate in vaccine trials across different countries in Europe.
A cross-sectional online study was developed and distributed via the VACCELERATE Consortium's National Coordinators Network across 11 European countries between June and November 2023. A standardized questionnaire was used to evaluate student attitudes towards vaccine trials, including COVID-19 and other infectious diseases preventable by vaccination. 1,381 students participated, revealing that 31% were willing to participate in/engage in vaccine trials, with notable concerns about the safety and potential side effects being the most significant deterrent. Additionally, 44% expressed a desire to understand the risks involved. Finally, the study stressed

the need for education at the early stage of this population's careers to increase confidence in vaccine trials amongst future HCPs.
Our findings provide valuable insights into the motivations and barriers that medical and paramedical students face in clinical trial participation, offering a foundational perspective for shaping educational programs and public health initiatives to enhance future vaccine trial enrolment and vaccine confidence.

The Challenges of Vaccine Trial Participation among Underserved and Hard-to-Reach Communities: An Internal Expert Consultation of the VACCELERATE Consortium

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Underserved and hard-to-reach population groups are under-represented in vaccine trials. Thus, we aimed to identify the challenges of vaccine trial participation of these groups in member countries of the VACCELERATE network.
Seventeen National Coordinators (NC), each representing their respective country (15 European countries, Israel, and Turkey), completed an online survey.
From 15 eligible groups, those that were more frequently declared underserved/hard-to-reach in vaccine research were ethnic minorities (76.5%), persons experiencing homelessness (70.6%), illegal workers and refugees (64.7%, each). When prioritization for education on vaccine trials was considered, ethnic groups, migrants, and immigrants (5/17, 29.4%) were the groups most frequently identified by the NC as top targets. The most prominent barriers in vaccine trial participation affecting all groups were low levels of health literacy, reluctance to participate in trials due to engagement level, and low levels of trust in vaccines/vaccinations.
This study highlighted population groups considered underserved/hard-to-reach in countries contained within the European region, and the respective barriers these groups face when participating in clinical studies. Our findings aid with the design of tailored interventions (within-and across-countries of the European region) and with the development of strategies to overcome major barriers in phase 2 and phase 3 vaccine trial participation.

SESSION IV: New approaches in clinical studies preparations and operations

Patient perspective in the involvement of clinical trials

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The involvement of patients‘ insights in the design of clinical trials is a critical component of the research and development process. This abstract explores the significant role of patients in the clinical trials design and implementation. The European Patients’ Academy on Therapeutic Innovation (EUPATI) places patient involvement at the core of its vision and mission.

The EUPATI roadmap for patient involvement in medicines research and development* emphasizes the importance to involve patients throughout the entire process, including design and implementation of clinical trials. Patient insights can provide valuable information on the relevance of the trial endpoints, the burden of interventions, and the overall patient experience. Furthermore, understanding patients' preferences and concerns can lead to more ethical and patient-centred trials, ultimately improving treatment adherence and health outcomes. By prioritising the patient perspectives, researchers can bridge the gap between clinical research and patient needs, ensuring that findings are meaningful and applicable to patients. EUPATI has always encouraged patient involvement in the different stages of medicines research and development and provides patient education on topics like clinical trials design. Patient involvement in clinical trials paves the way for a more inclusive and effective healthcare systems that values the voice of patients in the journey toward innovative therapies.

* Geissler, J., Ryll, B., Leto di Priolo, S., Uhlenhopp, M.: Improving Patient Involvement in Medicines Research and Development: A Practical Roadmap. Therapeutic Innovation & Regulatory Science 2017

AI in Clinical Trials: Potential, Challenges, and Outlook

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Artificial intelligence (AI) offers transformative potential for clinical trials at various levels. It is anticipated that AI applications can be integrated into all phases of clinical trials, including trial design, patient recruitment, data management, and data analysis. Key innovations include aspects such as optimizing cohort selection through machine learning, automating the creation of study protocols, and improving patient monitoring through real-time data collection. The use of synthetic data and AI-driven identification of subpopulations are examples related to patient diversity and trial scalability. Artificial intelligence will also play an increasingly important role in the ways in which drugs are approved.

However, AI will not just be a vehicle for clinical trials but will take on an increasingly important role in active medical applications. This means that AI will also increasingly be the subject of clinical trials. One of the major challenges in this context will be dealing with systems that are not frozen but capable of learning in the future and will, therefore, also change.

CZECRIN Annual Research Conference 2024

Abstracts Collection

Editor: Lenka Součková
Vydala: Masarykova univerzita, Žerotínovo nám. 617/9, 601 77 Brno
Vydání: 1., elektronické, 2024
ISBN 978-80-280-0588-7

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