ICN International Clinical Trial Center Network

NEWSLETTER

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ICN Annual General Meeting 2024: Reflections on a Successful Gathering in Kyoto

This issue is dedicated to the ICN General Meeting 2024, held in the vibrant city of Kyoto, Japan. Inside, you'll find detailed summaries of all presentations delivered during the event. We extend our heartfelt thanks to the speakers for sharing such valuable and thought-provoking insights.

The ICN Annual Steering Board Meeting and General Meeting held in Kyoto on October 30–31, 2024, was a resounding success, marked by insightful discussions, presentations, collaborative efforts, and meaningful connections among participants.

During the event, we were pleased to announce Dr. Tsutomu Nishimura (Associate Professor, iACT, Kyoto University, Kyoto University Hospital) as the new ICN Chairperson, and Ming Wan (Deputy Director and Deputy General Manager, Shanghai Clinical Research Center) as the new ICN Vice-Chairperson. Their leadership builds on the successful tenure of Christiane Blankenstein, bringing fresh perspectives and a strong commitment to advancing the network's mission.

ICN Annual General Meeting 2024: Reflections on a Successful Gathering in Kyoto

Special appreciation goes to Dr. Tsutomu Nishimura and Dana Lin for their exceptional organization and warm hospitality, which ensured the seamless flow of events. A highlight was the visit to the Center for iPS Cell Research and Application (CiRA), where attendees witnessed pioneering advancements in regenerative medicine. Beyond the formal agenda, Kyoto's cultural richness left a lasting impression, from exploring historic districts to enjoying traditional cuisine and serene temples. We extend heartfelt thanks to all participants for their enthusiasm and contributions. Your active engagement makes the ICN community vibrant and impactful.

We look forward to building on this momentum in the coming year!

ICN Annual General Meeting 2024 Abstracts

Patient Recruitment: Healthy Volunteer

by Prof Suvimol (Jess) Niyomnaitham, Siriraj Institute of Clinical Research

Siriraj Institute of Clinical Research (SICRES) has extensive experience in the recruitment, management, and retention of healthy volunteers for first-in-human (FIH) trials, Phase I clinical trials, bioequivalence studies (BE), and other clinical research. With dedicated Volunteer Relationship staff, we ensure effective communication throughout the study. Despite challenges in volunteer enrollment and retention, SICRES has developed a robust volunteer database system, updated at the end of each study to ensure accuracy and security. Satisfaction surveys are distributed twice a year to all stakeholders—including investigators, part-time staff, volunteers, and sponsors—allowing us to adapt and improve based on their feedback.

Contract Negotiation

by Dr Silvia Egert, Muenchner Studienzentrum, Technical University Munich, School of Medicine and Health

The initiation of clinical trials is complex and time-consuming particularly in a multi-centre setting. A major global challenge is the delay in study launch due to lengthy review and negotiation of study agreements. The presentation explores the intricacies of contract negotiation in clinical research from a university perspective, emphasising the critical role of tailored agreements in ensuring compliance with legal, ethical, and operational standards. It highlights challenges such as negotiation delays caused by multiple factors, data ownership disputes, and intellectual property conflicts, which can significantly impact research timelines and budgets. Key strategies for accelerating contract negotiations include effective and standardised preparation before and during the process, the use of master contract templates, interdisciplinary collaboration and sharing of expertise, and, in some situations, the use of start-up agreements. The presentation underscores the importance of fostering win-win outcomes through mutual understanding, prioritisation, and compromises, ensuring that all parties maintain their rights and responsibilities while advancing the objectives clinical research in accordance with good clinical practice.

Unveiling the beauty of digital platform for financial management in clinical trials – our story to tell!

by Dr Creany Wong, Clinical Trials Centre, The University of Hong Kong

This presentation provides an insightful journey of HKU-CTC into the evolution of financial management systems for clinical trials in the past two decades. It highlights the transition from manual excel-based worksheet, then into an excel-based workbook with various functionality and finally advance to an integrated digital platform with efficiency and transparency.

With an increased in complexity of study design and exponential growth of clinical trials globally, this presentation underscores the the necessity of digital transformation in addressing the challenges of financial management and streamlining operations for sustainable success.

Clinical Research Coordinator Management

by Ms Audrey Ooi, Clinical Research Malaysia

Clinical Research Malaysia (CRM) is a one-stop-centre and site management organisation (SMO) for sponsored clinical trials in Malaysia. As an SMO, CRM recruits, trains and places clinical research coordinators in all public hospitals actively conducting sponsored research throughout the country. To date, CRM has 196 clinical research coordinators that are supervised by 15 Associate Regional Managers. With the mission to develop clinical research coordinators as a profession, CRM has established its Centre of Excellence in early 2024 that provides a foundation programme to fresh graduates seeking to build their career in clinical research.

ICN Annual General Meeting 2024 Abstracts

Singapore's Clinical Trials Portal (CTSG)

by A/Prof Danny Soon, Singapore Clinical Research Institute

The Consortium of Research and Innovation Singapore (CRIS), Singapore Clinical Research Institute (SCRI), and the Singapore Clinical Trials Portal (CTSG) play pivotal roles in advancing clinical research in Singapore. CRIS fosters collaboration among public and private sectors, enabling cutting-edge research and innovation across various biomedical fields. SCRI, one of CRIS' business entities, supports clinical research by providing infrastructure, expertise, and resources, facilitating the development of high-quality clinical trials.

Meanwhile, the Singapore Clinical Trials Portal (CTSG) serves as a comprehensive online platform for information on clinical trials, enhancing transparency and accessibility for both researchers and participants. This is an initiative by SCRI to contribute to Singapore's position as a leading hub for clinical trial advancements and excellence.

Clinical trials in Africa

by Dr Atara Ntekim, University College Hospital Ibadan

Clinical trials in Africa face significant challenges but hold immense potential, as highlighted by Dr. Atara Ntekim, a clinical oncologist from Nigeria. Despite a population exceeding 1.5 billion, most trials are concentrated in few countries like South Africa, Egypt, and Algeria, leaving vast regions underrepresented. With Africa's unique genetic diversity and growing healthcare needs, there is a pressing demand for more trials across the continent. Recent initiatives aim to address these gaps, including partnerships with global institutions to enhance infrastructure, regulatory frameworks, and training programs. Efforts are also underway to establish robust clinical trial registries and promote industry-standard practices.As Dr. Ntekim notes, investing in Africa's clinical trial ecosystem can unlock new frontiers in global healthcare innovation.

Data Ethics

by Prof Ali Yagız Uresin, Istanbul University Center of Excellence for Clinical Research

Prof. Uresin explores the evolving field of data ethics within the context of data-driven science, spanning empirical research to artificial intelligence. In this presentation, he also discusses the transformative potential of data analytics, machine learning, and decentralized governance alongside ethical challenges such as privacy breaches, discrimination, and algorithmic bias.

Drawing from historical case studies, regulatory advancements, and modern practices, the talk emphasizes core principles of transparency, accountability, and fairness in the ethical handling of health and clinical data.

Innovative solutions like blockchain for decentralized data control, federated learning, and synthetic data generation are highlighted as tools to enhance privacy and foster ethical research. The concept of "data justice" is introduced, focusing on equitable representation and protection for marginalized communities. The presentation concludes with a call for interdisciplinary collaboration, dynamic ethics, and the integration of human-centered approaches to ensure responsible innovation in clinical and data-intensive research.

Updates of ICN

Message from Tsutomu Nishimura, ICN Chairperson 2025-2027

Dear Members of the International Clinical Trial Center Network (ICN),

I am honored to announce my appointment as the new Chairperson of ICN. Building upon the solid foundation established by my predecessors, I am committed to advancing our mission of promoting excellence and collaboration in clinical research worldwide.
I am eager to work closely with each of you. Your dedication and expertise are the driving forces behind ICN's success, and I encourage your active participation in our upcoming initiatives and events.

Thank you for your continued commitment to ICN. Together, we will strive to make significant contributions to the advancement of clinical research globally.

Message from Ming Wan, ICN Vice-chairperson 2025-2027

The International Clinical Trial Network (ICN) has been in existence for nearly a decade, and the Shanghai Clinical Research Center, as one of its steering members, has grown alongside ICN over these years. During this time, we have acquired invaluable clinical research experience from our steering and regular ICN members. As a center established by the Chinese government, we have leveraged the knowledge gained from ICN to foster and support investigator-initiated clinical trials (IITs), thereby enhancing the caliber of clinical research in China. For instance, in 2021, we facilitated a multi-center study, ensuring the consistency and accuracy of the trial process across various centers through quality control, which ultimately bolstered the study's reliability. Additionally, we have organized cross-border conferences with other nations to contribute to the advancement of clinical careers globally.

Looking ahead, as we face new challenges and opportunities, I am confident that we will achieve more significant progress and accumulate further clinical trial experiences to share with you all.
Finally, I eagerly anticipate the opportunity to see you all in Shanghai next year.

Message from Christiane Blankenstein, ICN Chairperson 2023-2025

As my term as chair of the ICN comes to a close, I find myself reflecting on the journey we have taken together. Throughout the last four years of my tenure – first as vice chair with Henry Yau as chair, then as chair with Tsutomu Nishimura as vice chair, always accompanied by a very professional and proficient operations team, I learned so much about true commitment and friendship.

While growing our team and remotely connecting during the corona years, we could finally meet face-to-face again, expand our outreach to an extended audience and share a great time together in Hongkong and Kyoto.
As I pass the baton to our esteemed steering board member Tsutomu Nishimura as chair and Ming Wan as vice chair, I wanted to take a moment to express my heartfelt gratitude to him and the ICN members for the support, camaraderie and dedication to our goals and extend the best wishes for their tenure to build on the efforts from years past.

By striving to master challenges, finding and sharing solutions on imminent topics arising in our daily lifes as academic clinical research organizations, I am certain we will continue to grow and to make a difference in the future.

It has been – and I am certain it will continue to be - such a privilege to be part of this dedicated group of people.

Global Focuses

WMA: New Version of the Declaration of Helsinki Released

The World Medical Association (WMA) has released the latest version of the Declaration of Helsinki (DoH). The 2024 version replaces all previous editions and is now the only official version. It remains a central document for the ethical principles of medical research involving human participants.
The Declaration is currently available in English, with additional languages to follow soon. More details can be found on the WMA website: https://bit.ly/4ftjEhs

WHO: Guidance on Best Practices for Clinical Trials

In September 2024, the WHO published new guidelines for clinical trials, providing a global framework for the design and conduct of trials. The aim is to improve research efficiency, minimize waste, and create a sustainable infrastructure for clinical trials that can rapidly respond to emergencies or pandemics. The guidelines update previous WHO work and promote well-designed studies.
Read more on the WHO website: https://bit.ly/4gJII4S

ICH: Recent Development: ICH E6(R3) Annex 2 Guidance on Good Clinical Practice (GCP)

The draft of ICH E6(R3) Annex 2 on "Good Clinical Practice" has recently reached Step 4. This new guidance addresses GCP requirements for studies incorporating decentralized elements, pragmatic designs, and real-world data (RWD).

Read more on the ICH website: https://www.ich.org/news/ich-e6r3-guideline-reaches-step-4-ich-process

US: New FDA Guidance on Integrating Decentralized Elements into Clinical Trials

The U.S. Food and Drug Administration (FDA) has published new guidance providing recommendations for integrating decentralized elements into clinical trials. This allows study-related activities, such as telemedicine visits or home visits by medical professionals, to be conducted at flexible, participant-friendly locations. The goal is to make clinical trials more accessible and efficient.
Read more on the FDA website: https://bit.ly/49N7oHn

European Union: EMA Launches Public Consultations on Research and Data Strategy

The European Medicines Agency (EMA) has launched three public consultations:

1. The 2024 update of the "Regulatory Science Research Needs."
2. A draft paper on the "European Platform for Regulatory Science Research."
3. A draft on the "European Data Strategy for Medicines Agencies" to improve data utilization for public and animal health benefits.

More information can be found here: https://bit.ly/3P10Qvt

Global Focuses

ICH: ICH Training Program for Q8/Q9/Q10

This training is aimed at pharmaceutical companies involved in the manufacturing of APIs and medicines, as well as professionals in development, production, quality, and regulation. It provides insights into ICH guidelines Q8(R1), Q9(R1), and Q10, and how these guidelines efficiently support the entire lifecycle of medicines. Learn how risk-based approaches improve product development, optimize technology transfer, and ensure continuous quality improvement throughout the product lifecycle.

Read more on the ICH website: https://bit.ly/3BDjK8q

Italy: Simplified Regulatory Processes and Updated Guidelines in the Official Gazette

Contributed by Clinical Trial Center – Dipartimento Attività Integrate Ricerca e Innovazione (DAIRI),
Azienda Ospedaliero-Universitaria SS Antonio e Biagio e Cesare Arrigo, Alessandria (AOU AL)

On 20 August 2024, the Italian Medicines Agency (AIFA) published in the Official Gazette Determination No. 424/2024 and Determination No. 425/2024.

Determination No. 424/2024 simplifies regulatory processes and integrates decentralized elements for clinical trials in line with EU Regulation 536/2014. It provides clarifications on the reimbursement of expenses for meals, accommodation, and transport for trial participants, with the possibility of extending reimbursements to an accompanying person. Moreover, the guideline allows the use of clinical centers outside traditional hospital settings, including nursing homes or equivalent facilities, and public institutions.

Determination No. 425/2024 provides updated guidelines for the classification and conduct of observational studies on medicines, aligning with EU Regulation 536/2014 and Ministerial Decree 30 November 2021. It emphasizes the importance of transparency and ethical oversight, requiring mandatory registration with the Observational Studies Registry (RSO) and evaluation by Ethics Committees. This guideline replaces the 2008 version, reflecting advancements in the regulatory and scientific landscape.

Members' Snapshots

Knowledge Exchange at Taipei for the Launch of UMMC Phase 1 Trial Centre

Contributed by University of Malaya Medical Centre, University of Malaya

On August 3rd, Krisna Veni , Zulaikha Syazwani, Akmal Hakimi (Clinical Investigation Centre (CIC), Universiti Malaya, Universiti Malaya Medical Centre) met with Dana Lin (Institute for Advancement of Clinical and Translational Science, Kyoto University Hospital) in Taipei to discuss the launch of UMMC's Phase I Trial Center. The conversation highlighted the critical need for Phase I trial internships and emphasized the importance of talent development in clinical trials. As a new ICN member, UMMC is looking forward to contributing to and benefiting from the network's expertise in advancing clinical research.

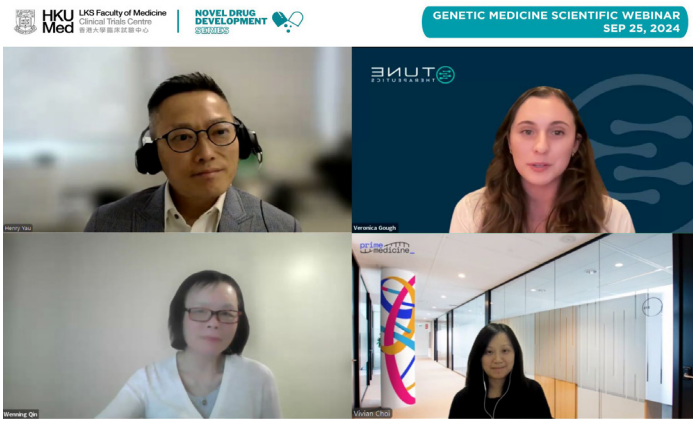
The discussion also focused on the ways of sharing knowledge and ideas among the ICN network members especially niche area at the global level of managing, conducting and coordinating clinical trials from the perspective of Investigator Initiated Trials and Industry Sponsored Research (ISR).

Genetic Medicine Scientific Webinar

Contributed by Clinical Trials Centre, The University of Hong Kong

Genetic Medicine Scientific Webinar, organized by HKU-CTC, was successfully concluded on September 25, 2024, in which we gathered over 300 international registrants, ranging from local government officials to research professionals from foreign institutions.

Deep appreciation to our expert speakers, Dr. Vivian Choi, Dr. Wenning Qin, and Dr. Veronica Gough for the insightful sharing. The dynamic idea exchange between the speakers and participants certainly foster a community of innovation in advancing the field of genetic medicine and novel therapeutic approaches.



Clinical Research Governance (CRGo) World Conference 2025

Contributed by Clinical Trials Centre, The University of Hong Kong

We are proud to organize the CRGo World 2025 on January 16, 2025. We brought together international experts to engage in insightful discussion this year. With the theme of "Realizing Good Governance in the Changing Paradigm for Global Clinical Research", it is our honour to have esteemed speakers joining us to share the most current updates in clinical research governance, including the ICH E6(R3) Guideline which was issued recently, and covered different regional practices in conducting good clinical trials.