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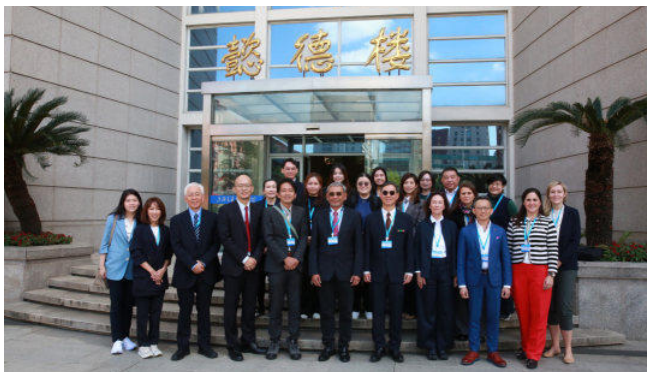
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Featured Article



ICN Annual General Meeting 2025: Successful Event & Key Insights

The International Clinical Trials Network (ICN) successfully hosted its Annual General Meeting (AGM) on Friday, 24 October 2025, marking a significant occasion for the global clinical research community. The hybrid event was held at the Shanghai Jiao Tong University School of Medicine, Shanghai, China, and online. The day began with a comprehensive Annual Meeting session, which included an ICN Review, the celebration of the network's 10th Anniversary, and the introduction of new members from organizations like TB-HIV Innovations & Clinical Research Foundation Corp, Philippines, Putra iCRU, Malaysia, and CTU NUMS Rawalpindi, Pakistan. The meeting also featured discussions on the Rotating System, Working Groups, ICN Webinars, and the planning for the ICN Meeting & Symposium 2026.



ICN Annual General Meeting 2025: Successful Event & Key Insights

Following the morning’s business, attendees were benefited from three insightful lectures: Mr. Ming Wan, Deputy Director of the Shanghai Clinical Research Center, spoke on “CTU Sustainability”; Dr. Akhmal Yusof, CEO of Clinical Research Malaysia, explored “Expanding Legal Horizon”; and Prof. Pope Kosalaraksa, Director of the Academic Clinical Research Office at Khon Kaen University, addressed “Talent Development for Clinical Trial Ecosystem in Thailand”.

The afternoon was dedicated to a major session on ICH GCP E6(R3) Implementation: Status and Challenges, led by Dr. Christiane Blankenstein and Mr. Henry Yau. This session featured detailed presentations from representatives across Asia and Europe, including Dr. Creany Wong (Clinical Trials Centre, The University of Hong Kong), Dana Lin on behalf of Dr. Tsutomu Nishimura (Kyoto University Hospital), Dr. Anja Eskat (University Hospital Zurich), Assoc. Prof. Dr. Sayime Basak Koc Senol (Istanbul University Center of Excellence), Dr. Suvimol Niyomnaitam (Siriraj Institute of Clinical Research, SICRES), and Dr. Kristina Schachtrup (Clinical Trials Unit Freiburg). The formal proceedings concluded with a summary, discussion, and closing remarks by the ICN Vice-Chair.

An optional, in-person Phase I Center Visit was also organized for the following day, Saturday, 25 October 2025, at the Phase I Clinical Research Center of Shanghai Xuhui District Central Hospital. Overall, the AGM provided a vital platform for sharing updates, discussing global trends, and strengthening the ICN network as it enters its next decade of collaboration.



We extend our sincere gratitude and appreciation to Mr. Ming Wan, ICN Vice-Chair, Deputy Director of the Shanghai Clinical Research Center, and his entire Shanghai team for their exceptional support and dedication in hosting the ICN AGM 2025. The success of this important meeting was made possible through their commitment and hard work.



ICN Annual General Meeting 2025 Abstracts

CTU Sustainability

by Mr Ming Wan, Shanghai Clinical Research Center

The Shanghai Clinical Research Center (SCRC) has developed into a comprehensive, one-stop platform for clinical research, leveraging the city's strong healthcare resources, including 35 top-tier hospitals and numerous national centers. Its model emphasizes integration of medical institutions and enterprises, supported by policy incentives and innovative platforms such as the Municipal Hospital-Industry Collaborative Research Innovation Platform and the Shanghai Ethics Committee for Clinical Research. Clinical trials in Shanghai show robust growth, with thousands of investigator-initiated trials (IITs) and a fluctuating share of industry-sponsored trials (ISTs). SCRC provides end-to-end services, including project design, statistical analysis, regulatory compliance, biobank management, data science solutions, and specialized facilities such as a WHO-accredited Phase I unit. Its operations follow international standards (ICH-GCP, ISO, CAP), ensuring quality, safety, and efficiency. Through its medical-enterprise integration, training programs, and international collaborations, SCRC strengthens Shanghai's position as a leading hub for innovative clinical research in Asia.



Expanding Legal Horizon

by Dr Akhmal Yusof, Clinical Research Malaysia



Dr. Akhmal Yusof, CEO of Clinical Research Malaysia (CRM), highlights Malaysia's progress in clinical research governance and efficiency. Since its establishment in 2012 as a corporatized entity under the Ministry of Health, CRM has grown into a one-stop centre and Site Management Organization, supporting sponsors, CROs, hospitals, and investigators. The number of clinical trial agreements (CTAs) has steadily increased from 437 in 2017 to 860 in 2024, reflecting CRM's role in streamlining processes. Significant milestones include ISO 9001:2015 Quality Management accreditation (2019) and ISO 37001:2016 Anti-Bribery accreditation (2021). Study Initiation that took 350 days in 2015 has now reduced to 90 days contributed by reduction of time reviewing CTA to 14 days. This is aided by digitalization submission with proper audit trails, and electronic signatures. CRM also publishes annual legal perspectives on clinical research and emphasizes principles of humanity, stability, and sustainability. Its reimagined legal processes aim to accelerate start-up timelines, strengthen governance, and expand Malaysia's clinical research ecosystem.

Talent Development for Clinical Trial Ecosystem in Thailand

by Prof Pope Kosalaraksa, Academic Clinical Research Office, Khon Kaen University

The presentation "Talent Development for the Clinical Trial Ecosystem in Thailand" by Prof. Pope Kosalaraksa highlights the role of the Academic Clinical Research Office (ACRO) at Khon Kaen University in advancing Thailand's clinical trial capacity. Established in 2013, ACRO-KKU provides one-stop services, including trial management, pharmacy, laboratory, and protocol development. It has supported over 260 studies, with a majority in Phase 3. The presentation outlines challenges in the clinical trial ecosystem, such as lengthy ethics approvals, limited sites, and shortages of trained personnel. Strategic initiatives focus on capacity building for investigators, research nurses, and pharmacists, expanding clinical research centers (CRCs), and implementing accreditation systems. National strategies emphasize harmonizing regulatory processes, streamlining trial start-up, strengthening networks of CRCs, and creating a centralized ethics review system. The roadmap envisions a National Clinical Research Organization, integrated digital data platforms, and enhanced public awareness to support sustainable growth and international collaboration.



ICN Annual General Meeting 2025 Abstracts

ICH GCP E6(R3) Implementation: Status and Challenges

(1) Hong Kong Lays the Groundwork for the Implementation

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

Hong Kong is progressing towards ICH GCP E6(R3) implementation by regulations, though it follows the principles of Good Clinical Practice (GCP) for conducting clinical trials, but it does not have local GCP guideline at current. The Hong Kong Department of Health under the Health Bureau announced the timetable in June 2025 for establishing the Centre for Medical Products Regulation (CMPR) and the aggressive roadmap for implementing “primary evaluation” for drug registration, marking a pivotal shift in drug registration regulations. Furthermore, Hong Kong is accessing to ICH as a regulatory member with a pressing timeline in 2027. A ICH taskforce was set up and convened its first meeting in July 2025 for guiding the process.

While the Chinese Mainland has advanced in a fast pace through successful implementation of its local GCP guideline since 2003, Hong Kong is still at the beginning stage for formal adoption.



(2) Navigating Transition: Regulatory Review in Japan

by Dr. Tsutomu Nishimura and Dana Lin, Institute for Advancement of Clinical and Translational Science, Kyoto University Hospital



Japan is currently in a transitional phase toward implementing ICH GCP E6(R3). The regulatory framework is based on the Pharmaceuticals and Medical Devices (PMD) Act and Japan GCP (last amended in 2022). Full adoption of E6(R3) requires revision of the J-GCP ordinance, but no formal Step 5 adoption has occurred as of October 2025. The Ministry of Health, Labour and Welfare (MHLW) is reviewing clinical trial procedures, with Annex 2 open for public comments earlier in 2025. Stakeholder consultations across industry and academia are ongoing, focusing on Quality by Design, risk-based monitoring, and audit readiness.

(3) Europe and Switzerland Take Steps Toward Clinical Trial Governance

by Dr Anja Eskat, Clinical Trials Center, University of Zurich and University Hospital Zurich

Switzerland and the EU are moving forward with ICH GCP E6(R3) implementation, marking a key step in modernizing clinical trials. The revised Principles and Annex 1 take effect in the EU on 23 July 2025 and in Switzerland on 15 August 2025, with Annex 2 expected in early 2026.

E6(R3) emphasizes risk-based quality management, flexible trial design, and digital innovation, while strengthening Sponsor Oversight. Sponsors are now explicitly accountable for monitoring sites, vendors, and systems, embedding oversight throughout the trial lifecycle.

In Switzerland, GCP certificate requirements have been updated in late 2025: holders of older certificates (before 2016) must complete updated R3-compliant training, those certified between 2016 and 2017 are recommended to refresh their training, while R2-compliant certificates from 2017 onward require self-study of R3 updates and a refresher course within one year.

To help academic sponsor-investigators meeting the sponsor requirements, the SCTO has established a dedicated working group. This group is developing tools, templates, training, and resources to support sponsors in implementing E6(R3) principles and ensuring high-quality, compliant clinical trials across Switzerland.



ICN Annual General Meeting 2025 Abstracts

ICH GCP E6(R3) Implementation: Status and Challenges

(4) Digital Tools and Compliance Strategy in Istanbul

by Dr. Sayime Başak Koç Şenol, Istanbul University Center of Excellence for Application and Clinical Research

The Istanbul University Center of Excellence for Application and Clinical Research (IUKAMM) is closely following developments related to ICH GCP E6(R3) and continues preparatory activities within this framework, with more than 50 ongoing clinical trials and over 150 enrolled participants.

ICH GCP E6(R3) represents a transition from a rule-based approach to a risk-based, technology-enabled quality management framework, emphasizing flexibility, scalability, and enhanced data integrity. In Türkiye, regulatory activities regarding ICH GCP E6(R3) are currently ongoing under the authority of the Turkish Medicines and Medical Devices Agency (TITCK), and the guideline has not yet been fully implemented at the national level.



Within this context, and in accordance with existing national regulations, study-specific remote monitoring practices are being conducted at Istanbul University under the responsibility of the principal investigators, and electronic communication with study participants is being utilized through approved and secure methods.

These remote monitoring and digital communication practices are implemented in compliance with ethics committee approvals and regulatory requirements, with the aim of supporting participant safety, data integrity, and study continuity. In parallel with the regulatory work led by TITCK, our center aims to further develop its infrastructure and institutional capacity to support the future implementation of ICH GCP E6(R3).

(5) From Training to Implementation: Thailand Prepares for ICH GCP E6(R3) Era

by Dr. Suvimol Niyomnaitham, Siriraj Institute of Clinical Research



Thailand is actively preparing for ICH GCP E6(R3) implementation, focusing on modernizing clinical trials with digital tools, decentralized designs, and risk-based quality management. Key updates emphasize data governance, clarified roles for sponsors and investigators, and flexibility for innovative trial approaches. Training has begun nationwide, including a major session at Siriraj Institute of Clinical Research (SICRES) in May 2025, attended by over 200 participants, and an NSTDA workshop in July 2025. Implementation steps include updating SOPs, protocols, and IT systems, aligning with Thai FDA guidance, and establishing institutional roadmaps to ensure readiness for regional enforcement.

Save the Dates for ICN Annual General Meeting 2026!

The upcoming ICN Annual General Meeting will be held in **Bangkok** from **11 - 13 November, 2026**, organised by Siriraj Institute of Clinical Research. Looking forward to meeting members across the globe again!

Global Focuses



WHO: New Global Research Agenda for Paediatric Clinical Trials

The World Health Organization (WHO) has released a new technical report defining a global research agenda to address key evidence gaps in paediatric clinical trials, with a focus on children aged 0–9 years. Building on the WHO Guidance for Best Practices for Clinical Trials and its call to improve representation of underserved populations, the agenda prioritizes research areas where clinical studies can deliver the greatest public health benefit—particularly in low- and middle-income countries.

Developed through an inclusive process involving more than 380 stakeholders worldwide, the agenda outlines 172 priority research areas across infectious diseases, noncommunicable diseases, newborn health, nutrition, and early childhood development. It further underscores the importance of regional collaboration, integration of research into national health systems, and sustained investment to ensure evidence generation leads to real improvements in child health.

By prioritising paediatric research where evidence gaps are greatest, this agenda helps ensure clinical trials deliver meaningful health benefits for children, particularly in low- and middle-income countries.

Find out more on WHO website: <https://bit.ly/3ZaUxKT>

WHO: Addressing Barriers to Equitable Access and Sustainable Financing for Future TB Vaccines

A new report from the Finance and Access Working Group of the TB Vaccine Accelerator Council presents a first-of-its-kind analysis of the barriers, bottlenecks and market dynamics that could affect timely, equitable and sustainable access to future TB vaccines.

Read more on WHO website:

<https://bit.ly/4tdqJe7>



United Kingdom: Updating Clinical Trials Regulations

Amended clinical trials regulations will take effect in the UK on 28 April 2026. The Health Research Authority (HRA), in collaboration with the Medicines and Healthcare products Regulatory Agency (MHRA) to update the regulations.

To help researchers and sponsors prepare, the HRA and MHRA have released a set of guidance materials ahead of the implementation date.

Read more here: <https://bit.ly/4ad4v3s>

Switzerland: Empowering Clinical Trial Management through Ethical AI

Across the research landscape, artificial intelligence (AI) is rapidly emerging as a powerful ally for improving the planning and conduct of clinical trials. Yet, as a recent PhD project by Lara Bernasconi at the Clinical Trials Center Zurich highlights, the promise of AI can only be realized if ethical, legal, and societal questions are addressed from the outset.

The research explored how stakeholders perceive AI tools used in trial management, with a special focus on recruitment processes and natural language processing applications. While many recognized AI's potential to streamline documentation, support participant screening, or enhance communication, they also stressed persistent concerns: inadequate regulation, limited AI literacy, risks to privacy, and the danger of over-reliance on automated systems.

One finding stood out across all four project components: trust and transparency are essential. AI in clinical trials is not merely a technical innovation; it is a sociotechnical transformation that must safeguard participant autonomy, equity, and data protection. The work calls for clearer governance frameworks, stakeholder engagement, and training to ensure meaningful human oversight.

As clinical researchers increasingly navigate digital transformation, these insights remind us that responsible innovation requires not only new tools, but also new conversations. Some study results have already been published and additional manuscripts are currently under review:

<https://bit.ly/4tg9wkg>

<https://bit.ly/3Mee17A>

Members' Snapshots



CRM's Milestones in 2025 and What Lies Ahead

Contributed by Clinical Research Malaysia

2025 marked a meaningful year of progress for Clinical Research Malaysia (CRM), as we continued strengthening partnerships, expanding regional engagement, and supporting Malaysia's growing role in high-quality clinical research.

One highlight was CRM's collaboration with Indonesia through the Strengthening Indonesia Clinical Trial Ecosystem workshop organised by WHO WPRO and INA-CRC. By sharing practical experiences from Malaysia, we contributed to mutual learning and closer ASEAN cooperation. Another key moment was CRM Trial Connect 2025, held on 8–9 May in Kuala Lumpur. Officiated by the Prime Minister of Malaysia and the Minister of Health, the event welcomed over 1,000 delegates from 190 organisations — our largest international conference to date. The programme featured pre-conference workshops, oncology-focused sessions, and the CRM Sponsored Research Awards 2025.

Operationally, CRM also launched its Site Operations Office to strengthen on-ground support for trial sites nationwide, while continuing to invest in talent development through our Centre of Excellence (CoE) programmes. Looking ahead, CRM Trial Connect 2026 (7–8 May 2026) will continue to serve as a strategic platform to foster collaboration, facilitate networking and provide timely insights into regional and global developments in clinical trial. Together, these efforts reflect CRM's ongoing commitment to supporting the research community and advancing clinical research across Malaysia and the region.



One-day Comparative Course in Collaboration with DIA China

Contributed by Clinical Trials Centre, The University of Hong Kong



It's our privilege to co-organise and conclude an insightful one-day comparative course, "Think like a Regulator: Turning Regulatory Insight into Global Drug Development Strategy," with DIA China on October 17, 2025.

Our lecturers and guest speaker who have in-depth experience working in international regulatory agencies engaged participants to immerse in the world of regulatory decision-making, undertaking a comparative analysis of the U.S. FDA and China NMPA. Guided by real-world case studies, we unpacked the mechanism and models behind the high-stakes regulatory judgements, providing a clear comparative lens on both systems' key parallels and distinctions.



HKU is now a Member of the WHO Global Clinical Trials Forum

Contributed by Clinical Trials Centre, The University of Hong Kong

We are pleased to announce that The University of Hong Kong (HKU) has become a member of the World Health Organization (WHO) Global Clinical Trial Forum (GCTF) through Clinical Trials Centre, The University of Hong Kong (HKU-CTC). This membership recognizes HKU-CTC's long-standing role in generating high-quality clinical evidence and its commitment to advancing global health research.

Being part of the GCTF is a great honour and also represents a reaffirmation of our long-term commitment to working with stakeholders worldwide to strengthen the global clinical research landscape. We are eager to continue our steps in facilitating diverse and robust clinical trials through Hong Kong's unique infrastructural advantage.



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