ICN International Clinical Trial Center Network

NEWSLETTER

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Table of Contents

Clinical Research Success through Good Governance

The recent ICN Steering Board Meeting (SBM) and Annual General Meeting (AGM) held on November 28, 2023, were monumental gatherings that charted the course for our collective future. Hosted graciously by our esteemed ICN member, Hong Kong University Clinical Trials Center (HKU-CTC), the meetings were nothing short of exceptional, offering an experience that surpassed all expectations.

The HKU CTC went above and beyond, providing everything we could have hoped for, including an exclusive opportunity to visit their Phase 1 unit at the HKU CTC on November 27, 2023. This added depth and insight for members keen on expanding their knowledge.

The SBM took place with 18 participants, with 9 out of 10 SB members present, alongside 2 members of the ICN Scientific Advisory Board. Discussions centered on the future trajectory of ICN and strategies to enhance member engagement. Excitingly, a new ICN member was approved and one Scientific Advisory Board member welcomed during this pivotal meeting, further enriching our network.

The subsequent AGM saw an even larger participation with around 50 attendees from 17 ICN member organizations, accompanied by 3 esteemed members from the Scientific Advisory Board. This robust attendance underscored the commitment of our members to collectively drive the ICN vision forward.

Clinical Research Success through Good Governance

The momentum didn't stop there. The CRGo World Conference & ICN Symposium on November 29, 2023, saw a staggering online participation of over 1600 attendees. Onsite participation was fully booked, underscoring the immense interest and engagement in the event. Alongside the compelling talks by Henry and Creany, four additional presentations by ICN members took center stage, demonstrating the wealth of knowledge and expertise within our network. Moreover, various ICN members hosted diverse sessions, showcasing the breadth and depth of our community's contributions.

The events have shown the dedication and collaborative spirit of ICN members. We extend our heartfelt gratitude to HKU CTC for their exceptional hosting and to all participants who made these gatherings immensely impactful. As we move forward, let's continue leveraging these connections and insights to pave the way for innovation and progress within clinical research.

Global Focuses

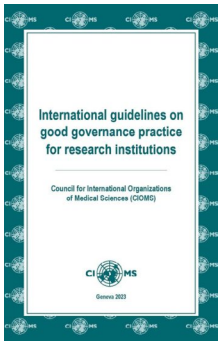
ICN's contribution to "International Guidelines on Good Governance Practice for Research Institutions"

Contributed by Institute for Advancement of Clinical and Translational Science (iACT) at Kyoto University Hospital

On behalf of ICN, Managing Director Henry Yau and Deputy Managing Director Creany Wong of Hong Kong University Clinical Trial Center participated in the work group under The Council for International Organizations of Medical Sciences (CIOMS), an international and non-profit organization built up by WHO and UNESCO. The mission of CIOMS is to set guidance for health research community to advance public health. The work group drafted "International Guidelines on Good Governance Practice for Research Institutions" and this guidelines file was released for comments in 2023. The guidelines provide comprehensive framework for the research institutions in:

1. Research Institution Management
2. Ethics, Law and Scientific Integrity
3. Scientific standards
4. Collections, storage, and use of data and/or biological materials in health-related research
5. Financial Management and Budgeting
6. Collaboration
7. Communication
8. Education and Learning
9. Institutional Research Oversight

Given each clinical trial unit has different nature due to the scale of services, these guidelines provide clear landscape with whole functionality for CTUs' advancement while safeguarding patient safety.



ICH GCP Revision (R3)

The ICH GCP revision (R3) represents a pivotal shift in clinical research standards. It emphasizes patient-centricity, focusing on participant rights, safety, and engagement. R3 integrates technology advancements, promoting electronic records and remote monitoring for streamlined data management. Enhanced risk-based monitoring prioritizes critical data points, reducing administrative burden. It fosters global harmonization, aligning regulatory requirements across regions, simplifying multinational trials. Collaboration with patient advocacy groups, sponsors, and regulators ensures robust study designs and informed consent processes. Overall, ICH GCP R3 marks a transformative evolution, elevating clinical research with a stronger patient focus, technological integration, and global unity in pursuit of safer, more efficient trials.

GCP
Good Clinical Practice

Brockwood Global

Brockwood Global is a platform for fine training and publications of papers in clinical research and other related fields. This platform has its origin in 1985, where it started with first trainings and issuing certificates. Until today, there are more than 90'000 people profiting from Brockwood from more than 100 countries. This academy provides products for GCP, PV, GDPR, GCLP, CDM, NIS and Regs.

More information about Brookwood can be found on their webpage https://www.brookwood-global.com/

Updates of ICN

Publication of two surveys distributed within ICN

Two surveys – two important topics – double thank you to all ICN participants!

Table 2 Action plan/checklist leading to a reduction in the carbon footprint of clinical trials

Trial phase	Measures to reduce the carbon footprint of clinical trials	Done?
Planning phase	Extensive literature search: answer only relevant research questions	☐
	Use of online CO_2e-calculators to assess greenhouse gas emissions	☐
	Feasibility—avoid delay due to slow recruitment:	
	Consider PPI for planning of study visits, check of eligibility criteria and PROs	☐
Submission phase	IRBs/ECs and competent authorities: assess greenhouse gas emissions of submitted clinical research projects	☐
Conduct phase	Patient care:	
	Decentralised concept	☐
	Local study nurse/flying study nurse	☐
	On-site visits only if unavoidable→visits by 'phone'	☐
	Shipping:	
	Local/regional products→local supply chains	☐
	Infrastructure:	
	Use of renewable energies	☐
	Waste prevention and recycling	☐
	Staff:	
	Use of teleconferencing and/or videoconferencing	☐
	Minimise travelling	☐
Quality control	Remote monitoring	☐
	Shared monitoring activities within network→common standards and procedures	☐
Results	Publication of trial results (positive and negative) in clinical trial registries and/or journals→avoid publication bias for future trials	☐

CO_2e, carbon dioxide equivalent; PPI, patient and public involvement; PROs, patient-reported outcomes.

The first paper assessed the status quo of the carbon footprint of clinical trials as well as current regulatory guidance. The manuscript was published in BMJ Global Health in September 2023. Currently, greenhouse gas emissions are neglected during the planning phase of a research project, and they are not yet addressed or assessed by default during the approval procedures by Institutional Review Boards (IRBs) / Ethics Committees (ECs) or competent authorities. Thus, all involved stakeholders within clinical research need to be made aware of it through advice from academic research institutions and IRBs/ECs, among others.

Link to full paper: https://gh.bmj.com/content/8/9/e012754

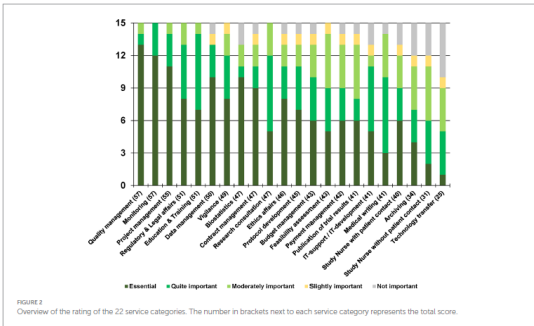


FIGURE 2
Overview of the rating of the 22 service categories. The number in brackets next to each service category represents the total score.

The ICN-Quality Standards working group developed the survey for the second paper aiming toward a global harmonization of service infrastructure in academic Clinical Trial Units (CTUs). The manuscript was published in Frontiers in Medicine in October 2023. To balance the range of services offered while meeting high international standards of clinical research, emerging CTUs should focus on offering (quality) management services and expertise in regulatory and legal affairs. Additionally, education and training services are required to ensure clinicians are well trained on GCP and legislation. CTUs should evaluate whether the expertise and resources are available to offer operative services.

Link to full paper: https://www.frontiersin.org/articles/10.3389/fmed.2023.1252352/full

Members' Snapshots

Structural Reformation at iACT, Kyoto University Hospital

Contributed by Institute for Advancement of Clinical and Translational Science, Kyoto University Hospital

Institute for Advancement of Clinical and Translational Science (iACT) at Kyoto University Hospital had gone through structure reformation and now iACT, an academic research organization of 140 staffs, provides full services for new drug/device development from early pre-clinical stage to clinical trials and regulatory approval. 3Three departments and three centers below demonstrate the expert functionalities:

- Department of Medical Development: Cultivating and supporting drugs/regenerative medical products/medical devices/ in-vitro diagnostics from basic to clinical and applications, in project management manner.
- Department of Clinical Trial Science: Providing contract research services including monitoring/data management etc.
- Department of Clinical Research Facilitation: Providing clinical trial administration/education-training/study management/ clinical research coordination/international collaboration/audit
- Kyoto Innovation Center for Next Generation Clinical Trials and iPS Cell Therapy (Ki-CONNECT): A dedicated Phase I trial center of 30 beds.
- Preemptive Medicine and Lifestyle Related Disease Research Center
- Clinical Bio-Resource Center (CBRC): Managing and providing biospecimen
- Clinical Research Center for Medical Equipment Development (CRCMeD)

Another part of iACT is administration support: Strategy and Public Relations Office, and Business Development Office. This enhances iACT operation efficiency and external communication. iACT aims to facilitate the new drug/device development in a timely and speedy manner for the best of patient's benefit while safeguarding patient's safety.

Members' Snapshots

ICN welcomes Professor Semra Demokan, who is the new Director of Istanbul University Center of Excellence for Clinical Research (IUKAMM)

Istanbul University is among the 10 oldest universities in the world. Their mission is to bring together humanity and produce knowledge through competent individuals. The IUKAMM makes science at national and international level and supports scientists in all fields of physical, social and health science. The main aim is to provide leadership on clinical research issues, to carry out quality controls and to organize events, to create learning opportunities and to give support in different fields. They are supported by sponsor clinical research but have also IITs. Future plans of the IUKAMM are the organization of training, scientific meetings, etc. So far they only had drug studies but want to set their focus among other things on cosmetic, vaccine, biological agent and gene therapy, maybe in partnership with ICN. They hope form ICN to create joint projects, joint meetings and to conduct other education programs.

Prof. Dr. Semra Demokan is a renowned principal investigator and basic oncologist She is founding members of the Departments of Experimental and Molecular Oncology and Supportive Care and Palliative Treatment in Oncology Institute and Basic Oncology Society and served as its President between 2021-2023. She is current Director of Center of Excellence for Application and Clinical Cancer Research in Istanbul University. She obtained her B.S in Molecular Biology and Genetics from Boğazici University and holds an MSc and PhD in Oncological Biology and Immunology. She worked as post-doctoral fellow at Johns Hopkins University in Department of Otolaryngology. She has authored over 60 publications with over 800 citations. Her outstanding contributions have been recognized with national and international awards. She is members of EACR, AACR (active) and ECHNO.

ICN welcomes Dr Joseph Kamgno, who is the General Manager and Founder of The Higher Institute for Scientific and Medical Research (ISM)

The Higher Institute for Scientific and Medical Research (ISM) founded in 2005, is among the very few institutions in Sub-Saharan Africa that have the objective of conducting high quality clinical trials including phase I trials. The ISM General Manager and founder Joseph KAMGNO is a Medical Doctor, trained at the Faculty of Medicine of the University of Yaounde I. He started his specialization at Institut Pasteur in Paris with a Diploma in Epidemiology of Communicable Human and Animal Diseases. He pursued his studies with a Diploma in Statistics applied to Medicine and Biology, a Master of Public Health, and a PhD in Epidemiology at the University of Paris 6. He is now Professor of epidemiology at the Faculty of Medicine at the University of Yaounde I and Head of Department of Public Health. He founded the CRFilMT in 2005 (renamed ISM in 2023). Within the framework of this Research Institute, he has conducted as PI large-scale research projects including epidemiological studies, clinical trials, evaluation of diagnostic tools. He is Fellow of the Cameroon Academic of Sciences and the African Academy of Sciences. He was awarded in 2015 the Islamic Development Bank Price for Sciences and Technology (US$ 100 000), and in 2022, the Christophe Mérieux Price (€ 500 000). He is author of 150 publications, with a H index of 38 in 2023. ISM is home to 40 young MDs, scientists and support staff.