

2024 REACTA

亞洲臨床試驗區域聯盟論壇

From Ideation to Validation :
Clinical Trials in the Digital Era



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(In Chinese)



On behalf of Taipei Medical University, it is a great honor to host REACTA 2024, a significant international event focused on clinical trials across Asia. I would like to extend a warm welcome to our esteemed delegates from Japan, Korea, Malaysia, Singapore, Taiwan, and other regions of Asia. Your presence signifies and strengthens the unity of our regional collaboration in advancing clinical research.

The theme of this year's Forum, "From Ideation to Validation: Clinical Trials in the Digital Era," is particularly relevant. As we navigate an era where artificial intelligence is revolutionizing various fields, the importance of integrating responsible AI into clinical trials cannot be overstated. The digital age presents us with unprecedented opportunities to enhance the efficiency, accuracy, and scope of our clinical trials.

Applying AI technology in clinical trials has also become a topic of discussion in scientific publications. Traditionally, screening participants for clinical trials has been a meticulous and time-consuming process. However, research shows that with the advent of AI solutions like GPT-4, we can significantly streamline this process through the utilization of Retrieval-Augmented Generation (RAG) to enhance the performance of generative AI. This not only reduces time and costs but also minimizes errors, ensuring more effective and inclusive trials. This is just one of the many remarkable benefits brought to us by the ever-evolving AI technology.

With opportunities come challenges. As we leverage these large language models, it is crucial to understand our institutional competencies and continually improve our delivery. I strongly believe that events like REACTA 2024 will prompt us to engage deeply with the future of clinical trials.

I wish all delegates a productive and enjoyable experience at REACTA 2024. May our collective efforts pave the way for groundbreaking advancements in clinical trials, benefiting patients and healthcare systems worldwide.

Welcome to REACTA 2024, and thank you for joining us

Chairman
Ray-Jade Chen
Taipei Medical University



As President of Taipei Medical University, I am honored to welcome our esteemed delegates from Japan, Korea, Malaysia, Singapore, Taiwan, and other parts of Asia to REACTA Forum 2024. It is a privilege for Taipei Medical University to host this significant event, bringing together researchers and practitioners to explore the future of clinical trials in the digital era.

Taipei Medical University has a longstanding commitment to advancing clinical research and healthcare innovation. Since 1976, our efforts, exemplified through our affiliated hospitals—Taipei Medical University Hospital, Taipei Municipal Wanfang Hospital, and Shuang Ho Hospital—have demonstrated our dedication. In collaboration with public entities such as the Taipei City Government and the Ministry of Health and Welfare, we have democratized access to quality healthcare, thanks to the tireless work of our healthcare professionals.

Our focus on clinical trials began in the early 2010s with the establishment of our first office dedicated to promoting trial participation. In under 15 years, we have grown into an integrated team of nearly 200 experienced clinicians leading numerous trial projects.

Looking ahead, clinical trials will continue to play a crucial role in advancing patient care by discovering better, faster, and more affordable solutions. The evolution from paper-based records to digital tools has transformed our operations, and embracing technology in clinical trials is essential. As a sector, we must leverage digital advancements while remaining grounded in our mission.

I am confident that REACTA 2024 will serve as a platform for profound discussions and pioneering advancements in clinical trials. I encourage all participants to engage actively and contribute constructively to the exchange of ideas. Together, let us pave the way for innovative solutions that will benefit patients and healthcare systems worldwide.

Welcome to REACTA 2024, and thank you for your participation.

President
Mai-Szu Wu

Taipei Medical University



Welcome to REACTA 2024. As the Dean of Human Research at Taipei Medical University and the Chairperson of this year's forum, it is my pleasure to welcome all our distinguished delegates from across Asia and beyond.

This year's theme, "From Ideation to Validation: Clinical Trials in the Digital Era," is especially relevant as we examine the transformative impact of digital advancements on clinical trials. Our comprehensive agenda reflects this theme, covering key topics such as streamlined clinical trials, data technology and clinical validation, and the future of decentralized trials. These sessions provide a deep dive into current trends and emerging technologies reshaping our field.

We are privileged to have an impressive lineup of speakers from across Asia who will share their experiences in managing significant trials in therapeutic areas ranging from oncology and personalized medicine to neuroscience. They will also offer insights into developing international networks for collaborative, cross-border trials. We are particularly honored to feature perspectives from our industrial representatives in the Industrial Leaders' Panel Discussion. Their insights are invaluable as we work together to address the challenges and opportunities of the digital era.

This year, we have also expanded our discussions to include pre-clinical studies. These foundational studies are crucial to the advancements we see in clinical settings, and their inclusion underscores the comprehensive nature of our forum.

At the Office of Human Research, we emphasize the smooth and effective implementation of clinical studies. Our mission is to support our researchers, investigators, and partners in bringing scientific and clinical benefits to our societies. We are committed to fostering an environment that encourages innovation and collaboration.

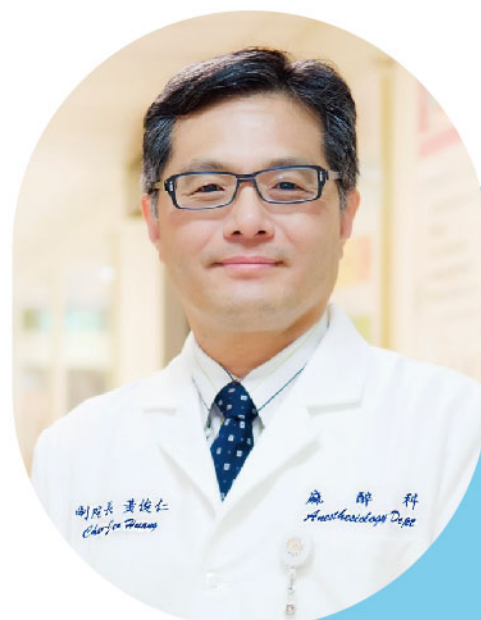
I extend my gratitude to all our friends and partners for their unwavering support. Special thanks to the organizing team for crafting an exciting and diverse agenda, and to all participants for joining us. Your presence and engagement are essential to the success of this event.

I wish everyone a productive and inspiring forum.

Thank you for being here, and enjoy REACTA 2024!

Dean
Office Of Human Research
Chun-Jen Huang

Taipei Medical University



Day 1

AUGUST 02

From Ideation to Validation : Clinical Trials in the Digital Era	
08:00-08:40	Registration
08:40-08:45	Welcome and Opening Ceremony by Chairman, TMU
08:45-08:50	Welcome and Opening Ceremony by President, TMU
08:50-08:55	Welcome and Opening Ceremony by Deputy CEO, CDE
08:55-09:00	Take Group Photographs
Session 1	Clinical trials in new era : trends and emerging technologies
Part I : Streamlined Clinical Trials	
09:00-09:40	Streamlined academic renal trials: trends and key success
09:40-09:50	Discussion
Part II : Data Technology and Clinical Validation	
09:50-10:05	The New Era of AI in Clinical Research
10:05-10:20	Supporting and Validating Clinical Trials through Global RWD/RWE Collaboration with OHDSI
10:20-10:25	Discussion
Part III : Trends and New Technology in Cell Therapy	
10:25-10:40	Clinical trial of adaptive cell therapy
10:40-10:55	Next-generation Cell-based Immunotherapy via Antibody Cell Conjugation
10:55-11:00	Discussion
11:00-11:10	Break
Part IV : Future of Decentralised Clinical Trials	
11:10-11:20	Embracing the Future: Preparing Sites for Decentralized Clinical Trials (DCT) Innovation
11:20-11:30	Activities to promote DCTs in Japan
11:30-11:40	Local Care Model - Patient Centric Approach in Malaysia
11:40-11:55	Practical implementation of decentralized clinical trials in Japan and prospects in Asia
11:55-12:05	Discussion
12:05-13:05	Lunch Time
Part V : Sharing from Clinical Research Centers in Taiwan	
13:05-13:45	Introduction and best practice sharing from Clinical Trial Centers
Session 2	International collaborative trials : opportunities and challenges
13:45-13:55	Communication tips from past experience in establishing new international collaboration for clinical trials
13:55-14:10	Enhancing Innovative and Investigator-Initiated Clinical Trials in Malaysia
14:10-14:25	Rethinking Clinical Trials: Patient Reported Outcome Measures
14:25-14:30	Discussion

Day 1

AUGUST 02

14:30-14:40	Phase 4 clinical trial for cyclosporine A for Kawasaki disease
14:40-14:55	Evolving Global Clinical Trials Sites landscape
14:55-15:10	Collaborative networks for clinical cardiovascular trials
15:10-15:15	Discussion
15:15-15:25	Break
Session 3	Experience sharing of key clinical trial studies in Taiwan
15:25-15:35	Precision diagnosis, Translational Research, and Multicenter IIT Phase II Trial of Atypical Teratoid Rhabdoid Tumors in Children: Experience in Taiwan
15:35-15:45	Clinical Trials for Neurological Diseases in Taipei Medical University, Taiwan
15:45-15:55	Xpert MTB/RIF assay as the initial diagnostic test for pulmonary tuberculosis in Taiwan: A prospective, multi-center, randomized, pragmatic trial
15:55-16:05	Clinical Trials for Cardiovascular Diseases in Taipei Medical University, Taiwan
16:05-16:15	Discussion
Session 4	Industrial Leaders' Panel Discussion
16:15-17:25	Dialogue with industry representatives
17:25-17:30	Closing remarks

Day 2

AUGUST 03

From Ideation to Validation : Clinical Trials in the Digital Era

08:00-08:30	Registration
08:30-08:35	Opening of Day 2 by Executive Vice President, TMU
Session 5	Country sessions from the REACTA Board Members
08:35-08:50	CCRC Activities and Clinical Trial Networks as AROs in Japan
08:50-09:05	Reflections on Clinical trials in the era of Evidence-based Medicine
09:05-09:20	Challenges and opportunity of cancer clinical trials in Taiwan
09:20-09:35	Opportunities in conducting Multi-Regional Clinical Trials in Malaysia
09:35-09:45	Discussion
09:45-10:00	Introduction to REACTA 2025
10:00-10:10	Break
Session 6	Research innovation and clinical validation
10:10-10:20	Allogeneic platelet lysates for brain administration and treatment of neurological disorders
10:20-10:30	Translational research experience sharing using TMU biobank
10:30-10:40	Novel HDAC6 Inhibitor G211 : Preclinical Study and Potential in Human Cancer Treatment
10:40-10:50	Electrospun nanofiber artificial bone substitutes
10:50-11:00	Discussion
Session 7	Updates on latest regulations and management practices on clinical trials (中文演講)
11:00-11:15	藥品臨床試驗執行分散式措施指引 (Decentralized Clinical Trial, DCT)
11:15-11:35	臺灣再生醫療挑戰與展望 (The Challenges and Future Developments of Regenerative Medicine in Taiwan)
11:35-11:45	Discussion
Session 8	Oral Presentation: PhD student's participation
11:45-11:50	OncoPharmGuard: Enhancing Cancer Treatment through AI-Driven Pharmacogenomics
11:50-11:55	EpCAM-targeted combinatorial therapeutics attenuates cancer stemness : A platform for colorectal cancer treatment
11:55-12:00	Elevated serum GDF15 level as an early indicator for proximal tubular cell injury in acute kidney injury
12:00-12:05	The Anti-inflammation Effects of Exosomal Delivery of hsa-let-7i-5p and the Underlying Mechanism
12:05-12:20	Discussion and Awards
12:20-12:30	Closing remarks

ONE^{NESS}

Oneness Biotech Co., Ltd.

“New drug development for unmet medical needs in chronic disorders in dermatology and immunology”

Oneness Biotech is dedicated to developing first-in-class new drugs and medtech products for chronic dermatology and immunology. After 15 years of development, Oneness has had its lead product, ON101 (Fespixon® / Bonvadis®) successfully commercialized for the treatment of chronic wounds globally.

The rest of the pipeline is under clinical development with an approximate total \$100-billion-dollar target addressable market. Meanwhile, licensing opportunities are being actively engaged. Oneness is open for discussions on commercialization and co-development partnerships.

ON101

First-in-class M1/M2 macrophage-regulating topical agent that promotes wound healing with significant clinical outcomes.

FB825

First-in-class antibody targeting IgE-expressing B cells for allergic diseases, including atopic dermatitis and allergic asthma. Partnered with LEO Pharma since 2020 for new drug development.

FB704A

Anti-IL-6 antibody for the treatment of severe asthma.

SNS812

SNS812 First and only siRNA for broad-spectrum coronavirus variants.

OB318

First-in-class new drug for hepatocellular carcinoma (HCC).

FB825
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for Allergic Diseases

Breakthrough!

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Welcome to

REACTA 2024

Professional growth, business development,
and social networking!





Taipei Medical University

Taipei Medical University (TMU) has been a leader in Taiwan's healthcare system since its establishment in 1960. Through its 11 colleges and 6 affiliated hospitals, TMU works with prestigious institutions from around the world to contribute to the advancement of education programs, healthcare provision, and translational research.

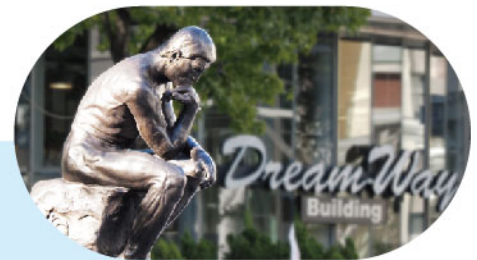
TMU leads in many research areas including cancer translational medicine, neuroscience, pulmonary medicine, AI in medicine, cell therapy & immunotherapy, and medical device development. With its research strengths and results being recognized by the government and funding agencies, TMU has already secured several major research grants in these areas. Moreover, TMU has helped incubate 25 startups and raised an Entrepreneurship Fund that offers support to accelerate the commercialization of research findings along with the establishment of TMU Biomed Accelerator. Finally, the imminent launch of TMU Biotech Park in Shuang Ho Campus will complete the ecosystem to support TMU's innovative entrepreneurship. TMU's education offers have expanded with the university's devotion to health service worldwide, accommodating interests of students from around the globe to develop area expertise and service their own communities.

TMU's commitment to internationalization has resulted in over 55,000 alumni working to improve healthcare systems around the world. In 2024, TMU continues to contribute to the advancement of sciences and healthcare, making a positive social impact on our communities and the society

World University Rankings:

- #401-450 in THE World University Rankings 2024
- QS World University Rankings 2024 by Subject
 - #151-200 in Medicine
 - #151-200 in Pharmacy & Pharmacology
 - #25 in Nursing

Scan for research collaboration >>





Taipei Medical University Hospital

Taipei Medical University Hospital (TMUH), affiliated with Taipei Medical University (TMU), was founded in 1976, excelling in clinical service, research, and education. Since 2018, TMUH has renovated its facilities, culminating in the 2022 opening of the Tsai Wan-Tsai Cancer Building and the TMU Proton Center. By 2024, it was upgraded to a pre-medical center with nearly 800 beds and over 2,000 staff, becoming a benchmark for medium-sized hospitals.

Located near the TMU campus, TMUH integrates service, education, and research, offering specialized care in cancer, cardiology, geriatrics, pediatrics, and international healthcare. Responding to an aging society, it expanded into long-term care, opening the TMUH Geriatric Clinic in 2023 and introducing telemedicine in 2024. The hospital promotes holistic healthcare, addressing mental well-being and community health.

TMUH actively engages in community health, telemedicine, and international outreach, notably in Eswatini since 2009. It has received awards for sustainability, focusing on health, education, and environmental measures. TMUH aims to become an internationally renowned medical center, fostering high-quality care and innovation.





Taipei Municipal Wanfang Hospital

Taipei Municipal Wanfang Hospital is the first public hospital in Taipei City to be privately operated. It currently has 761 beds and an additional 39 beds in a nursing home, providing excellent medical care to the citizens of Taipei City. The Hospital not only provides excellent care to the citizens, but also actively engages in various national health policies. It has garnered recognition from the authorities in the areas of prevention and control of severe and highly contagious respiratory disease, cancer screening and prevention, vaccination service, smoking cessation and health education, health check-ups for the elderly, child development screening, diabetes care, and community long-term care. In accordance with the core values of "Community-oriented, Patient-first," Wanfang Hospital continuously introduces specialized medical services, improves and optimizes the care quality, and establishes a collaborative referral network with community-based medical institutions.

In accordance with the philosophy of "Continuously pursuing quality and creating value together", the Hospital actively optimizes intelligent healthcare and promotes holistic medical care. We expand the network of community health services, strengthen elderly-friendly care, and provide comprehensive medical care for acute and critical conditions, cancer, chronic diseases as well as holistic care.

The Hospital owns a common laboratory, a translational research laboratory and 12 research & development centers, including center for cell therapy, centers of regional anesthesia & pain center, cancer center, comprehensive care center for cancer peritoneal metastasis, and cardiovascular research center.

Taipei Municipal Wanfang Hospital has sent personnel to various countries for many years to provide short-term and long-term medical services, and execute the "Early Diagnosis and Treatment Project for Cancer" in the Kingdom of Eswatini, deployed professional medical team in Jamhuuriyadda Somaaliland of Geeska Afrika. Additionally, Taipei Municipal Wanfang Hospital works with relevant government department for training the foreign health professionals.

Taipei Wanfang Hospital actively promotes clinical trial cooperation and innovation, links up the clinical trial ecosystem of the domestic biomedical innovation industry, and participates in multinational multi-centre clinical trials of drugs and medical materials. Through excellent electronic system integration, the facilitating the joint recruitment for international multicenter clinical trials across three hospitals. The self-developed Holmes system is utilized to quickly identify potential subjects, saving 97.9% of screening time and accelerating the trial progress by 63.2%. This achievement earned the 2020 National Healthcare Quality Award in the category of Smart Healthcare for the Teaching and Research Field. In terms of organizational operations, we have not only established a dedicated area for subject recruitment but also focused on training clinical trial professionals. From 2020 to 2023, we received a total of NT\$87,699,000 in funding from the Ministry of Health and Welfare for the Clinical Trial Development Program. Additionally, we have passed the AAHRPP accreditation for the protection of human research subjects three consecutive times, ensuring that the quality of subject protection in human research at our hospital meets international standards.





Shuang Ho Hospital

Taipei Medical University Shuang-Ho Hospital is located in Zhonghe District of New Taipei City, very close to Taiwan Taoyuan International Airport. Shuang-Ho Hospital is the third affiliated hospital of Taipei Medical University, which was established in 1960 and has expanded to ten colleges and a general education center. In the past half century, thousands of excellent and outstanding medical professions have graduated from Taipei Medical University and made great contributions for Taiwan with their dedication.

Grand opening on July 1st 2008, Shuang-Ho Hospital is not only the first BOT hospital in Taiwan and the biggest hospital in Zhonghe and Yonghe district, but also the first green building certified hospital in New Taipei City.

Shuang-Ho Hospital has a very strong and professional medical team with high quality and international medical experiences. Shuang-Ho Hospital also provides very good training and practices opportunities and study resources to Taipei Medical University which is looking forward to becoming one of the world-top medical schools

To develop the international medical care interactions according to the Government and Taipei Medical University's directions, Shuang-Ho Hospital is working on the development of various international medical care services, education training, and research development. Meanwhile, to upgrade and achieve an internationally certified medical quality management system, Shuang-Ho Hospital is initiating some hospital-wide projects, such as SOP standardization and optimization, human resource development training from international point of view, in order to acquire JCI (Joint Commission International) certification in shortly. With the acquisition of a WHO-qualified international certification, the hospital can continually upgrade and improve the medical quality management system, and provide the best quality and service to people and community.





CHIBA UNIVERSITY

Chiba University Hospital Clinical Research Center

Chiba University Hospital, founded in 1874, has a long tradition of excellence in healthcare services with about 500,000 outpatient visits per year, and is recognized as one of Japan's leading clinical research institutions contributing to the development of medicine.

The Chiba University Clinical Research Center (CCRC) was established at Chiba University Hospital in 2000 for the advancement of clinical research. The CCRC has conducted extensive clinical trials with its professional expertise, and in 2022 alone, the CCRC executed over 140 clinical trials.

In 2012, the Ministry of Health, Labor, and Welfare (MHLW) launched the 5 Year Clinical Trial Activation Plan and designated the top five hospitals showing initiative in developing clinical research in Japan as "core research centers." The CCRC is one of these centers, and we place a high priority on creating a productive and unique clinical trial environment by strengthening our Academic Research Organization (ARO) through collaborations with regulatory agencies and university hospitals in Japan, Asia, the United States, and Europe.

Coordinating system provided by the CCRC for clinical trials

The CCRC provides comprehensive support to researchers who conduct investigator-initiated registry clinical trials. The support includes coordination, monitoring, data management, and statistical analysis. We provide one-stop support, from obtaining research funds and negotiating with pharmaceutical companies in the start-up phase of clinical trials to publishing papers and regulatory approval after the clinical trials are completed. We also support researchers by coordinating consultations with PMDA, the Japanese regulatory agency and submitting the IND (Investigational New Drug) application to start clinical trials. Placement of dedicated staff to conduct clinical trials and setup of a specific project teams for each trial enable us to establish a comprehensive support system.

Collaborating with global partners

To accelerate the clinical trial process, the CCRC is engaged in strengthening a clinical research network with domestic and global partners such as regulatory agencies, academic research organizations, local clinics and hospitals, pharmaceutical companies, and venture companies.

The CCRC aims to collaborate with AROs around the world forming a global partnership. Since 2003, the CCRC has partnered with the Duke Clinical Research Institute (DCRI), focusing on information exchange. We also actively conduct informational exchange between other Asian, the United States, and European university hospitals.

Moreover, with the intention of promoting international clinical trials through the synergistic effects of strategic collaboration, nine hospitals that are affiliated with eight Japanese national universities in the Kanto Koshinetsu region, including Chiba University have joined forces to establish the University Hospital Clinical Trials Alliance. Currently, the alliance is working on developing international seeds while responding to the rapidly changing environment surrounding clinical research.





Dong-A University Hospital Clinical Trial Center

Since our inception in 2009 as a government-designated Regional Clinical Trial Center in Busan, we have progressed rapidly in scope and vision. Our philosophy is built on the idea that progress in clinical science can only occur with a strong foundation of quality assurance, the highest respect for ethical standards and an absolute focus on scientific rigor. To meet these needs, we stress the importance of maintaining international standards and dynamic education programs for our staff.

As one of the major centers for clinical research in Busan, an area encompassing seven-million residents, Dong-A University Hospital strives to engage with the local community via patient outreach programs and the latest in web and cell phone technology.

The Dong-A University Hospital CTC is an attractive solution for your clinical trial needs for a number of reasons. With FERCAP accreditation achieved in 2010 and our most recent designation by the government as a Global Clinical Trial Center of Excellence in 2013, our center also offers the latest in cutting-edge technology and ready access to a large patient pool. In addition, our center places a high degree of importance on providing frequent opportunities for education and training by hosting annual seminars and conferences for industry members and the future leaders of medicine.

We invite you to learn more about our center as we rise to meet the challenges of tomorrow. Through careful progress and cautious analysis, together we can aim for new heights in our mission statement.





Clinical Research Malaysia

Clinical Research Malaysia (CRM) is a Global Trusted Research Management Organisation established by the Ministry of Health Malaysia in 2012. The organisation is guided by the principles of Humanity, Stability and Sustainability in providing global clinical trial solutions and enabling a thriving clinical research ecosystem in the country. At its very core, CRM aims to bring clinical research that addresses the unmet needs of patients and transforms health outcomes in Malaysia.

CRM delivers sponsored clinical trials with Speed, Reliability and Quality through operational excellence and working with stakeholders by providing end-to-end clinical research support services. Certified with both ISO 9001:2015 (Quality Management System) and ISO 37001:2016 (Anti-Bribery Management System), and being aligned to international regulations, our core values and code of conduct are ingrained throughout CRM. The strength of this organisation lies in the people of CRM as we strive in our vision to make Malaysia the preferred clinical research hub in Asia.



SESSION 1

Clinical trials in new era : trends and emerging technologies

Part I | Streamlined Clinical Trials

MODERATOR



Wen-Chang Chang

Academician of Academia Sinica &
Chair Professor,
Graduate Institute of Medical Sciences,
Taipei Medical University

MODERATOR



Akhmal Yusof

Chief Executive Officer,
Clinical Research Malaysia

Keynote

Streamlined academic renal trials : trends and key success

1. Streamlined Academic Trials & EASi-KIDNEY

by Mai-Szu Wu President, Taipei Medical University

2. Streamlined academic renal trials : An EMPA-KIDNEY case study

by Lai Seong Hooi Consultant Nephrologist & Editor, Malaysian Dialysis and Transplant Registry

Mai-Szu Wu

President
Taipei Medical University

Streamlined Academic Trials & EASi-KIDNEY

This session will delve into the transformative impact of streamlined clinical trials, comparing them to traditional methodologies. Streamlined trials are recognized for their efficiency, flexibility, and enhanced patient experience, marking a significant advancement in clinical research.

The session will begin with an overview of streamlined clinical trials, highlighting their advantages over traditional approaches. Streamlined trials reduce administrative burdens, accelerate timelines, and often yield higher-quality data, ultimately improving patient outcomes.

A key component of this session is a comprehensive case study on EMPA-KIDNEY, an independent topic showcasing its strengths and implications. EMPA-KIDNEY has set a benchmark in clinical research by demonstrating the effectiveness of streamlined trials in producing robust, actionable results.

Following this, the session will introduce EASi-KIDNEY, a follow-up trial inspired by the findings from EMPA-KIDNEY. With an ambitious target of enrolling over 10,000 participants worldwide, EASi-KIDNEY represents a significant leap in the scale and scope of clinical trials. The discussion will cover the project's implementation design, emphasizing its innovative approaches and logistical challenges.

The session will also spotlight the rollout of EASi-KIDNEY in Taiwan, coordinated by Taipei Medical University. This section will provide insights into the university's strategic role in facilitating the trial, underscoring its capabilities in conducting large-scale, high-quality clinical research.

Furthermore, the session will reflect on the strengths and capabilities required for organizations to deliver superior clinical research. It will highlight Taipei Medical University's commitment to developing comprehensive and rapid health solutions, reinforcing its position as a leader in clinical research innovation.



- Renal Cellular Physiology and Biology
- Fluid and Electrolytes disorders
- Clinical Nephrology
- Renal Replacement Therapy
- Epidemiology

Wu, a graduate of TMU School of Medicine, returned to his alma mater in 2012. Since then, he has held various managerial roles, including Vice Dean of the College of Medicine, Vice President of TMU, and Superintendent of TMU Shuang Ho Hospital. Currently, he serves as President of the Taiwan Society of Nephrology and Chairman of the Taiwan Kidney Foundation.

Trained at INSERM, Wu established a nephrology lab and has led several important clinical trials across Taiwan, significantly contributing to improving the treatment of chronic kidney disease. He initiated a translational lab at TMUH, emphasizing doctor-patient relationships and leveraging resources from TMU's affiliated hospitals.

With extensive experience in clinical trials and healthcare management, Wu aims to elevate TMU to a premier international medical university by prioritizing value-based healthcare, digital transformation, a talent-friendly campus, and sustainable development. He envisions TMU as a key player in shaping Taiwan's medical future.



Lai Seong Hooi

Consultant Nephrologist, Johor Baru,
Editor, Malaysian Dialysis and Transplant Registry

hooilaiseong@gmail.com

- Nephrology

Dr Lai Seong Hooi completed her undergraduate degree at the University of Cambridge, UK in 1982.

She practised nephrology and medicine at Sultanah Aminah Hospital, Johor Bahru for 34 years, becoming Head of Department of Medicine and National Head of Nephrology Service for the Ministry of Health, Malaysia. She retired in 2018.

She was the President of the Malaysian Society of Nephrology 2004 - 2006. She had coordinated many multinational trials in Malaysia including SHARP (2002), FAVOURED (2008), IMPROVE-CKD (2015), TESTING (2017), EMPA-KIDNEY (2018), ACHIEVE (2018), VALID (2019), and EASI-KIDNEY (2023).

Within Malaysia she had taken part in three CAPD RCTs, an MMF RCT for lupus nephritis, 2 cost-effectiveness studies on dialysis and 2 population studies on the prevalence of CKD.

She has more than 70 publications. She is on the editorial board of Transplantation Proceedings (from 2023) and is the editor of the Malaysian Dialysis and Transplant Registry (since 2022).

Streamlined academic renal trials: An EMPA-KIDNEY case study

Clinical trials are now excessively costly and burdensome with Contract Research Organization costs rising exponentially. This is a major threat to high quality clinical care and public health. The streamlined academic model of clinical trial design is a solution to the current crisis in trials.

EMPA-KIDNEY is a streamlined international trial: extra work for collaborating doctors and hospitals was kept to a minimum, and only essential information was collected. Participant reported information was recorded by participant interview directly into bespoke computer systems (web-based system called Livia), and centrally measured creatinine were the main means of data collection. Primary source was participant interview. Verification with medical records was focused on important outcomes e.g., safety outcomes, or key outcome with complex diagnosis.

In a streamlined trial there is generalizable wide inclusion criteria and minimal exclusion criteria. There are dedicated large centres with lower number of sites enrolling high number of participants per site. Visit procedures are short and simple. On-site monitoring is focused and infrequent, supplemented by risk-based central statistical processes. Streamlining facilitates complete and high-quality follow-up and helps maintain adherence.

EMPA-KIDNEY trial had a double-blind placebo-controlled design. It assessed the effects of SGLT2 inhibition in a broad range of ~6000 patients with chronic kidney disease at risk of progression. The intervention was Empagliflozin 10 mg/day vs placebo.

A total of 6609 patients from 8 countries underwent randomization. During a median of 2.0 years of follow-up, progression of kidney disease or death from cardiovascular causes occurred in 432 of 3304 patients (13.1%) in the empagliflozin group and in 558 of 3305 patients (16.9%) in the placebo group (hazard ratio, 0.72; 95% confidence interval [CI], 0.64 to 0.82; P<0.001).

Most recent publications

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Lv J, Wong MG, Hladunewich MA, Jha V, Hooi LS, et al, TESTING Study Group. Effect of oral methylprednisolone on decline in kidney function or kidney failure in patients With IgA nephropathy: The TESTING Randomized Clinical Trial. JAMA. 2022 May 17;327(19):1888-1898.

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SESSION 1

Clinical trials in new era : trends and emerging technologies

Part II | Data Technology and Clinical Validation

MODERATOR



Min-Huei Hsu

Dean,
Office of Data Science,
Taipei Medical University

MODERATOR



Zu-Hao Chang

Director,
Graduate Institute of
Biomedical Informatics,
Taipei Medical University

Topic

- **The New Era of AI in Clinical Research**
by Yu Chuan Jack Li Distinguished Professor, Graduate Institute of Medical Informatics, Taipei Medical University
- **Supporting and Validating Clinical Trials through Global RWD/RWE Collaboration with OHDSI**
by Jason C. Hsu Associate Professor, International Ph.D. Program in Biotech and Healthcare

Yu Chuan Jack Li

Distinguished Professor, Graduate Institute of Medical Informatics, Taipei Medical University
 Dermatologist, Taipei Medical University, Wan Fang Hospital
 Chief, International Center for Health Information Technology, College of Medical Science, Taipei Medical University
 Vice Director and CEO, TMU Research Center for Artificial Intelligence in Medicine
 Editor-in-Chief, BMJ Health & Care Informatics Journal

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The New Era of AI in Clinical Research

In the AI era, clinical trials are transforming through "Technology to Trial," where cutting-edge technologies streamline processes and enhance accuracy. Before a new technology can be applied in clinical practice, it must undergo systematic testing and evaluation to determine its effectiveness, safety, and feasibility in the medical field. Such trials may involve medical devices, software, diagnostic tools, and treatment methods. Not only technology vendors but hospitals and universities also play pivotal roles in this ecosystem. Effective interdisciplinary communication and collaboration are critical. Through clinical trials, the performance of the technology in real-world clinical settings can be assessed, providing support and evidence for its future widespread application.

In this session, Professor Yu-Chuan Li will share the clinical trial experience of the innovative cancer immunotherapy AI tool, Medigator. This case demonstrates how synergy accelerates innovation, ensuring safe and effective treatments reach patients faster.

Most recent publications

1. Lee L, Yang H, Nguyen P, Muhtar M, Li Y, Machine Learning Approaches for Predicting Psoriatic Arthritis Risk Using Electronic Medical Records: Population-Based Study, *J Med Internet Res* 2023;25:e39972.
2. Usman Iqbal, Leon Tsung-Ju Lee, Annisa Ristya Rahmanti, Leo Anthony Celi, Yu-Chuan Jack Li, Can large language models provide secondary reliable opinion on treatment options for dermatological diseases?, *Journal of the American Medical Informatics Association*, 2024;, ocae067.
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4. Chih-Wei Huang, Bethany C.Y. Wu, Phung Anh Nguyen, Hsiao-Han Wang, Chih-Chung Kao, Pei-Chen Lee, Annisa Ristya Rahmanti, Jason C. Hsu, Hsuan-Chia Yang, Yu-Chuan Jack Li, Emotion recognition in doctor-patient interactions from real-world clinical video database: Initial development of artificial empathy, *Computer Methods and Programs in Biomedicine*, Vol 233, 2023, 107480, ISSN 0169-2607.
5. Uddin M, Dhanta R, Pitti T, Barsasella D, Scholl J, Jian W-S, Li Y-C, Hsu M-H, Syed-Abdul S. Incidence and Mortality of Malignant Brain Tumors after 20 Years of Mobile Use. *Cancers*. 2023; 15(13):3492.



- AI in Medicine
- Translational Biomedical Informatics
- Dermatology

Yu-Chuan Jack Li is a leading expert in AI in medicine and translational biomedical informatics, ranked in the top 2% of scientists worldwide. He has been actively involved in international collaborations and has led numerous national projects focused on advancing the use of AI in disease prevention, patient safety, and "earlier medicine".

Li's research on temporal phenomic stochastic models has evolved into the largest model ever constructed based on medical data elements.

He has been recognized for his outstanding achievements with fellowships in the Australian College of Health Informatics, the American College of Medical Informatics, and the International Academy of Health Science Informatics.

He has also received numerous awards for his remarkable contributions.

Jason C. Hsu

Associate Professor
International Ph.D. Program in Biotech and Healthcare Management
Taipei Medical University

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Supporting and Validating Clinical Trials through Global RWD/RWE Collaboration with OHDSI

In this talk, we will delve into the pivotal role that the Observational Health Data Sciences and Informatics (OHDSI) initiative plays in supporting and validating drug clinical trials through global real-world data (RWD) and real-world evidence (RWE) collaboration. We will discuss how OHDSI's extensive international network and robust data integration methodologies can enhance the reliability of clinical trial outcomes, improve patient safety, and expedite the drug development process. Key topics will include the strategies for incorporating RWD/RWE into clinical trials, successful case studies of OHDSI-facilitated global collaborations, and the future prospects of these approaches in advancing precision medicine. Attendees will gain valuable insights into the challenges and opportunities associated with global RWD/RWE initiatives through OHDSI and how they can be effectively leveraged to transform clinical research and healthcare delivery.

Most recent publications

1. Nguyen, P.A.; Hsu, M.H.; Chang, T.H.; Yang, H.C.E.; Huang, C.W.; Liao, C.T.; Lu, C.Y.; Hsu, Jason C.* (2024), "Taipei Medical University Clinical Research Database (TMUCRD) - A Collaborative Hospital EHR Database Aligned with International Common Data Standards", *BMJ Health & Care Informatics*
2. You, S.C.; Seo, S.I.; Falconer, T.; Yanover, C.; Duarte-Salles, T.; Seager, S.; Posada, J.D.; Shah, N.H.; Nguyen, P.A.; Kim, Y.; Hsu, J.C.; Zandt, M.V.; Hsu, M.H.; Lee, H.L.; Ko, H.; Shin, W.G.; Pratt, N.; Park, R.W.; Reich, C.G.; Suchard, M.M.; Hripcsak, G.; Park, C.H.; Prieto-Alhambra, D. (2023) "Ranitidine use and incident cancer in a multinational cohort", *JAMA Network Open*, 2023 Sep 5;6(9):e2333495
3. Lu, Y.*; Zandt, M.V.; Liu, Y.; Li, J.; Wang, X.; Chen, Y.; Chen, Z.; Cho, J.; Dorajoo, S.R.; Feng, M.; Hsu, M.H.; Hsu, J.C.; Iqbal, U.; Jonnagaddala, J.; Li, Y.C.; Liaw, S.T.; Lim, H.S.; Ngiam, K.Y.; Nguyen, P.A.; Park, R.W.; Pratt, N.; Reich, C.; Rhee, S.Y.; Sathappan, S.M.K.; Shin, S.J.; Tan, H.X.; You, S.C.; Zhang, X.; Krumholz, H.M.; Suchard, M.A.; Xu, H. (2022) "Analysis of Dual Combination Therapies Used in Treatment of Hypertension in a Multinational Cohort", *JAMA Network Open*, 5(3):e223877
4. Chen, S.M.; Phuc, P.T.; Nguyen, P.A.; Lin, S.J.; Lin, W.C.; Lu, C.Y.; Hsu, M.H.; Cheng, C.T.; Hsu, J.C.* (2023) "A novel prediction model of the risk of pancreatic cancer among diabetes patients using multiple clinical data and machine learning", *Cancer Medicine*
5. Quynh, N.T.N.; Wang, C.J.; Nguyen, P.A.; Phuc, P.T.; Lin, R.K.; Hung, C.S.; Kuo, N.H.; Cheng, Y.W.; Cheng, C.T.; Hsu, M.H.*; Hsu, J.C.* (2023) "Machine Learning and Deep Learning Approaches for Predicting 5-year Survival of Patients with Breast Cancer", *Cancer Science*
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- RWD / RWE

Jason C. Hsu PhD is an expert in real-world data (RWD) and real-world evidence (RWE) in the field of medicine.

He is currently an Associate Professor in the International Ph.D. Program in Biomedical and Healthcare Management at the College of Management, Taipei Medical University.

He also holds several key data-related leadership positions, including Director of the Clinical Data Center, Director of the Research Center of Health Care Industry Data Science at the College of Management, Director of the Clinical Big Data Research Center at Taipei Medical University Hospital, and Taiwan Chapter Leader of the Observational Health Data Sciences and Informatics (OHDSI).

He received training at Harvard Medical School (HMS) and has led numerous large-scale RWD/RWE projects.

Dr. Hsu aims to enhance the quality of digital medicine, precision medicine, and biomedical healthcare management through global data collaboration.

SESSION 1

Clinical trials in new era : trends and emerging technologies

Part III | Trends and New Technology in Cell Therapy

MODERATOR



Long-Sheng Lu

Associate Director,
Center of Cancer Translational Medicine,
Taipei Medical University

MODERATOR



Yi-Fang Chang

Vice Superintendent,
Taitung MacKay Memorial Hospital

Topic

- **Clinical Trial of Adaptive Cell Therapy**
by Sung Yong Oh Professor, Department of Internal Medicine, Dong-A University Hospital
- **Next-generation Cell-based Immunotherapy via Antibody Cell Conjugation**
by Sonny Hsiao CEO/CSO, President and Co-Founder of Acepodia

Sung Yong Oh

Professor
Hematology-Oncology, Department of Internal Medicine
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Clinical trial of adaptive cell therapy

Adaptive cell therapy is a type of immunotherapy that involves modifying a patient's own immune cells to better recognize and attack cancer cells or other harmful cells in the body. Conducting a clinical trial of adaptive cell therapy involves several key steps to ensure the safety of participants, gather reliable data, and comply with regulatory requirements.

Trial Design : The trial protocol is developed, outlining the objectives, eligibility criteria, treatment regimen, endpoints, and study procedures. The protocol must be approved by regulatory authorities and an institutional review board (IRB) or ethics committee.

Obtaining Regulatory Approval : Investigators must obtain approval from regulatory agencies such as the FDA (in the United States) or EMA (in Europe) before initiating the clinical trial.

Treatment Administration : Participants receive the adaptive cell therapy according to the treatment regimen specified in the protocol. This may involve apheresis to collect immune cells from the patient, genetic modification of the cells in a laboratory setting, and subsequent infusion of the modified cells back into the patient.

Monitoring and Data Collection : Throughout the trial, participants are closely monitored for safety and efficacy outcomes. Data on adverse events, treatment responses, and other relevant parameters are collected and documented according to the trial protocol.

Data Analysis : Statistical methods are used to evaluate treatment outcomes and compare them to predefined endpoints.

Throughout the entire process, adherence to ethical principles, patient safety, and regulatory requirements is paramount. Close collaboration between researchers, clinicians, regulatory agencies, and participants is essential for the successful conduct of a clinical trial of adaptive cell therapy.

Most recent publications

Zhang Y, Patel RP, Kim KH, Cho H, Jo JC, Jeong SH, Oh SY, Choi YS, Kim SH, Lee JH, Angelos M, Guruprasad P, Cohen I, Uguwanyi O, Lee YG, Pajarillo R, Cho JH, Carturan A, Paruzzo L, Ghilardi G, Wang M, Kim S, Kim SM, Lee HJ, Park JH, Cui L, Lee TB, Hwang IS, Lee YH, Lee YJ, Porazzi P, Liu D, Lee Y, Kim JH, Lee JS, Yoon DH, Chung J, Ruella M. *Mol Cancer*. 2023 Dec 9;22(1):200. doi: 10.1186/s12943-023-01886-9.

Comparison of first-line treatment with CHOP versus ICED in patients with peripheral T-cell lymphoma eligible for upfront autologous stem cell transplantation.

Kim SJ, Jo JC, Yoon DH, Yang DH, Yoon SE, Lee GW, Kong JH, Park Y, Kang KW, Lee HS, Oh SY, Shin HJ, Lee WS, Choi YS, Jeong SH, Kim MK, Kang HJ, Yi JH, Lim SN, Yhim HY, Do YR, Yun HJ, Eom HS, Lee MH, Suh C, Kim WS. *Front Oncol*. 2023 Aug 22;13:1230629. doi: 10.3389/fonc.2023.1230629.

A Multicenter, Prospective, Observational Study to Evaluate Ethanol-Induced Symptoms in Patients Receiving Docetaxel Chemotherapy.

Won YW, Kang JH, Kwon JH, Koo DH, Kang JH, Maeng CH, Ahn HK, Oh SY, Lee DW, Sohn J, Oh SY, Lee KH, Koh SJ, Lee KS, Kim CK, Kim JY, Ji JH, Kim SB, Ha JY, Kim HY.

Cancer Res Treat. 2023 Oct;55(4):1096-1103. doi: 10.4143/crt.2022.1565.

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Kim DJ, Jeong S, Kong SG, Lee S, Lim SN, Oh SY, Do YR, Lee WS, Lee MH, Bae SH, Kim SH, Kim MK, Lee HS; Consortium for Improving Survival of Lymphoma (CSL).

Sci Rep. 2023 Feb 13;13(1):2551. doi: 10.1038/s41598-023-27465-y.

Outcomes in Refractory Diffuse Large B-Cell Lymphoma: Results from Two Prospective Korean Cohorts.

Yi JH, Jeong SH, Kim SJ, Yoon DH, Kang HJ, Koh Y, Kim JS, Lee WS, Yang DH, Do YR, Kim MK, Yoo KH, Choi YS, Yun WJ, Park Y, Jo JC, Eom HS, Kwak JY, Shin HJ, Park BB, Yi SY, Kwon JH, Oh SY, Kim HJ, Sohn BS, Won JH, Hong DS, Lee HS, Lee GW, Suh C, Kim WS.

Cancer Res Treat. 2023 Jan;55(1):325-333. doi: 10.4143/crt.2022.008. Epub 2022 Apr 22.

- Clinical trial
- Regenerative Medicine
- Palliative Care

Dr. Oh is a distinguished clinician with extensive expertise in hematology and oncology. Currently serving as a Professor in the Department of Hematology/Oncology at Dong-A University Medical Center since March 2020, Dr. Oh has been instrumental in advancing research and patient care in the field.

He holds a PhD degree from Dong-A University Graduate School, earned between March 2006 and February 2008, following a Master's degree obtained from the same institution between March 2004 and February 2006.

Dr. Oh also serves as the Director of Dong-A University Hospital Clinical Trial Center since August 2019 and holds the esteemed position of Principal of the Busan, Ulsan, and Gyeongnam Regional Society of Medical Oncology since March 2022.

With a wealth of experience and dedication to his profession, Dr. Oh continues to make significant contributions to the medical community.

Sonny Hsiao

CEO/CSO
President and Co-Founder of Acepodia

sonny@acepodia.bio.com



- Oncology
- Immunology
- Cell Biology
- Bioorthogonal Chemistry

Dr. Sonny Hsiao, CEO, President, and Co-Founder of Acepodia, was awarded the Dr. Y-T Lee Prize for his achievements in Chemistry.

He has extensive experience in immune cell therapy development, leading to the creation of Acepodia's novel ACC platform, based on Nobel Laureate Professor Carolyn Bertozzi's work in biorthogonal chemistry.

Dr. Hsiao worked on this pioneering research while earning his Ph.D. at UC Berkeley.

He holds a B.S. in Chemistry from National Taiwan University and a Ph.D. in Chemistry and Molecular Cell Biology from UC Berkeley.

Next-generation Cell-based Immunotherapy via Antibody Cell Conjugation

Antibody-Cell Conjugation (ACC), is inherited from the bioorthogonal chemistry invented by Nobel Laureate Dr. Carolyn Bertozzi in Chemistry, which conjugates the effector cells with targeting moiety including antibodies. $\gamma\delta 2$ T cells, Acepodia's proprietary cell composition, are a subpopulation of T cells with innate and adaptive phenotypes expanded from PBMC of healthy donors. When combining the ACC platform with $\gamma\delta 2$ T cells, two allogeneic cell therapy pipelines at clinical stage have been developed.

The first one is ACE1831 (CD20 mAb-conjugated $\gamma\delta 2$ T cells) targeting non-Hodgkin's lymphoma, and the other is ACE2016 (EGFR mab-conjugated $\gamma\delta 2$ T cells) for EGFR-expressing solid tumor treatment. Without genetic engineering, antibody-conjugated $\gamma\delta 2$ T cells elicit antigen-specific cytotoxicity and cause no risk of CRS, ICANS, and potential secondary T cell malignancy compared to CAR-T cell therapy. Furthermore, the cost-effective manufacturing process and off-the-shelf application enhance the accessibility of the antibody-conjugated $\gamma\delta 2$ T cell products. These features are expected to bring a paradigm shift in the landscape of cell therapy.

Most recent publications

1. Li, H.-K.; Wu, T.-S.; Kuo, Y.-C.; Hsiao, C.-W.; Yang, H.-P.; Lee, C.-Y.; Leng, P.-J.; Chiang, Y.-J.; Cheng, Z.-F.; Yang, S.-H.; et al. "A Novel Allogeneic Rituximab-Conjugated Gamma Delta T Cell Therapy for the Treatment of Relapsed/Refractory B-Cell Lymphoma" *Cancers* 2023, 15, 4844.
2. Li, H.-K.; Hsiao, C.-W.; Yang, S.-H.; Yang, H.-P.; Wu, T.-S.; Lee, C.-Y.; Lin, Y.-L.; Pan, J.; Cheng, Z.-F.; Lai, Y.-D.; Hsiao, S.-C.; Tang, S.-W. "A Novel off-the-Shelf Trastuzumab-Armed NK Cell Therapy (ACE1702) Using Antibody-Cell-Conjugation Technology" *Cancers*. 2021, 13, 2724.
3. Cheng, Z.F.; Li, H.K.; Yang, H.P.; Lee, C.Y.; Tang, S.W.; Lin, Y.L.; Hsiao, S.C., "A Novel Endogenous CD16-Expressing Natural Killer Cell for Cancer Immunotherapy" *Biochemistry and Biophysics Reports*. 2021, 26, 100935.

SESSION 1

Clinical trials in new era : trends and emerging technologies

Part IV | Future of Decentralised Clinical Trials

MODERATOR



Teh-Ying Chou

Professor,
Graduate Institute of Clinical Medicine

MODERATOR



Chien-Tai Hong

Director,
Department of Medical Research,
Taipei Medical University
Shuang Ho Hospital

Topic

- **Embracing the Future : Preparing Sites for Decentralized Clinical Trials (DCT) Innovation**
by Sung Yong Oh Professor, Department of Internal Medicine, Dong-A University Hospital
- **Activities to Promote DCTs in Japan**
by Mariko Kawakami Pharmacist, ARO HQ Office, Chiba University Hospital Clinical Research Center
- **Local Care Model - Patient Centric Approach in Malaysia**
by Nor Hafiza Johari Clinical Operations Manager, Clinical Research Malaysia
- **Practical Implementation of Decentralized Clinical Trials in Japan and Prospects in Asia**
*by Shinsuke Muto President, DCT Japan Co. and Tetsuyu Institute Healthcare Corporation
Chairman, IntegrityHealthcare Co., Ltd.*

Mandy Yang

Associate Director
Global Country Operation, Site and Patient Solution
Syneos Health

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Embracing the Future : Preparing Sites for Decentralized Clinical Trials (DCT) Innovation

The landscape of clinical trials is evolving with the advent of Decentralized Clinical Trials (DCT), offering innovative solutions to enhance efficiency, patient engagement, and data collection. This topic provides an in-depth exploration of DCT, beginning with its definition and fundamental concepts. Attendees will gain insights into Syneos Health's DCT and Patient Solutions, showcasing our extensive experience and the dynamic assembly methodology that ensures bespoke solutions tailored to specific trial needs.

Further, we delve into practical applications with two case studies from Japan, highlighting pioneering site innovations in DCT implementation. The first case study focuses on the Satellite Site model, illustrating how it increases participant recruitment and improves access while maintaining trial integrity. The second case study examines the Tokyo Center Clinic's unique mobile solution, where customized vans equipped with necessary medical tools facilitate patient interactions without compromising care quality.

This session aims to equip site staff and clinical trial professionals with actionable strategies and insights to effectively prepare for and execute DCTs, ensuring readiness for future trials in a decentralized model.

Mandy Yang is a seasoned professional with over 15 years of experience in the clinical trial industry.

She currently serves as the Country Head of the Clinical Operations team at Syneos Health.

Throughout her extensive career, Mandy has held various roles, including Clinical Research Associate, Clinical Lead, and People Manager, showcasing her comprehensive expertise and leadership capabilities.

She leads the Taiwan team in conducting global trials across various therapeutic areas, providing her with diverse and extensive experience through collaborations with different sponsors and studies.

Prior to joining the clinical trial industry, Mandy worked in hospital for several years, gaining invaluable clinical and patient care experience.

Her deep understanding of both clinical practice and trial operations drives her commitment to ensuring that Taiwan keeps pace with global clinical trial innovations, including the trend towards decentralized clinical trials (DCTs).

Mariko Kawakami

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Chiba University Hospital Clinical Research Center

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Activities to promote DCTs in Japan

The spread of Coronavirus disease has reaffirmed the importance of developing and producing vaccines in our own country. Therefore, the Japanese government is encouraging medical institutions to establish hospital networks and promote DCTs to prepare for the next pandemic. The number of DCTs are increasing in pharmaceutical company clinical trials, although there are still few DCTs conducted in investigator-initiated clinical trials.

To overcome this situation, Chiba University is participating in a project led by the Core Clinical Research Hospitals to promote DCTs. Core Clinical Research Hospitals are hospitals which play a central role in developing innovative drug and medical technology through international-level clinical trials, and Chiba University has been designated as these hospitals since 2017. This project led by the Core Clinical Research Hospitals has established seven working groups to promote DCTs. Each working group is working on the following issues: WG1: Creating mock PRT and IC documents for DCT simulation, WG2: Developing of the eWorksheet system, WG3: Examination of ePRO and eConsent systems that can be utilized in DCT, WG4: Simulation of online medical examination and clinical trial operation using satellite facilities, WG5: Preparation and training for DCT, WG6: Simulation of drug delivery, WG7: Consider the IRB issues in DCT. To promote this project throughout Japan, a similar simulation of DCTs is operated, such as the project by the University Hospital Clinical Trial Alliance.

Today, I would like to introduce these projects and discuss how we should promote DCTs in investigator-initiated clinical research.

- Clinical Pharmacology

Ms. Mariko Kawakami has graduated from Tokyo University of Pharmacy and Life Sciences and became a pharmacist.

After her graduation, she joined the Chiba University Hospital Clinical Research Center in 2021.

She was first in charge of working with the Institutional Review Board and was mainly involved in the review of research involving genome analysis.

From 2023, she started her career as a study manager for investigator-initiated registry trial.

Nor Hafiza Johari

Clinical Operations Manager
Clinical Operations
Clinical Research Malaysia

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Local Care Model - Patient Centric Approach in Malaysia

Decentralised Clinical Trials (DCTs) have been an emerging trend in clinical research, with many sponsors and investigators adopting DCT trial design when conducting studies. Different terms are used to define DCT, including virtual, remote, site-less, home-based, but the unifying concept is that DCTs move away from the conventional Clinical Trial Site, and adopts tools/technologies to facilitate the conduct of trial activities outside the Clinical Trial Site.

The Local Care Model (LCM) is an innovative DCT model that offers participants an opportunity to have certain clinical trial assessments performed at a nearby healthcare facility i.e. a Health Clinic instead of the Clinical Trial Site. It is designed to deliver alternative models for conducting clinical trials with the objective of increasing operational agility, enabling greater access to clinical trials, improving participant diversity, and enhancing recruitment and retention. This model has recently been implemented in Malaysia, leveraging on the existing, well-established network of government Health Clinics with robust infrastructure.

Most recent publications

1. CRM Study Coordinators - Making a Difference in Clinical Trial Conduct in Malaysia, 24 Journal for Clinical Studies Volume 15 Issue 1
2. Patient Perspective on Factors Contributing to Nonadherence to Dietary Therapy: A Qualitative Study in Multicultural Population of Kedah, Malaysia, 2019 Jul;39(4):217-223. Epub 2018 Dec 26.

Nor Hafiza Johari graduated from the University of Putra Malaysia with a Bachelor of Science (Hons) in Biology.

She started her career as a full-time study coordinator, managing trials in various therapeutic areas. Currently, she is the Clinical Operations Manager at Clinical Research Malaysia (CRM).

For the past 12 years, she has engaged with different sponsors, CROs, investigators, and trial sites to assist in the conduct of trials.

She also provides leadership to her direct reports, ensuring the smooth running of operations while maintaining compliance with relevant industry regulations and internal policies, thereby achieving the company's objectives.

Shinsuke Muto

President, DCT Japan Co., Ltd.
 Chairman, Integrity Healthcare Co., Ltd.
 President, Tetsuyu Institute Healthcare Corporation

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Practical implementation of decentralized clinical trials in Japan and prospects in Asia

Decentralized Clinical Trial, or DCT, a new way of conducting clinical trials designed to maximize patient enrolment and minimize patient dropout mid-trial, was originally developed and has become popular at an unprecedented rate in the U.S. and Europe and was expected to follow the same path in Japan.

However, according to a report published in February 2023 by a task force team consisting of members of the National University Hospital Clinical Research Advancement Conference, only 3 out of 44 national university hospitals surveyed have completed preparations for home nursing and telemedicine in DCTs (less than 1%), due to a lack of guidelines and instructions from relevant authorities and delays in infrastructure reforms within their organizations.

As for Japanese pharma companies, only 11% had implemented DCTs as of August 2022, according to a survey conducted by the Japan Pharmaceutical Manufacturers Association, and so far, they have taken a cautious approach rather than jumping on the bandwagon of a flurry of DCTs overseas.

Despite the myriad difficulties faced by academia and pharma in Japan in ushering in the faster, nationwide dawn of the DCT era, DCT Japan has already conducted hundreds of home visits by its qualified nurses, provided telemedicine, and created so-called satellite medical institutions network in several DCTs, thanks to the unparalleled expertise both individually and collectively developed in DCT and a vast network of global DCT clients around the world.

With the recent increase in demand for DCTs in Taiwan and other Asian regions from global customers, DCT Japan is keen to contribute its experience and expertise to the development of localized and culturally appropriate DCTs in Taiwan and Asia as a whole.

Most recent publications

1. Wakimizu, R., Kuroki, H., Ohbayashi, K., Ohashi, H., Yamaoka, K., Sonoda, A., & Muto, S. (2021). Perceptions and attitudes toward telemedicine by clinicians and patients in Japan during the COVID-19 pandemic. *Telemedicine Reports*, 2(1), 197-204. Mary Ann Liebert, Inc., publishers.
2. Furukawa, H., Takeuchi, T., Yano, E., & Muto, S. (2015). Factors influencing psychological distress after the Great East Japan Earthquake and Tsunami. *Journal of Community Psychology*, 43(5), 521-526.
3. Matsumoto, S., Yamaoka, K., Inoue, M., Inoue, M., Muto, S., & Teikyo Ishinomaki Research Group. (2015). Implications for social support on prolonged sleep difficulties among a disaster-affected population: second report from a cross-sectional survey in Ishinomaki, Japan. *PLoS One*, 10(6), e0130615. Public Library of Science.
4. Inoue, M., Matsumoto, S., Yamaoka, K., & Muto, S. (2014). Risk of social isolation among Great East Japan Earthquake survivors living in tsunami-affected Ishinomaki, Japan. *Disaster Medicine and Public Health Preparedness*, 8(4), 333-340. Cambridge University Press.
5. Senda, M., Muto, S., Horikoshi, M., & Senda, T. (2008). Effect of leucine-to-methionine substitutions on the diffraction quality of histone chaperone SET/TAF-1 β /INHAT crystals. *Acta Crystallographica Section F: Structural Biology and Crystallization Communications*, 64(10), 960-965. International Union of Crystallography.

- Digital transformation
- Data management
- Patient-center healthcare delivery

Dr. Muto worked as a cardiologist at the University of Tokyo Hospital, and later served on the medical team of Their Majesties the Emperor and Empress of Japan, and then joined McKinsey & Company.

He founded Tetsuyu Institute Medical Corporation in 2010 and became Chairman of Integrity Healthcare in 2016 and is clinical professor at Tokyo Medical and Dental University. Additionally, DCT Japan was founded in 2022 as a subsidiary of Integrity Healthcare.

He has held many key government positions, including advisor to the Ministry of Health, Labour and Welfare on medical information systems policy, and recently was appointed a member of Regulatory Reform Committee of Japan Association of Corporate Executives.

Education

- The University of Tokyo, School of Medicine (MD)
- The University of Tokyo, Graduate School of Medicine (Ph.D.)
- INSEAD (Executive MBA)
- Johns Hopkins (MPH, MSc)

SESSION 1

Clinical trials in new era : trends and emerging technologies

Part V | Sharing from Clinical Research Centers in Taiwan

MODERATOR



Shian-Ying Sung

Professor,
Graduate Institute of
Biomedical Informatics,
Taipei Medical University

MODERATOR



Hideki Hanaoka

Head of Clinical Research Center,
Chiba University Hospital

Topic

- **Sharing from Clinical Research Centers in Taiwan**
*by Chun-Jen Liu Director of the Hepatitis Research Center and Clinical Trial Center,
National Taiwan University Hospital*
- **Embedding information technology to benefit clinical trial implementation :
the TMU experience**
by Chun-Jen Huang Dean, Office of Human Research, Taipei Medical University

Chun-Jen Liu

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 Director, Hepatitis Research Center
 National Taiwan University Hospital

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Sharing from Clinical Research Centers in Taiwan

Clinical Trial Center of National Taiwan University Hospital was established in 2001. Since 2005, the Clinical Trial Center has participated in the National Clinical Trial and Research Excellence Program of the Ministry of Health and Welfare of Taiwan for many years, and has gradually built a link the international biotechnology and pharmaceutical industry through the five-phase national plan. Now the CTC NTUH has become an important clinical trial research center in the Asia-Pacific region. In 2023, we successfully applied for the sixth phase of the Ministry of Health and Welfare's subsidy program, "113-116 Clinical Trial Novel Excellence Program", with a total of 5 CTC clinical trial teams and 7 TCTC clinical trial teams.

Over the past 20 years, the Center has been actively linking the industry-academia community of clinical trial research in Taiwan and around the world, committed to the development of translational medicine in Taiwan, enhancing the strength of biomedical science and technology, and introducing new clinical treatment technologies to bring treatment vitality to patients. At present, it has cooperated with eight international pharmaceutical companies in the research and development of clinical trials of new drugs, vaccines and medical devices, and has cooperated with various international pharmaceutical companies to design and execute clinical trials with the quality of international first-class clinical trials. In 2022, CTC NTUH was invited to join Merck's Global Prospective Clinical Trial Collaboration Program, and we jointly pledged to continue to improve new drug discovery technologies through forward-looking drug discovery cooperation programs. In addition, Pfizer, the world's largest pharmaceutical company, has designated our hospital as one of its 20 key clinical trial sites around the world. The world's largest CRO company has also chosen the hospital as one of its priority cooperation centers (PRIME sites). Our clinical trial research technology and throughput capacity have been recognized by the world's top clinical trial research industry-academia community, and will begin to evolve from the consistent industry-academia commission model to participate in the world's most important prospective clinical trial research model. By 2023, there are multiple global benchmark prospective clinical trial research alliances in which we are negotiating cooperation.



- Pathogenesis and natural / treatment outcomes of chronic hepatitis B and C
- Dual viral hepatitis B and C
- Dual etiology of liver disease
- SLD and HCC

Chun-Jen LIU is a Professor at the Department of Internal Medicine, National Taiwan University College of Medicine, and Director of the Hepatitis Research Center, Clinical Trial Center, and Division of Gastroenterology & Hepatology, National Taiwan University Hospital, Taipei, Taiwan.

He achieved his MD and PhD at the National Taiwan University.

He won the YZ Hsu Scientific Paper Award in 2020 and research award from National Taiwan University Hospital in 2022.

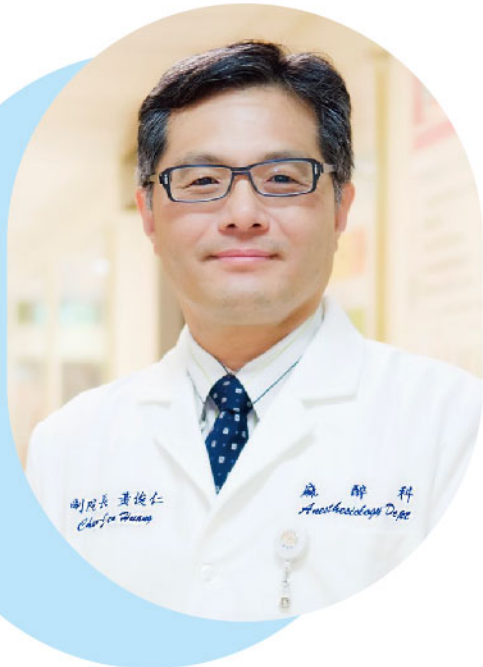
He had been served as the associate editor for Liver International. He is now the associate editor of the Journal of the Formosan Medical Association & JMII.

He has authored 380 papers in international, peer-reviewed journals including Gastroenterology, Hepatology, Gut and Journal of Hepatology.

Chun-Jen Huang

Dean
Office of Human Research
Taipei Medical University

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- Sepsis
- ARDS
- Stem cells
- Exosomes
- Mice

Dr. Huang, an anesthesiologist with over 30 years of experience in health services, holds a Ph.D. in Pharmacology from National Yang-Ming University. He is a distinguished medical researcher with over 150 publications in renowned journals.

Previously, he served as Vice Superintendent for Research at Taipei Municipal Wan Fang Hospital and Vice Dean for Internationalization at TMU College of Medicine. Since May 2019, he has been a professor in the Department of Anesthesiology at Taipei Medical University.

Currently, Dr. Huang serves as the Dean of the Office of Human Research at Taipei Medical University, leveraging his clinical expertise to enhance the implementation and management of clinical study projects.

His extensive background in research, education, and clinical practice underscores his commitment to advancing medical knowledge and improving patient care.

Embedding information technology to benefit clinical trial implementation : the TMU experience

TMU Office of Human Research was established in 2013 as the university's initial attempt to consolidate its resources and expertise to drive the development of clinical trial implementation across all three of its affiliated hospitals. Within 15 years, the TMU Healthcare System has evolved to become one of the largest clinical study organizations in Taiwan, with extensive experience in a full spectrum of therapeutic areas and over 170 new trials conducted on a yearly basis.

As the scope of work expands and the size of the team grows, the need for technology-assisted tools has become apparent in ensuring efficiency and effectiveness in resource allocation, progress monitoring, and project management. This session focuses on the journey of Taipei Medical University and introduces the range of tools and systems implemented to support clinical study teams throughout the project life cycle. These tools aim to create a positive impact on feasibility and scoping exercises, contract and budgeting, submission progress tracking, and potential subject pooling. With the aid of information technology, trial specialists and project management professionals across the TMU Healthcare System can better respond to the fast-changing external environment and focus on the ongoing quest of improved trial quality, enhanced patient experience, and increased health benefit.

SESSION 2

International collaborative trials : opportunities and challenges

MODERATOR



Jiunn-Horng Kang

Dean,
College of Biomedical Engineering,
Taipei Medical University

MODERATOR



Jer-Hwa Chang

Director,
Clinical Research Center,
Taipei Municipal Wanfang Hospital

Topic

- **A Fork in the Road: Hypothesis Testing with a Clinical Strategy Example**
by Lee Farrand CEO, Yuhan Australia& New Zealand
- **Enhancing Innovative and Investigator-Initiated Clinical Trials in Malaysia**
by Sheamini Sivasampu Director, National Institutes of Health, Ministry of Health Malaysia
- **Rethinking Clinical Trials: Patient Reported Outcome Measures**
by Angela Wang, Clinical Professor, Duke-NUS Medical School

Lee Farrand

CEO, Yuhan Australia & New Zealand
Business Development Director, GI Innovation

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- Oncology

Dr Farrand manages operations in Australia and New Zealand for South Korea's largest pharmaceutical company, Yuhan Corporation.

He also supports licensing activities for a rapidly growing Korean bio-venture called GI Innovation.

Communication tips from past experience in establishing new international collaboration for clinical trials

The benefits of ethnic diversity in clinical data are driving an increasing number of sponsors to seek international collaborative partnerships for their early phase trials. However, this often necessitates reaching out to overseas site staff and investigators, who are often complete strangers. Getting the language right in the first email can make all the difference in getting a reply.

This talk will provide some examples of international collaborative clinical trials and examples of effective communication etiquette.

Most recent publications

The HSP90 inhibitor HVH-2930 exhibits potent efficacy against trastuzumab-resistant HER2-positive breast cancer. *Theranostics*. 2024; 14(6): 2442-2463.

Suppression of TNBC metastasis by doxazosin, a novel dual inhibitor of c-MET/EGFR. *Journal of Experimental & Clinical Cancer Research*. Volume 42, article number 292, (2023)

Ebastine impairs metastatic spread in triple-negative breast cancer by targeting focal adhesion kinase. *Cell Mol Life Sci*. 2023 Apr 25;80(5):132

Sheamini Sivasampu

Director

Institute for Clinical Research, National Institutes of Health , Ministry of Health Malaysia

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Enhancing Innovative and Investigator-Initiated Clinical Trials in Malaysia

The inaugural plenary talk, titled " Enhancing Innovative and Investigator-Initiated Clinical Trials in Malaysia," focuses on the significance of Investigator-Initiated Research/Trial (IIR/T) in addressing patient-centred research needs and bridging gaps within the clinical research landscape in Malaysia. IIR/T plays a paramount role in generating relevant and impactful data that benefits the local healthcare system and patient care, exemplified by the initiation of the RAVIDA trial, which led to the treatment of Hepatitis C with Ravidasvir.

Additionally, the talk covers the World Health Organization (WHO) 2022 Resolution, the WHO Global Clinical Trials Forum, and the recommendations from the WHO Western Pacific Region (WPRO) Clinical Trial Workshop co-organised with the Institute for Clinical Research (ICR) in Malaysia in 2024.

Emphasizing the importance of building capacity in clinical research, the talk advocates for the development of high-quality and innovative clinical trials and calls for a collaborative effort among all stakeholders, including researchers, healthcare providers, policymakers, and funding bodies, to foster a unified approach in advancing clinical research. In conclusion, the talk accentuates the collective responsibility in enhancing the clinical trial ecosystem to ultimately improve health outcomes for the nation, setting a forward-looking tone for the conference and encouraging all attendees to contribute actively to the progress of clinical research.



- Healthcare surveys
- Healthcare systems
- Clinical epidemiology
- COVID-19 vaccine surveillance and antimicrobial resistance

Dr Sheamini Sivasampu is a Public Health Physician. She is currently the Director of the Institute for Research Centre (ICR), National Institutes of Health, Ministry of Health (MOH), Malaysia.

ICR is the clinical research arm of MOH and has a network of 37 clinical research centres (CRCs) that are in all major MOH hospitals. Dr Sheamini supervises the investigator initiated clinical trials, Phase 1 clinical trials units, clinical epidemiology, and digital health innovation research for MOH.

She has a wide span of experience and has served in various departments of the Ministry of Health Malaysia (MOH).

Her expertise ranges from synthesising evidence, conducting, and translating research that culminates into evidence-based policymaking.

She was a visiting Scientist in Health System Group Program in the Department of Global Health and Population at the Harvard TH Chan School of Public Health. She is currently the President of the Association of Clinical Research Malaysia.

Angela Wang

Clinical Professor
Duke-NUS Medical School



Professor Angela Wang is currently a Clinical Professor at the SingHealth Duke-NUS Academic Medical Centre and Senior Consultant at Singapore General Hospital.

She has an international reputation for her research in cardiovascular - kidney - metabolic health, chronic kidney disease, and biomarkers for personalized care.

Her latest work focuses on clinical trials and innovations in kidney disease outcomes, including precision and preventive medicine, and she leads several major clinical trials.

Rethinking Clinical Trials : Patient Reported Outcome Measures

The Food and Drug Administration (FDA) defined a patient-reported outcome (PRO) as “any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else.” PROs typically include information about health-related quality of life (HRQOL), symptoms, function, satisfaction with care or symptoms, adherence to prescribed medications or other therapy, and perceived value of treatment. PROs play a significant role as study endpoints in the development and evaluation of new therapies and are used to inform and guide patient-centered care, clinical decision-making, and health policy decisions and is now required by FDA to support claims in medical product labelling. However, there is a mismatch in the number of kidney trials that evaluated PROs or a measure relevant to the assessment of quality of life as a study endpoint in clinical trials.

In the recent years, there is an increasing number of studies evaluating the use of electronic PROs in patients with kidney disease. However, selecting a robust and validated PRO measure (PROM) from the plethora of available measures for patients with kidney disease remains challenging. And not all PROMs are feasible to be used routinely in clinical trials or research.

Additionally, the specific type of PROMs chosen would depend on the research question, outcome of interest, feasibility and clinical validation data. In my talk, I will review some of the PROMs studied in patients with kidney disease, especially in the dialysis patients and also present some examples of clinical trials that utilize PROMs as study endpoints. Broader international multi-stakeholder and healthcare providers engagement and collaborations will be needed to standardize PROMs assessment and maximize the impact of PROMs data in advancing kidney care.

SESSION 2

International collaborative trials : opportunities and challenges

MODERATOR



Chih-Hwa Chen

Vice Superintendent,
Taipei Medical University
Shuang Ho Hospital

MODERATOR



Jaw-Wen Chen

Professor,
Division of Cardiology

Topic

- **Phase 4 Clinical Trial for Cyclosporine A for Kawasaki Disease**
by Tai-Tong Wong Professor, Graduate Institute of Clinical Medicine, Taipei Medical University
- **Evolving Global Clinical Trials Sites Landscape**
by Luis Segovia Sordo Director, Site Alliances APAC & Hong Kong Office
- **Collaborative Networks for Clinical Cardiovascular Trials**
by Derek John Hausenloy Professor and Research Director, National Heart Centre Singapore



Hiromichi Hamada

Professor
Department of Pediatrics
Graduate School of Medicine, Chiba University, Chiba, Japan

hiromichi.hamada@gmail.com

- Kawasaki disease
- Pediatric cardiology

Medical School
Chiba University School of Medicine
1984-1990 awarded MD, May 22, 1990.

Postgraduate Training
Chiba University Hospital, Chiba, Japan
1990-1997

Doctor of Medical Science
Chiba Graduate School of Medicine, Chiba,
Japan, 1997-2000 awarded PhD Degree May 9,
2000

Postdoctoral Fellow, Cell biology
Developmental biology, Graduate School of
Medicine, Chiba University, Chiba, Japan.
2001-04

Postdoctoral Fellow, Vascular biology
Cardiovascular Research, St. Elizabeth
Medical Center of Boston, Tufts University
2004-2006

Staff physician and Faculty of Medicine,
Tokyo Women's Medical University 2007-2019,
and Professor of Pediatrics, Tokyo Women's
Medical University Yachiyo Medical Center
2019-2021

Professor of Pediatrics, Graduate School of
Medicine, Chiba University 2021-

Phase 4 clinical trial for cyclosporine A for Kawasaki disease

Kawasaki disease (KD), an acute vasculitis in children, more frequently affects Asian children, are resistant to intravenous immunoglobulin (IVIG), which is a current standard therapy, and 8% have coronary artery abnormalities (CAAs), which is the leading cause of acquired heart disease in children. Genetic studies have highlighted possible involvement of the Ca²⁺/NFAT pathway upregulation in the pathogenesis of KD and suggested cyclosporin A (CsA), an immunosuppressant targeting the pathway, as a promising treatment option for refractory KD. To establish evidences of usefulness of CsA in protecting KD patients against CAAs, initially we conducted a phase 2 clinical study to assess the safety and efficacy of CsA. The phase 3 clinical study, "KAICA trial", a multicenter, prospective, randomized, open-label, blinded endpoints trial, was then conducted and revealed the significantly lower incidence of CAAs in the study treatment group. Interestingly in the study treatment group, CAAs were completely prevented when patients were carriers of the risk alleles at the risk-associated variants in both ITPKC and CASP3. In contrast, 29% of the patients who received IVIG alone and had risk alleles in both genes developed CAAs (0/15 [0%], 4/14 [29%]). We have started a phase 4 trial (FORKiDs trial) with the aim of exploring clinical indicators for selecting the best patients for CsA treatment for KD. The primary endpoint is the association between ITPKC risk allele and CAAs outcome. In this presentation, we'd like to show the study design of FORKiDs trial and hear REACTA participants' opinions on the feasibility of conducting it as an international clinical study.

Most recent publications

Kobayashi H, Kimura MY, Hasegawa I, ---Hamada H, et al. Increased Myosin light chain 9 expression during Kawasaki disease vasculitis. *Front Immunol* 2023;13:1036672.

Murayama Y, Hamada H, Shiko Y et al. Risk factors for coronary artery abnormalities and resistance to immunoglobulin plus ciclosporin A therapy in severe Kawasaki disease: subanalysis of the KAICA trial, randomized trial for ciclosporin A as the first-line treatment. *Front Pediatr* 2023;11:1321533.

Ae R, Shibata Y, Kosami K, Nakamura Y, Hamada H. Kawasaki Disease and Pediatric Infectious Diseases During the Coronavirus Disease 2019 Pandemic. *J Pediatr* 2021;239:50-58.

Hamada H, Suzuki H*, Onouchi Y*, Ebata R, Terai M, Fuse S, Okajima Y, Kurotobi S, Hirai K, Soga T, Ishiguchi Y, Okuma Y, Takada N, Yanai M, Sato J, Nakayashiro M, Ayusawa M, Yamamoto E, Nomura Y, Hashimura Y, Ouchi K, Masuda H, Takatsuki S, Hirono K, Ariga T, Higaki T, Otsuki A, Terauchi M, Aoyagi R, Sato T, Fujii Y, Fujiwara T, Hanaoka H, Hata A. Efficacy of primary treatment with immunoglobulin plus cyclosporine for prevention of coronary artery abnormalities in Kawasaki disease patients predicted to be at increased risk of IVIG non-response (KAICA study): a controlled, phase 3, randomised, open-label, blinded-endpoints trial. *Lancet* 2019;393(10176): 1128-1137.

Luis Segovia Sordo

Director Site Alliances APAC & Hong Kong Office GMBA
Parexel

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Evolving Global Clinical Trials Sites landscape

The landscape is shifting, First in the US, then Europe, at some point in Asia-Pacific. It is shifting from mainly academic or big institutions to a mix of big institutions, community hospitals, clinics, and Site networks. While in APAC we might not see the same landscape as in the US, we can say that the use of primary care institutions will be larger through the years. This is a result of COVID; the need to minimize the impact of a new pandemic makes the front line of health care critical in this mitigation action.

Hence primary care centers will be more involved in clinical trials too; either by participating actively as a study center or by referring patients to larger institutions. This will help achieving other goals for clinical trials: facilitate inclusion and access of patients to clinical trials, which should result in larger diversity. We will also look into what sponsors/ CROs are looking for when selecting sites; how and why sponsors and CROs are focusing on profiling sites in some therapeutic areas.

Luis has over 25 years of experience in clinical trials. He has lived and worked in Europe, US and Asia.

His experience expands from clinical operations, project management, feasibility strategy, site relationship development and management, to decentralized engagement solutions.

He is particularly talented in building and grooming clinical trial teams across continents and cultures.

Luis is an experienced developer and leader with great focus on site relationships and business development.

He is passionate about the importance of relationships between sites and industry that foster growth and mutual enrichment.

Recently Luis is very excited about the increased use of Real World Data and AI in Health Care and Clinical Research.

Derek Hausenloy

REACTA 2024 • FROM IDEATION TO VALIDATION • CLINICAL TRIALS IN THE DIGITAL ERA

Professor and Research Director
National Heart Centre Singapore

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- Cardioprotection
- Heart failure
- Clinical trials
- Acute myocardial infarction

Derek Hausenloy is Professor in the Cardiovascular & Metabolic Disorders Signature Program, Duke-National University of Singapore Medical School, and Research Director and Senior Consultant Cardiologist at the National Heart Research Institute, Singapore.

He is also Professor in the Institute of Cardiovascular Sciences, University College London, UK. He is a NMRC STaR Investigator Award who conducts basic, translational and clinical research in the areas of ischaemic heart disease, heart failure, cardioprotection, and cardiac MRI.

He is Executive Director of the CADENCE National Clinical Translation Program, a national platform for cardiovascular research with focus on data science, clinical trials and AI/digital health.

He has been PI on over 40 research grants and has authored 373 papers (with 50,000 citations), and his H-index is 108. In 2018, 2020, 2021, 2022 and 2023 he was named Highly Cited Researcher by Clarivate Analytics (awarded to the top 1% of researchers worldwide).

Collaborative networks for clinical cardiovascular trials

The Cardiovascular Disease National Collaborative Enterprise (CADENCE) National Clinical Translational Program (NCTP) is a national-level cardiovascular research programme that synergises basic, translational and clinical research strengths across Singapore to drive cardiovascular research forward through collaboration and innovative approaches, in order to improve patient outcomes globally. CADENCE has established a national clinical trials platform within Singapore and now wishes to partner with countries in the Asia Pacific (APAC) region to create an cardiovascular research network to support international clinical cardiovascular trials.

Most recent publications

1. Guo W, Zhao W, Li D, Jia H, Ren C, Li S, Zhao J, Yu B, Dong J, Guo R, Zhu K, Cao Y, Wang Y, Wang Y, Li Z, Wang Z, Wang D, Hou C, Hausenloy DJ, Chu X, Ji X. Chronic Remote Ischemic Conditioning on Mild Hypertension in the Absence of Antihypertensive Medication: A Multicenter, Randomized, Double-Blind, Proof-of-Concept Clinical Trial. *Hypertension*. 2023 Jun;80(6):1274-1282. doi: 10.1161/HYPERTENSIONAHA.122.20934. IF 10.190
2. Chew NWS, Chong B, Kuo SM, Jayabaskaran J, Cai M, Zheng H, Goh R, Kong G, Chin YH, Imran SS, Liang M, Lim P, Yong TH, Liew BW, Chia PL, Ho HH, Foo D, Khoo D, Huang Z, Chua T, Tan JWC, Yeo KK, Hausenloy D, Sim HW, Kua J, Chan KH, Loh PH, Lim TW, Low AF, Chai P, Lee CH, Yeo TC, Yip J, Tan HC, Mamas MA, Nicholls SJ, Chan MY. Trends and predictions of metabolic risk factors for acute myocardial infarction: findings from a multiethnic nationwide cohort. *Lancet Reg Health West Pac*. 2023 May 31;37:100803. doi: 10.1016/j.lanwpc.2023.100803. eCollection 2023 Aug. IF 7.4
3. Sim HW, Koh KWL, Poh SC, Chan SP, Marchesseau S, Singh D, Han Y, Ng F, Lim E, Prabath JF, Lee CH, Chen R, Carvalho L, Tan SH, Loh JPY, Tan JWC, Kuwelker K, Amanullah RM, Chin CT, Yip JWL, Lee CY, Gan J, Lo CY, Ho HH, Hausenloy DJ, Tai BC, Richards AM, Chan MY. Remote intensive management to improve antiplatelet adherence in acute myocardial infarction: a secondary analysis of the randomized controlled IMMACULATE trial. *J Thromb Thrombolysis*. 2024 Feb 1. doi: 10.1007/s11239-023-02931-6. Online ahead of print. IF 4.0
4. van Essen BJ, Tharshana GN, Ouwerkerk W, Yeo PSD, Sim D, Jaufeerally F, Ong HY, Ling LH, Soon DKN, Lee SGS, Leong G, Loh SY, San Tan R, Ramachandra CJ, Hausenloy DJ, Liew OW, Chong J, Voors AA, Lam CSP, Richards AM, Tromp J. Distinguishing heart failure with reduced ejection fraction from heart failure with preserved ejection fraction: A phenomics approach. *Eur J Heart Fail*. 2024 Feb 4. doi: 10.1002/ejhf.3156. Online ahead of print. IF 8.2
5. Bulluck H, Chong JH, Bryant J, Annathurai A, Chai P, Chan M, Chawla A, Chin CY, Chung YC, Gao F, Ho HH, Ho AFW, Hoe J, Imran SS, Lee CH, Lim B, Lim ST, Lim SH, Liew BW, Yun PLZ, Ong MEH, Paradies V, Pung XM, Tay JCK, Teo L, Ting BP, Wong A, Wong E, Watson T, Chan MY, Keong YK, Tan JWC, Hausenloy DJ; PITRI Investigators. Effect of Cangrelor on Infarct Size in ST-Segment Elevation Myocardial Infarction Treated By Primary Percutaneous Coronary Intervention: A Randomized Controlled Trial (The PITRI Trial). *Circulation*. 2024 May 14. doi: 10.1161/CIRCULATIONAHA.124.068938. Online ahead of print. IF 39.918.

SESSION 3

Experience Sharing of Key Clinical Studies in Taiwan

MODERATOR



Shian-Ying Sung

Professor,
Graduate Institute of Biomedical Informatics,
Taipei Medical University

MODERATOR



Chun-Che Shih

Executive Vice President,
Taipei Medical University

Topic

- **Precision diagnosis, Translational Research, and Multicenter IIT Phase II Trial of Atypical Teratoid Rhabdoid Tumors in Children: Experience in Taiwan**
by Tai-Tong Wong Professor, Graduate Institute of Clinical Medicine, Taipei Medical University
- **Clinical Trials for Neurological Diseases in Taipei Medical University, Taiwan**
by Chaur-Jong Hu Dean, Medical College, Taipei Medical University
- **Xpert MTB/RIF Assays as the Initial Diagnostic Test for Pulmonary Tuberculosis in Taiwan: a Prospective, Multi-center, Randomized, Pragmatic Trial**
by Chen-Yuan Chiang Vice Superintendent, Taipei Municipal Wanfang Hospital
- **Clinical Trials for Neurological Diseases in Taipei Medical University, Taiwan**
by Ju-Chi Liu Vice Superintendent, Taipei Medical University Shuang Ho Hospital

Tai-Tong Wong

Professor, Graduate Institute of Clinical Medicine
Taipei Medical University



Dr. Wong is a renowned specialist in pediatric neurosurgery, focusing on pediatric brain and spinal tumors, epilepsy surgery in children, and hydrocephalus.

Currently serving as Chairman of the Division of Pediatric Neurosurgery at TMUH and Director of the Pediatric Brain Tumor Program, Dr. Wong has extensive experience in neurosurgical care.

He has held significant leadership positions, including President of the International Society of Pediatric Neurosurgery and the Taiwan Society for Pediatric Neurosurgery.

Precision diagnosis, Translational Research, and Multicenter IIT Phase II Trial of Atypical Teratoid Rhabdoid Tumors in Children: Experience in Taiwan

Atypical teratoid/rhabdoid tumors (ATRTs) are highly malignant central nervous system tumors predominantly diagnosed in young children. Characterized by large rhabdoid cells and various neuroepithelial, epithelial, and mesenchymal components, ATRTs involve SMARCB1/INI1 or, rarely, SMARCA4/BRG1 deficiencies. These tumors often associate with rhabdoid tumor predisposition syndrome (RTPS), complicating their management.

Background and Taiwan Cohort Study: A retrospective study was conducted on 58 children with CNS rhabdoid tumors treated at Taipei VGH and TMUH from 1982-2022. The cohort comprised 40 SMARCB1-deficient ATRTs, 5 INI1 and BRG1 retained embryonal tumors with rhabdoid features (ETRF), and 13 unclassified tumors. Median age at diagnosis varied across groups, with overall survival rates at 30.2%. Conventional dose chemotherapy was the most common initial treatment. Upfront radiotherapy resulted in significantly higher overall survival, though subsequent primary neoplasms were observed in some survivors.

Translational Research: RNA-Seq and DNA methylation analysis revealed distinct epigenetic subgroups and therapeutic targets, including PSMB4, PSMD4, and RRM2. These findings provided a foundation for targeted treatments.

Clinical Trial: A multicenter Phase II trial investigated bortezomib as an add-on therapy in newly diagnosed ATRT patients. Six children received bortezomib, with the majority also undergoing radiotherapy and chemotherapy. Despite high rates of grade 3/4 toxicities, the trial demonstrated manageable safety profiles for bortezomib. Upfront radiotherapy appeared crucial in preventing early relapse.

Conclusion: High-dose chemotherapy and radiotherapy improve tumor control in ATRT, though infectious complications and secondary neoplasms pose significant risks. The Phase II trial highlighted the potential of bortezomib, underscoring the need for new, safer therapies to enhance treatment outcomes. Future efforts should focus on minimizing complications and exploring international collaborations to increase trial enrollment and efficacy.

Chaur-Jong Hu



Dean, Medical College, Taipei Medical University, Taiwan
 Professor, Department of Neurology, School of Medicine, College of Medicine, Taipei Medical University, Taipei, Taiwan
 Consultant, Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan
 Executive Supervisor, Taiwan Neurological Society
 Supervisor, Taiwan Dementia Society

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- Clinical Neurology
- Molecular Neurology
- Dementia
- Clinical Trial

Dr. Chaur-Jong Hu is the founding director of the Dementia Center in Taipei Medical University-Shuang Ho Hospital, New Taipei City, Taiwan. He is also a professor, Dean of the College of Medicine, Taipei Medical University.

Dr. Hu obtained his medical degree from Taipei Medical University, Taipei, Taiwan in 1990. He completed the Neurology residency training in Taipei Municipal Jen-Ai Hospital.

He also has ever worked as a research fellow in the Department of Neurology, stroke center, Washington University School of Medicine, St. Louis, Missouri, USA.

Dr. Hu has extensive experience in clinical trials of therapies for stroke, Alzheimer Disease and other neurological diseases.

He has published over 250 peer-reviewed papers and 2 book chapters on the pathophysiology of ischemic injury of brain and use of botulinum toxin for neuropathic pain.

Dr. Hu is currently the Executive supervision of the Taiwan Neurological Society. He is also a fellow of the American Heart Association (FAHA).

Clinical Trials for Neurological Diseases in Taipei Medical University, Taiwan

There are a lot of unmet needs in treatment and diagnosis of neurological diseases, including stroke, Alzheimer disease (AD), Parkinson disease (PD) and amyotrophic lateral sclerosis (ALS). We establish a team which can serve ischemic stroke patients with most advanced skill and technology and an unique dementia ward sponsored by Taiwanese government for the difficult patients with dementia. We have been participating in many global and domestic trials for acute ischemic stroke and AD. We also initiated trials of photobiomodulation therapy for PD, tamoxifen (autophagy enhancer) for ALS and cell therapy for ischemic stroke.

We will report our experience in this presentation and focus on the clinical trials of AD.

Most recent publications

1. Tamoxifen for amyotrophic lateral sclerosis: A randomized double-blind clinical trial. Chen PC; Hsieh YC; Huang CC; Hu CJ*. *Medicine (Baltimore)* 2020 May 29;99(22):e20423. *corresponding author
2. Clinical trials of new drugs for Alzheimer disease. Huang LK, Chao SP, Hu CJ*. *J Biomed Sci.* 2020 Jan, 27(1): 18. (SCI) *corresponding author.
3. Hydrolyzed chicken extract (ProBiotigen®) on cognitive function in healthy middle-aged people: A randomized double-blind trial. Wu D, Yang CC, Chen KY, Lin YC, Wu PJ, Hsieh PH, Nakao Y, Ow MYL, Hsieh YC*, Hu CJ*. *Nutrients.* 2020 May, 12(5): 1362. (SCI) *corresponding author.
4. Effects of concomitant use of hydrogen water and photobiomodulation on Parkinson disease: A pilot study. Hong CT, Hu CJ, Lin HY, Wu D. *Medicine (Baltimore)* 2021 Jan, 100(4): e24191. (SCI)
5. Effectiveness of the 10 cm2 rivastigmine patch in Taiwanese Patients with mild-to-moderate Alzheimer's dementia: A 48-week real-world observational study. Chang CC, Chan L, Chou HH, Yang YW, Chen TF, Chen TB, Chen CI, Yang A, Hu CJ*. *Adv Ther.* 2021 Sep, 38(10): 5286-5301. (SCI) *corresponding author.
6. Clinical trials of new drugs for vascular cognitive impairment and vascular dementia. Linh TTD, Hsieh YC, Huang LK*, Hu CJ*. *Int J Mol Sci.* 2022 Sep, 23(19): 11067. (SCI) *corresponding author.
7. Clinical trials of new drugs for Alzheimer disease: a 2020-2023 update. Huang LK, Kuan YC, Lin HW, Hu CJ*. *J Biomed Sci.* 2023 Oct 2; 30(1): 83. (SCI) *corresponding author.

Chen-Yuan Chiang

MD, DrPhilos, MPH

Vice Superintendent, Wan Fang Hospital,
Professor of Medicine, Taipei Medical University

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- Tuberculosis
- Asthma

Dr Chiang is a clinician trained in Taiwan, specialized in respiratory and critical care medicine, obtained the degree of MPH at UC-Berkeley, US and DrPhilos at University of Bergen, Norway.

He joined The International Union Against Tuberculosis and Lung Disease (The Union), Paris, France in 2003 and was Director, Department of Lung Health, The Union, between 2007-2015.

Currently, he is a Vice Superintendent of Wan Fang Hospital, and Professor of Medicine at Taipei Medical University.

Xpert MTB/RIF assay as the initial diagnostic test for pulmonary tuberculosis in Taiwan: A prospective, multi-center, randomized, pragmatic trial

To explore the impact of Xpert MTB/RIF assay as the frontline test in reducing delay diagnosis of pulmonary tuberculosis (PTB).

Presumptive PTB patients who had frontline nucleic acid amplification tests (NAATs) requested by clinicians were classified as group A, else were randomized into group B for whom frontline Xpert MTB/RIF tests was performed as intervention, or group C without frontline NAATs. The trial was registered at clinicaltrials.gov (ClinicalTrials.gov ID: NCT04433195).

Ju-Chi Liu

Vice Superintendent, Taipei Medical University Shuang Ho Hospital
Department of Cardiovascular Medicine, School of Medicine, Taipei Medical University
Division of Cardiology, Department of Internal Medicine, Shuang Ho Hospital



Dr. Ju-Chi Liu is a Professor in the Division of Cardiology, Department of Internal Medicine at the School of Medicine.

His research interests include atherosclerosis, hypertension, and molecular biology in the cardiovascular system.

Dr. Liu currently serves as the Deputy Director of the School of Medicine and Superintendent of Taipei Medical University Shuang Ho Hospital.

Clinical Trials for Cardiovascular Diseases in Taipei Medical University, Taiwan

Clinical trials play an important role in the field of cardiovascular medicine. Many recommendations for patients with cardiovascular diseases in the international guidelines based on key results of landmark clinical trials. Recent years, physicians of cardiovascular medicine not only participated in recruited patients for international clinical trials and also initiated trials for patients with cardiovascular medicine in Taipei Medical University affiliated hospitals.

Our faculties recruited patients with atrial fibrillation to evaluate the efficiency and safety of new oral anticoagulants compared with warfarin (RE-LY trial). We also participated in the clinical trial for outcomes of ARNI (angiotensin receptor antagonist plus neprilysin inhibitor) in heart failure patient with reduced ejection fraction (PARADIGM-HF trial).

Some investigator initiated clinical trials for cardiovascular diseases in Taipei Medical University showed significant clinical implications, including AI-microcirculation assessment predicted risk of adverse effects of COVID-19 vaccines, AI-wearable devices decreased readmission rate of patients with heart failure by detection of ECG rhythm at home. Recently, we collect gene of patients with cardiac-kidney-metabolic (CKM) and clinical data to create precise managements for these patients.

In the near future, we will initiate next-generation sequencing (NGS) studies in patients with atrial fibrillation, heart failure, and CKM in Taipei Medical University affiliated hospitals.

SESSION 4

Industrial Leaders' Panel Discussion

MODERATOR



Chin-Wei Wang

Director,
Division of Periodontics,
Department of Dentistry,
Taipei Medical University Hospital

MODERATOR



Tina Sun

President,
Taiwan Clinical Research Association
(TCRA)



Carol Chen

Oncology Country Head | Site Management & Monitoring (SMM) Taiwan | AstraZeneca Taiwan Limited

Carol, the Oncology Country Head at AstraZeneca in Taiwan, brings over 18 years of experience in clinical trials, having worked with Novartis, Eli Lilly, and ICON, covering APAC countries. She manages SMM Oncology operations, overseeing staff and resources for large regional and global studies from feasibility to closure. Her expertise spans oncology, immunology, dermatology, cardiology, diabetes, neuroscience, and cell and gene therapy. Carol's background includes roles such as Clinical Research Associate, Clinical Study Manager, and senior management positions in APAC, as well as experience in sales and market research. Additionally, she serves as the Executive Director, the board member of the Taiwan Clinical Research Association for years. This extensive background makes her a highly knowledgeable professional with a comprehensive understanding of operational strategy in drug development.

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Tien Li Chen

Associate Director | Site and Patient Solution | Syneos Health

Tien Li Chen is an accomplished clinical trial professional with around 15 years of industry experience, currently serving as the Associate Director of Clinical Trial Management at Syneos Health. He has extensive experience in leading and mentoring clinical operations teams across APAC countries, with several years of line management experience, and is skilled in onboarding and training Clinical Trial Managers. His role also involves overseeing clinical trial operations, ensuring compliance, and participating in client meetings. Tien's past roles include Clinical Research Associate, Clinical Trial Manager, and Clinical Operations Manager.

Tienli.chen@syneoshealth.com

Shuling Cheng

President | Oneness Biotech

Shuling Cheng, Ph.D. in Virology, training in Cellular & Molecular Biology, with over 25 years of experience in the pharmaceutical, medical device, and biotech industries, as well as experience in entrepreneurial ventures. She currently serves as President of Oneness Biotech, with extensive experience in IP, products development from proof of concept through clinical trials, GMP production, and regulatory approval. Previously, she served as the President of Diamond Biofund, a publicly listed biotech investment company, a partner at Alira Health, an international consulting firm, and the Chief Strategy Officer of Medeon Biodesign, a publicly listed medical device company in Taiwan. She is proficient in the management of innovative product development, global clinical trials, commercialization strategies, technology licensing, and international collaboration.

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Anchi Huang

Head of Site Management | Medical Department | Bayer Taiwan Co., Ltd.

Anchi Huang received her master degree in biotechnology and bachelor degree in biomedical science from University of Queensland, Australia. She is/was the Country Head of Site Management for both Taiwan and Philippines (2015 to 2022) at Bayer for the last 12 years. Anchi has worked in the clinical trial industry for 20 years and had positions at Boehringer Ingelheim, ICON and PPC. She has extensive working knowledge of project management, clinical operation and people management. Anchi and her team contribute to and implement global strategic direction to ensure quality delivery of study data across all therapeutic areas are conducted in line with quality, legal, regulatory and compliance requirements. Anchi ensures appropriate organizations of Taiwan and Philippines are structured to secure the quality of clinical trial and achieve country commitments timely.

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Keris Huang

Executive Director | Global Clinical Trial Operations, Taiwan | MSD Taiwan

Keris is a highly experienced clinical research leader with around 25 years of industry expertise. She joined MSD Taiwan in 1999 as a Clinical Research Associate and has since held various positions of increasing responsibility. In 2010, Keris was appointed as the Clinical Research Director and later took on the additional responsibility of managing MSD Clinical Research Team Hong Kong and forming the Taiwan/Hong Kong cluster in 2018. With her leadership, the organization has grown significantly. Keris is widely recognized for her contributions to the clinical research community in Taiwan. She served as the President and various key roles of the Taiwan Clinical Research Association. Her focus is on improving the clinical research environment, attracting more R&D investments to Taiwan, and nurturing future talents in the field. Keris holds a Bachelor of Science in pharmacy and a Master of Science in physiology from Taipei Medical University. She is also certified as a Six Sigma Green Belt and Change Agent.

Keris.huang@msd.com

SESSION 5

Country Updates from the Region

MODERATOR



Kang-Yun Lee

Executive Vice President,
Taipei Medical University

MODERATOR



Sung Yong Oh

Professor,
Department of Internal Medicine,
Dong-A University Hospital

Topic

- **Challenges and Solutions of New Initiatives at Chiba University ARO (CCRC)**
by Hideki Hanaoka Head of Clinical Research Center, Chiba University Hospital
- **Reflections on Clinical trials in the era of Evidence-based Medicine**
by Edwin Chan Chief Scientific Officer, Singapore Clinical Research Institute
- **Challenges and Opportunity of Cancer Clinical Trials in Taiwan**
by Chao-Hua Chiu Vice Superintendent, Taipei Cancer Center, Taipei Medical University
- **Opportunities in Conducting Multi-Regional Clinical Trials in Malaysia**
by Akhmal Yusof Chief Executive Officer, Clinical Research Malaysia

Hideki Hanaoka MD.,PhD

Professor of Chiba University
Head of Clinical Research Center, Chiba University Hospital Deputy director of
Chiba University Hospital

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- Allergy immunology
- Clinical Trial
- Regulatory science

Dr. Hideki Hanaoka graduated from Chiba University Medical School.

After his residency at Yokohama Labor Hospital and Chiba University Hospital, he joined PMDIC (PMDA) as a medical reviewer of NDA in 2000. He was chief reviewer at NDA 5th review division of PMDIC.

In 2003, he moved to Chiba University Hospital Clinical Research Center (CCRC). He has been director of CCRC since 2008 and professor of the hospital since 2010.

In 2013, he became professor at Chiba University and chairman of CCRC. In 2023, he became deputy director of Chiba University Hospital.

Chiba University Hospital has been one of the core clinical research hospitals since 2012 and he is the leader of CCRC.

He is a member of various committees of PMDA and MHLW.

Challenges and Solutions of New Initiatives at Chiba University ARO (CCRC)

Three new projects are currently underway at Chiba University ARO (CCRC). The first is a vaccine development project: the pandemic caused by the new coronavirus infection that began in 2020 resulted in a significant delay in Japan's own vaccine development compared to Europe and the US. Several reasons were identified, not only in scientific terms, but also in terms of the clinical research system. Therefore, a national project was launched to rebuild the fragile Japanese vaccine development infrastructure, and Chiba University was selected as one of five institutions in Japan to establish a project team in 2022. The CCRC also joined the vaccine development team, and will be working on Phase 1 of vaccine development at the Chiba University Hospital, and started the development of facilities to carry out Phase 2 of the project.

The second is a new form of clinical trial initiative based on a master protocol. While pharmaceutical companies are already developing drugs based on master protocols, the CCRC has started discussions with relevant parties to start clinical trials as study designs based on PMDA guidelines.

Third, the CCRC is preparing to conduct clinical studies in Asia. In particular, the results of a clinical trial using CyA for Kawasaki disease were published in the journal LANCET in 2019 and the PMDA approved the indication of CyA for Kawasaki disease patients in 2020, but the indication is limited to severe Kawasaki disease. We would like to discuss the challenges of conducting clinical trials in Asia for all Kawasaki disease patients.

Most recent publications

1. Effect of Reduced-Dose vs High-Dose Glucocorticoids Added to Rituximab on Remission Induction in ANCA-Associated Vasculitis: A Randomized Clinical Trial. JAMA. 325:2178-2187, 2019
2. Randomized trial of granulocyte colony-stimulating factor for spinal cord injury. Brain 144:789-799, 2021.
3. Factors Influencing Classifications of Safety Specifications in a Risk Management Plan for Antineoplastic Agents Approved in Japan: A Review and Descriptive Analysis. Ther. Innov. Regul. Sci. Actions. 55:1075-1081, 2021.
4. Investigator-Initiated Registry Trials in Japan and the REACTA Network in Asia., <https://globalforum.diaglobal.org/issue/april-2020/investigator-initiated-registry-trials-in-japan-and-the-reacta-network-in-asia/>

Edwin Chan

Chief Scientific Officer
Singapore Clinical Research Institute
Consortium for Clinical Research and Innovation Singapore

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- Evidence synthesis
- Meta-analysis
- Critical appraisal of research literature
- Evidence-based Medicine

A/Prof Edwin Chan is a clinical epidemiologist with extensive expertise in clinical research and evidence synthesis.

He teaches research literature critical appraisal skills to medical students (Duke-NUS Medical School) and mentors students in clinical research (MCI programme, NUS).

He has taught many research methodology courses on clinical trials, biostatistics, epidemiology, clinical practice guidelines (CPG) development, meta-analysis & evidence-based medicine (EBM).

His interests are in the teaching of critical appraisal skills, epidemiology, health technology assessment and evidence synthesis.

Reflections on Clinical trials in the era of Evidence-based Medicine

Evidence-based Medicine is the deliberate and balanced fusion of the current best evidence, clinical expertise and patient values to guide decision-making in clinical care and population health. I will reflect on how EBM-related concepts of synthesized evidence, recruitment for precision of evidence, appraising study risk of bias and assessing certainty of evidence can continue to improve the planning, and reporting of clinical trials and application of its results.

Most recent publications

1. Lim SG, Teo AED, Chan ESY, et al. Stopping nucleos(t)ide analogues in chronic hepatitis B using HBsAg thresholds: A meta-analysis and meta-regression. *Clin Gastroenterol Hepatol.* 2024 Jun 12;S1542-3565(24)00516-0. doi:10.1016/j.cgh.2024.05.040.
2. Liu E, Smyth RL, Li Q et al. Guidelines for prevention and management of children and adolescents with COVID-19. *Eur J Pediatr.* 2022 Dec;181(12):4019-4037.
3. Tan YK, Han MX, Tan BYQ et al. The role of head-up cardiopulmonary resuscitation in sudden cardiac arrest: a systematic review and meta-analysis. *Ann Transl Med.* 2022;10(9):515.doi:10.21037/atm-21-4984
4. Lim SG, Yang WL, Ngu JH et al. Switching to or Add-on Peginterferon in patients on Nucleos(t)ide analogues for chronic hepatitis B: the SWAP RCT. *Clin Gastroenterol Hepatol.* 2022; Feb;20(2):e228-e250.
5. Patel A, Irani FG, Pua U et al. Randomized controlled trial comparing drug-coated balloon angioplasty versus conventional balloon angioplasty for treating below-the-knee arteries in critical limb ischaemia: The SINGA_PACLI trial. *Radiology* 2021; 300(3):715-724.

Chao-Hua Chiu

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Challenges and opportunity of cancer clinical trials in Taiwan

A key stage in bringing a new drug or device to market is the clinical trial. It also serves as a crucial catalyst in elevating an institution from a conventional hospital to a distinguished medical center. Taiwan boasts numerous advantages in this arena, including a robust healthcare infrastructure and a wealth of highly skilled professionals, positioning it favorably as a prime destination for international pharmaceutical companies seeking clinical trial candidates. Nonetheless, Taiwan faces challenges such as a relatively small patient population and a less expansive drug market compared to larger nations.

In this presentation, I will share the experience of a pivotal clinical trial that exemplified a four-win scenario.

Most recent publications

1. Chang GC, Chiu CH, Yu CJ, et al. Low-dose CT screening among never-smokers with or without a family history of lung cancer in Taiwan: a prospective cohort study. *Lancet Respir Med.* 2024 Feb;12(2):141-152. (Co-first author)
2. Chiu CH, Lin MC, Wei YF, et al. Efficacy and Tolerability of Ramucirumab Plus Erlotinib in Taiwanese Patients with Untreated, Epidermal Growth Factor Receptor-Mutated, Stage IV Non-small Cell Lung Cancer in the RELAY Study. *Target Oncol.* 2023 Jul;18(4):505-515. (First author)
3. Chiu CH, Yang PC. Never Say No to Never-Smokers. *J Thorac Oncol.* 2023 Jun;18(6):689-693. (First author)
4. Che TF, Chiu CH, Wu YC, et al. Proliferative ability of circulating tumor cells is a prognostic factor in Early-Stage lung adenocarcinoma. *Lung Cancer.* 2023 Apr;178:198-205. (Co-first author)
5. Yang SC, Yeh YC, Chen YL, Chiu CH. Economic analysis of exclusionary EGFR test versus up-front NGS for lung adenocarcinoma in high EGFR mutation prevalence areas. *J Natl Compr Canc Netw.* 2022 Apr 6;20(7):774-782.e4. (Corresponding author)



- Lung cancer
- Cancer clinical trials

Dr. Chao-Hua Chiu is currently the Professor at the School of Medicine, the Vice Superintendent at Taipei Cancer Center, and the Chief of the Clinical Research Center at Taipei Medical University Hospital, Taipei Medical University, Taipei, Taiwan.

He received his MD degree at Taipei Medical University and his specialty training in both Pulmonology and Medical Oncology at Taipei Veterans General Hospital during 1999-2003.

Dr. Chiu was a visiting scientist at the Department of Molecular and Cellular Oncology, MD Anderson Cancer Center during 2006-2008.

His main clinical and research interests include the low-dose CT lung cancer screening, as well as the management and new drug development for lung cancer, mesothelioma and thymic malignancies.

Akhmal Yusof

Chief Executive Officer,
Clinical Research Malaysia

akhmal.yusof@clinicalresearch.my



Dr Akhmal Yusof graduated from the Royal College of Surgeons in Ireland in 1992.

He practiced medicine in the public and private hospital for 10 years and later worked with the American International Assurance Malaysia as Medical Manager.

Later in 2002, he leads the Medical Department in AstraZeneca Malaysia, Singapore & Brunei for 13 years where he gained extensive experience in the pharmaceutical industry clinical research management, regulatory, medical and government affairs.

He currently heads Clinical Research Malaysia (CRM) as Chief Executive Officer since 2015.

Dr Akhmal Yusof is also a member the National Committee for Clinical Research and Board of Trustee National Institute of Biotechnology Malaysia.

Education :
MBCh, BAO (National University of Ireland),
LRCP & LRCS (Ireland)

Opportunities in conducting Multi-Regional Clinical Trials in Malaysia

Malaysia is committed to conduct Multi-Regional Clinical Trials (MRCT) with Speed, Reliability & Quality since decades ago. This is attributed by the formation of Clinical Research Malaysia (CRM) a research management organisation wholly owned by Ministry of Health Malaysia. CRM is also an accredited ISO 9001 Quality Management System & ISO37001 Anti Bribery Management System accredited making it a trusted research management organization.

The organisation is guided by the principles of Humanity, Stability and Sustainability in providing global clinical trial solutions and enabling a thriving clinical research ecosystem in the country. At its very core, CRM aims to bring clinical research that addresses the unmet needs of patients and transforms health outcomes in Malaysia.

Since 2012, Malaysia has conducted over 2300 global sponsored clinical research, all amounting to USD 300 million of gross national income contributed through contract values of clinical trials agreements. The value proposition offered by Malaysia with a third of world genomics resides in the country, dedicated investigators & clinical research sites with world class achievements has attracted global clinical trials into the country from variety global companies and organisations.

We have observed professional careers mushrooming in the field of clinical research within the country all spelling the growth this sector has come to over the years, with 260 trial centres and over 1700 investigators across multi-therapeutic areas. In addition, Malaysia has early phase experience with accredited centres having conducted FIH studies. This presentation aims to share more about Malaysia's capabilities and explore new opportunities to conduct MRCT.

Most recent publications

Early phase oncology clinical trials in Malaysia: current status and future perspectives Asia-Pac J Clin Oncol. 2022; 1-9

SESSION 6

Research Innovation and Clinical Validation

MODERATOR



Pei-Shan Tsai

Dean,
College of Nursing,
Taipei Medical University

MODERATOR



Yi-Hua Chen

Dean,
College of Public Health,
Taipei Medical University

Topic

- **Allogeneic platelet lysates for brain administration and treatment of neurological disorders**
by Thierry Pierre Robert Burnouf Vice Dean, College of Biomedical Engineering, Taipei Medical University
- **Translational research experience sharing using TMU biobank**
by Wei-Chung Yang Jointly Appointed Professor, Master Program in Clinical Genomics and Proteomics, Taipei Medical University
- **Novel HDAC6 Inhibitor G211 : Preclinical Study and Potential in Human Cancer Treatment**
by Wei-Chun HuangFu Vice Dean, College of Medical Science and Technology, Taipei Medical University
- **Electrospun nanofiber artificial bone substitutes**
by Yi-Jie Kuo Director, Department of Orthopaedics, Taipei Municipal Wanfang Hospital

Thierry Burnouf

Distinguished Professor
College of Biomedical Engineering
Taipei Medical University

thierry@tmu.edu.tw



- Regenerative medicine and cell therapy
- Platelet factors and extracellular vesicles biotherapy
- Neurodegenerative disorders
- Blood biotechnology

Thierry Burnouf, PhD, is distinguished professor at TMU College of Biomedical Engineering.

An international authority on plasma fractionation and blood safety, Dr. Burnouf has significantly contributed to the development of blood-derived therapeutics and viral inactivation technologies.

He has published over 250 papers and holds more than 20 international patents. Co-founder of InVenis Biotherapies, he has pioneered platelet lysate treatments for neurological diseases.

His accolades include the 2019 IPFA Award for his contributions to plasma fractionation.

At TMU since 2008, he has played a crucial role in enhancing Taiwan's biomedical research and education, mentoring students in dual degree programs with the University of Lille.

Dr. Burnouf's work continues to impact regenerative medicine and global blood safety standards.

Allogeneic platelet lysates for brain administration and treatment of neurological disorders

Platelets are abundant anucleated blood cells well known for their vital hemostatic role and contribution to wound healing. Allogeneic platelet concentrates (PCs) collected from healthy donors by blood establishments are a WHO essential medicine currently used in hospitals to transfuse patients with platelet dysfunctions or low platelet counts, thereby protecting them from severe bleeding episodes. Moreover, platelets contain an exceptional proteome composed of multifaceted trophic factors, including neurotrophic factors (PDGF, BDNF, EGF, b-FGF, HGF, etc.), pro-angiogenic factors (PDGF, VEGF, etc.), anti-inflammatory molecules (TGF- β , etc.), and antioxidants (GPX, catalase, SOD, etc.), making them suitable for regenerative medicine. Platelets are also prone to releasing extracellular vesicles (p-EVs), which carry this biomolecular cargo.

For over a decade, our laboratory, in collaboration with the ULille Neuroscience and Cognition Center and Inserm in France, has pioneered the development of dedicated human platelet lysates for the treatment of neurological disorders. This work has involved engineering a platelet lysate with biochemical characteristics compatible with brain administration, implementing and validating robust virus reduction treatments, and assessing functionality and safety in preclinical models of various brain disorders, including Parkinson's disease, traumatic brain injury, and amyotrophic lateral sclerosis (ALS). The project is now mature enough to proceed towards dose-finding and toxicity studies in large animals and clinical studies in patients with ALS.

The starting platelet concentrates, meeting French drug agency regulatory requirements, are collected from healthy donors by the French Blood Establishment, and the platelet lysate is GMP-produced by a CDMO using pools of 240 platelet donations. The platelet lysate will be administered to patients through the intracerebroventricular route using a catheter and a pump implanted in their abdomen, ensuring optimal control and monitoring of the delivered dose. The project is receiving an 8.3 million euro grant from the French RHU to support innovative clinical developments from universities and hospitals.

Most recent publications

Le NTN, Han CL, Delila L, Nebie O, Chien HT, Wu YW, Buée L, Blum D*, Burnouf T*. Proteomics of Human Platelet Lysates and insights from animal studies on platelet proteins diffusion to hippocampus upon intranasal administration. *APL Bioengineering*, 2024; May 6;8(2):026111. doi: 10.1063/5.0196553.

Livkisa D, Chang TH, Burnouf T*, Czosseck A, Le NTN, Shamrin G, Yeh YT, Kamimura M, Lundy DJ* Extracellular vesicles purified from serum-converted human platelet lysates offer strong protection after cardiac ischaemia/reperfusion injury. *Biomaterials*, 2024;306:122502.

Delila L, Nebie O, Le N-T-N, Barro L, Chou M-L, Wu Y-W, Watanabe N, Takahara M, Buée L, Blum D, Devos D, Burnouf T*. Neuroprotective activity of a virus-safe nanofiltered human platelet lysate depleted of extracellular vesicles in Parkinson's disease and traumatic brain injury models. *Bioengineering & Translational Medicine*, 2023; 8(1): e10360.

Nebie O, Carvalho K, Barro L, Delila L, Faivre E, Renn TY, Chou ML, Wu YW, Nyam-Erdene A, Chou SY, Buée L, Hu CH, Peng CW, Devos D, Blum D, Burnouf T*. Human platelet lysate biotherapy for traumatic brain injury: pre-clinical assessment. *Brain*, 2021; 144(10): 3142-3158.

Chou ML, Wu JW, Gouel F, Jonneaux A, Timmerman K, Renn TY, Laloux C, Chang HM, Lin LT, Devedjian JC, Devos D*, Burnouf T*. Tailor-made purified human platelet lysate concentrated in neurotrophins for treatment of Parkinson's disease. *Biomaterials*, 2017; 142: 77-89.

Wei-Chung Vivian Yang

Professor, The PhD Program for Translational Medicine,
College of Medical Science and Technology, Taipei Medical University

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Translational research experience sharing using TMU biobank

Dr. Vivian Yang's research interests on biomarker discovery and validations for women's diseases. Because of her long-term research and teaching experiences on translational medicine, Dr. Yang participated in setting up the first generation of the infrastructure of TMU biobank, not only to guide the establishment of the SOPs for various specimen collection, Dr. Yang also contributed some input on the medical informatic infrastructure setting. Until now, more than 10000 new cases (mostly cancer) and >300000 clinical data were collected in TMU biobank and TMU clinical research database (TMU-CRD) every year.

In this presentation, Dr. Vivian Yang will use her research project as an example to share her experiences and point out the importance and the value of biobank to support on translational research.

Most recent publications

1. V. K. Yadav, T-Y Lee, J. B-K Hsu, H-D Huang, W-C V. Yang*, Tzu-Hao Chang*. Computational analysis for identification of the extracellular matrix molecules involved in endometrial cancer progression. PLoS ONE 2020, 15(4): e0231594.
2. Chen, S-Y; Chang, T-C; Lin, C-Y; Lai, C-H; Wu, R-C; Yang, L-Y; Chang, W-Y; Lee, Y-S; Yang, W-C V*; Chao, A*. Serum levels of alpha1-antitrypsin isoforms in patients with ovarian clear cell carcinoma: An exploratory study, Journal of the Chinese Medical Association 2021, 84: 1048-1053.
3. Young, SHR, Chang, YE, Yang, W-C V, Lu, BJ, Chou, SY, Chen, CH. Maximize the safety and efficacy of fertility preservation by random start/dual ovarian stimulation for early breast cancer patients. Taiwanese Journal of Obstetrics & Gynecology 2023, 62, 330-333.
4. Inggriani, RC, Chang, CC, Yang, W-C V*. Potential candidate gene and underlying molecular mechanism involving in tumorigenesis of endometriosis-associated ovarian cancer (EAOC) in Asian populations. Medical Science Forum. 2023, 20(1), 7.
5. Nguyen, TTT, Lee, HH, Huang, LK, Hu, CJ, Yeh, CY, Yang, W-C V, Lin, MC. Heterogeneity of Alzheimer's disease identified by neuropsychological test profiling. PLoS ONE 2023, 18(10): e0292527.

- Protein Chemistry
- Biomarker Discovery
- Translational Medicine

Dr. Vivian Yang, a Full Professor of the PhD Program for Translational Medicine in Taipei Medical University (TMU), is also a founder and CEO of V-CHECK, a start-up company spun off from TMU in 2017.

Dr. Yang also served as a director of the PhD program for translational medicine in 2011-2017.

Before became a faculty member in TMU, Dr. Vivian Yang received post-doctorate training in Academia Sinica and her PhD from Graduate School of Biomedical Sciences, University of Texas in Houston, USA.

Wei-Chun HuangFu

Vice Dean
College of Medical Science and Technology
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- Drug design and development
- Cancer biology
- Molecular toxicology

Dr. Wei-Chun HuangFu received her BSc from National Tsing-Hua University, her MSc from Duke University, and her PhD from North Carolina State University.

She completed her postdoctoral training at the University of Pennsylvania, USA. Currently, she is an Associate Professor at the Graduate Institute of Cancer Biology and Drug Discovery.

She is Vice Dean for International Affairs at the College of Medical Science and Technology (CoMST), Taipei Medical University, Taiwan.

Dr. HuangFu is dedicated to drug discovery, drug pharmacology, efficacy evaluation, and investigating the mechanisms of action of therapeutic agents.

Novel HDAC6 Inhibitor G211 : Preclinical Study and Potential in Human Cancer Treatment

TARK BioPharma is a company advancing from pre-clinical to clinical stages, concentrating on drug development for rare diseases and unmet medical needs. Our current focus is developing MPT0G211, a first-in-class, oral selective small-molecule HDAC6 inhibitor targeting gynecologic cancers and multiple myeloma. Additionally, MPT0G211 holds potential for various indications, including other cancer types and neurodegenerative disorders such as Alzheimer's disease and neuropathic pain.

We have completed GLP toxicology studies and aim to file a US FDA Investigational New Drug (IND) application in Q1 2025. The phase 1 clinical trial will be conducted globally and is expected to conclude in 2027. Post-phase 1, we are seeking co-development or licensing opportunities to advance the development and commercialization of MPT0G211 further.

Most recent publications

1. Tony Eight Lin, Dyan Yen, Wei-Chun HuangFu, Yi-Wen Wu, Jui-Yi Hsu, Shih-Chung Yen, Tzu-Ying Sung, Jui-Hua Hsieh, Shiow-Lin Pan, Chia-Ron Yang, Wei-Jan Huang, Kai-Cheng Hsu., An ensemble machine learning model generates a focused screening library for the identification of CDK8 inhibitors. *Protein Science*. 2024 (33):1-15 {SCI}
2. Tze-Sian Chan, Li-Hsin Cheng, Chung-Chi Hsu, Pei-Ming Yang, Tai-Yan Liao, Hsiao-Yen Hsieh, Pei-Chun Lin, Wei-Chun HuangFu, Chih-Pin Chuu, Kelvin K. Tsai., ASPM stabilizes the NOTCH intracellular domain 1 and promotes oncogenesis by blocking FBXW7 binding in hepatocellular carcinoma cells. *undefined*. 2024 (18):562-579 {SCI}
3. Chen-Wei Chiang, Yun-Shih Lin, Fu-Ling Chang, Tsai-Yu Lin, Keng-Chang Tsai, Wei-Chun HuangFu*, Yu-Ching Lee*. Single-chain fragment antibody disrupting the EphA4 function as a therapeutic drug for gastric cancer. *Biochemical and Biophysical Research Communications*. 2023 (680):161-170{SCI}
4. Ting-Yi Sung, Han-Li Huang, Chun-Chun Cheng, Fu-Ling Chang, Po-Li Wei, Ya-Wen Cheng, Cheng-Chiao Huang, Yu-Ching Lee, Wei-Chun HuangFu*, Shiow-Lin Pan*. EGFL6 promotes colorectal cancer cell growth and mobility and the anti- \square cancer property of anti-EGFL6 antibody. *Cell & Bioscience*. 2021 (11):1-14{SCI}
5. Yi-Wen Wu, Min-Wu Chao, Huang-Ju Tu, Liang-Chieh Chen, Kai-Cheng Hsu, Jing-Ping Liou, Chia-Ron Yang, Shih-Chung Yen, Wei-Chun HuangFu*, Shiow-Lin Pan*. A novel dual HDAC and HSP90 inhibitor, MPT0G449, downregulates oncogenic pathways in human acute leukemia in vitro and in vivo. *Oncogenesis*. 2021 (10):1-14{SCI}

Yi-Jie Kuo

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 Assistant Professor, Department of Orthopaedics, School of medicine, College of medicine, Taipei Medical University

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Electrospun nanofiber artificial bone substitutes

The market assessment of bone grafts shows that the global bone grafts and substitutes market size was USD 2.78 billion in 2020 and is expected to grow at a CAGR of 5.8% from 2021 to 2028. Bone defects caused by trauma, infection, fractures, spinal deformities, bone tumors, etc. all require bone grafts for treatment. Patient-specific bone autografts are the first choice for treatment; however, their use is still limited by donor site morbidity and availability; while allografts carry the risk of immune reactions. Therefore, highly biocompatible synthetic grafts have received increasing attention as the best alternative strategy. Poly(lactic-co-glycolic acid) (PLGA) is currently approved by the US FDA for medical and biological applications. However, traditional PLGA still has some clinical use problems, such as the inability to provide appropriate mechanical properties according to the corresponding bone position. Electrospinning is a nanofiber technology with high surface-to-area ratio and porosity properties, making it ideal for producing composite fibers for medical applications.

Our team developed a PLGA three-dimensional biological scaffold made of electrospinning as a filling material for bone defects. Based on PLGA's excellent biocompatibility, adjustable degradability, and improvement of its traditional mechanical properties through electrospinning, it will be used in different bone tissue repairs. Our team has three core technologies and has developed machines that can be mass-produced, solving the huge bottleneck of mass production in electrospinning technology. Furthermore, the raw materials of the technology used by our team are natural polymer materials, breaking through the past Limitations on the use of synthetic polymers; finally, no organic solvents are used to improve the biocompatibility of the product for application in medical devices.

Our team's technology has self-rated TRL6 level. We have now produced a prototype product on a machine that can be used for mass production of electrospinning in the future. For this product, our team has conducted biocompatibility and biotoxicity tests, and passed Animal experiments verify its usability; subsequent verification will be conducted based on the preclinical testing specifications for inspection and registration.

Most recent publications

Lin YC, Hu CC, Nguyen TT, Dhawan U, Chou CY, Lee YL, Yen HW, Kuo YJ, Chung RJ. Study on surface hydrogenated Ti6Al4V alloy for orthopedic implants. Journal of Materials Research and Technology. 28 (2024) 1504-1513



- Spine surgery
- Orthopaedic research

2005-2011
 Attending Physician
 Department of Orthopedic Surgery Taipei
 City Hospital Taipei, Taiwan

May. 2011-Nov. 2017
 Attending Physician
 Department of Orthopedic Surgery Taipei
 Medical University Hospital Taipei, Taiwan

Nov. 2017-to date
 Director, Department of Orthopedic Surgery
 Wan Fang Hospital Taipei Medical University
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Apr. 2015 to Aug. 2021
 Assistant Professor, Department of
 Orthopedic Surgery School of Medicine,
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5 Aug. 2021 to date
 Associate Professor, Department of
 Orthopedic Surgery School of Medicine,
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REACTA 2024
Day 02

SESSION 7

Updates on the Latest Regulations and Practices on Clinical Trials (In Chinese)

MODERATOR



Chih-Shung Wong

Director,
Anesthesiology Department,
Cathay General Hospital

MODERATOR



Chih-Han Lin

Director,
JIRB Administration Section,
Taipei Medical University

Topic

- **藥品臨床試驗執行分散式措施指引 (Decentralized Clinical Trial, DCT)**
by Yi-Ling Lu Section Chief, Division of Regulatory Affairs and Compliance
- **臺灣再生醫療挑戰與展望**
by Liu Yueh-ping Director-General, Department of Medical Affairs, Ministry of Health and Welfare



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· 醫藥法規

財團法人醫藥品查驗中心
專案經理、小組長
2014 -

東生華製藥股份有限公司
專案開發專員
2011 - 2014

百博生技有限公司
產品經理
2009 - 2010

友霖生技醫藥股份公司
研發專員
2008 - 2009

台北醫學大學 基礎醫學研究所
2004 - 2006

藥品臨床試驗執行分散式措施指引 (Decentralized Clinical Trial, DCT)

近年來隨著後疫時代的來臨以及數位科技的進步，臨床試驗的執行由過往以試驗機構為中心轉換至以病人為中心，受試者可不用親赴試驗機構，透過遠端訪診、居家訪視等遠距分散式措施執行臨床試驗。然而，為兼顧臨床試驗發展趨勢、國內臨床試驗環境需求及維護臨床試驗品質，食藥署制定並公告「藥品臨床試驗執行分散式措施指引」，說明執行數位招募受試者、數位化告知同意、交付及提供試驗藥品、遠端監測受試者的安全、受試者通報不良事件、遠端資料監測及資訊系統及電子資料收集、處理與儲存等分散式措施時，應確保受試者安全與權益、數據資料品質，以及資料之保密性、完整性與正確性，同時也應考量執行各種分散式措施之風險。

Most recent publications

財團法人醫藥品查驗中心當代醫藥法規月刊
第153期 - 細胞治療製劑臨床試驗法規及申請概況

Yueh-Ping Liu

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臺灣再生醫療挑戰與展望

衛生福利部於110年2月9日因應細胞治療技術管理需求，修正「特定醫療技術檢查檢驗醫療儀器施行或使用管理辦法」部分管理規定。透過法規之修正與訂定，健全細胞治療技術法規治理環境，階段性開放細胞治療技術，使細胞治療能早日運用於有需要的病人，及透過有效管理，保障病人安全與醫療品質，並可促進我國生技研發與產業發展。

目前新興生物醫學科技迅速發展時代，再生醫療相關領域之技術與知能已逐漸成熟，並加速擴大應用至臨床醫學，鑒於再生醫療之異質性、特殊性及治療複雜性，衛生福利部制定「再生醫療法」業於113年6月19日經總統公布。

希望透過再生醫療專法，從醫療執行端、製劑端、細胞製備端全面納管，落實分級分流之安全管理，鼓勵再生醫療相關學研、產業共同投入，建構再生醫療產業鏈，營造永續發展環境。

- 急診醫學
- 兒科急重症
- 公共衛生
- 醫療法律

我是國內少數兼具急診及小兒科雙專科訓練之醫師，曾任台大醫院急診醫學部主治醫師、衛生福利部臺北區緊急醫療應變中心副執行長、臺灣急診醫學會兒童急症委員會主任委員、台灣兒科醫學會兒童急診委員會委員和台北市消防局醫療顧問，由於在民間專業團體中主要的角色是研議專業團體之醫療政策建言，所以台北市衛生局於民國100年向台大醫院借調我，擔任台北市衛生局醫護管理處處長，這也是我首度擔任行政職，也開始逐漸成為醫界與醫政業務重要溝通橋樑之一。

104年借調期滿，我歸建台大醫院，除了原本醫療專業之外，也開始擔任台灣兒童健康聯盟秘書長和中華民國醫師公會全聯會副秘書長，從幕僚角色開始接觸擔任發言人的角色。106年開始轉換跑道到衛福部擔任醫事司簡任技正，108年更面臨百年大疫的挑戰，協助規劃醫療動員計畫。109年接任醫事司司長，更於111年擔任器官移植捐贈登錄中心執行長推動組織變革，將中心任務擴大為器官移植和病人自主推廣。

由於上述經歷，可以知道我是個樂於接受挑戰的人。但也因此必須時時刻刻學習新的事物，所以對於有學習新知的機會，我都希望能把握，除了提升自我能力之外，更希望能應用於自己的工作之中。

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