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保存年限：

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發文日期：中華民國110年8月25日

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速別：普通件

密等及解密條件或保密期限：

附件：(附件1 c15aa222f9eaf27c1d1dbd01f16b6e39_2021國際研討會-海報.png、附件2 c15aa222f9eaf27c1d1dbd01f16b6e39_2021.9.17研討會議程與C.V.pdf)

主旨：本院臨床試驗中心與財團法人醫藥品查驗中心共同舉辦「2021藥物開發之關鍵臨床計畫國際研討會(2021 Conference of Critical Clinical Initiatives in Drug Development)」，敬邀貴機構相關領域有興趣者踴躍報名參加並請協助公告周知，請查照。

說明：

一、研討會資訊：

(一)研討會日期：2021年09月17日（週五）。

(二)研討會時間：8:30~17:30。

(三)報名網址：[https://www.accupass.com/go/](https://www.accupass.com/go/DrugDevelopment)

DrugDevelopment，報名完成後以Youtube直播授課。

(四)參加對象：試驗主持人、研究護理師、試驗相關研究人員及有興趣了臨床試驗領域者。

(五)檢附「2021藥物開發之關鍵臨床計畫國際研討會」活動海報及相關資訊1份。

(六)主辦單位保留最終修改、變更、活動解釋及取消本活動之權利，若有相關異動將公告於報名網站。

二、因應臺灣嚴重特殊傳染性肺炎(COVID-19)防疫措施，

臺中榮民總醫院



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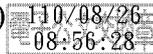


本研

討會採線上直播，以降低群聚傳播風險。

正本：國防醫學院三軍總醫院北投分院、中國醫藥大學附設醫院臺北分院、高雄市立大同醫院(委託財團法人私立高雄醫學大學附設中和紀念醫院經營)、聯新國際醫院、國立成功大學醫學院附設醫院、衛生福利部臺北醫院、衛生福利部彰化醫院、衛生福利部南投醫院、中國醫藥大學附設醫院、台灣社區醫院協會、高雄市立小港醫院(委託財團法人私立高雄醫學大學經營)、大千綜合醫院、基督復臨安息日會醫療財團法人臺安醫院、中國醫藥大學新竹附設醫院、國泰醫療財團法人汐止國泰綜合醫院、瑞芳礦工醫院、醫療財團法人羅許基金會羅東博愛醫院、臺北榮民總醫院、衛生福利部桃園醫院、衛生福利部苗栗醫院、衛生福利部臺東醫院、衛生福利部花蓮醫院、高雄市立聯合醫院、仁愛醫院、行天宮醫療志業醫療財團法人恩主公醫院、國泰醫療財團法人新竹國泰綜合醫院、臺北醫學大學附設醫院、彰化基督教醫療財團法人彰化基督教醫院、秀傳醫療財團法人彰濱秀傳紀念醫院、天成醫療社團法人天晟醫院、天主教耕莘醫療財團法人永和耕莘醫院、童綜合醫療社團法人童綜合醫院、光田醫療社團法人光田綜合醫院、高雄榮民總醫院、衛生福利部嘉義醫院、衛生福利部臺南醫院、臺北市立聯合醫院、中山醫學大學附設醫院、義大醫療財團法人義大醫院、衛生福利部豐原醫院、衛生福利部朴子醫院、國軍高雄總醫院、員榮醫療社團法人員榮醫院、臺中榮民總醫院、衛生福利部新營醫院、基隆市立醫院、衛生福利部雙和醫院(委託臺北醫學大學興建經營)、新北市立聯合醫院、振興醫療財團法人振興醫院、敏盛綜合醫院、衛生福利部基隆醫院、國防醫學院三軍總醫院、國立陽明交通大學附設醫院、國立臺灣大學醫學院附設醫院、醫療財團法人徐元智先生醫藥基金會亞東紀念醫院、國泰醫療財團法人國泰綜合醫院、台灣藥物臨床研究協會

副本：財團法人醫藥品查驗中心(含附件)



裝



線

2021 Conference of Critical Clinical Initiatives in Drug Development- Adaptive Designs, Precision medicine, and RWD/RWE

2021藥物開發之關鍵臨床計畫國際研討會 調適性設計、精準醫療及真實世界資料/證據

Date: 2021/9/17

Time	Agenda	Session Moderator
08:30 - 08:50	Registration	
08:50 - 09:10	Opening Remarks	Wen Jin Cherng , Chairman, Chang Gung Steering Committee, TW Yang Chih Shih , Counselor, Ministry of Health and Welfare, TW Ming Hsun Liu , Chief Executive Officer, Center for Drug Evaluation,
Keynote Speech 1		
9:10 - 10:00	Prof. Shein Chung Chow Biostatistics and Bioinformatics, Duke University, USA Topic : Innovative Approach on Rare Disease Drug Development	Chin Fu Hsiao , Investigator, National Health Research Institutes, TW Chyong Huey Lai , Vice Superintendent, Linkou Chang Gung Memorial Hospital, TW
10:00 - 10:10	Break	
Session1: RWD/RWE		
10:10 - 10:50	Prof. Toshimitsu Hamasaki Biostatistics Center and the Department of Biostatistics and Bioinformatics, George Washington University, USA Topic : Statistical opportunities and challenges in using real-world data for medical product development	Churn Shiouh Gau , Director, Preparatory Office of International Research Platform of Regulatory Science and Administration for Medicinal Products, TW
10:50 - 11:30	Prof. Chin Fu Hsiao Institute of Population Health Sciences, National Health Research Institutes, TW Topic : Is real world evidence real?	
11:30 - 11:50	Discussion	
11:50 - 12:50	Lunch	
Keynote Speech 2		
12:50 - 13:30	Prof. Haruko Yamamoto Pharmaceutical and Medical Devices Agency, JP Topic : PMDA perspective on the utilization of RWD/RWE for regulatory	Tsang Wu Liu , Investigator, National Institute of Cancer Research, TW
Session 2 : Precision Medicine		
13:30 - 14:10	Prof. Chien Feng Li Chi Mei Medical Center, TW Topic : Precision Medicine driven by Cancer Genomics	Tsang Wu Liu , Investigator, National Institute of Cancer Research, TW
14:10 - 14:30	Discussion	
Session 3: Adaptive Design		
14:30 - 15:00	Prof. Guei Feng Tsai Center for Drug Evaluation, TW Topic : Adaptive design in clinical trials	Yung Chang Lin , Director, Clinical Trial Center, Linkou Chang Gung Memorial Hospital, TW
15:00 - 15:20	Discussion	
15:20 - 15:40	Break	
Session 4: RWD/RWE		
15:40 - 16:20	Prof. Wen Yi Shau Senior Medical Director of Taiwan, Pfizer Inc. Topic : RWD/RWE general introduction, experiences, and difficulties	Chee Jen Chang , Distinguished Professor, Chang Gung University, TW
16:20 - 17:00	Prof. Ya Lei Wang Center for Drug Evaluation, TW Topic : RWE for use in regulatory perspective of view	
17:00 - 17:20	Discussion	

Opening Guest 開幕致詞

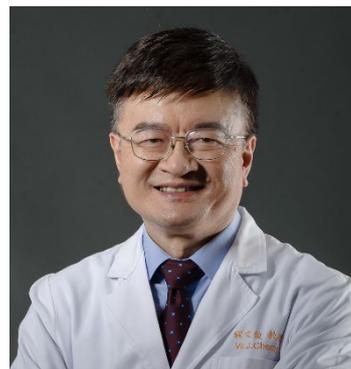
Wen Jin Cherng(程文俊), MD., FACC., FAHA, FESC.

Chairman

Chang Gung Steering Committee, Taiwan

Superintendent

Linkou Chang Gung Memorial Hospital, Taiwan



Education

Kaohsiung Medical University, College of Medicine, Taiwan

Post-Graduate Education

Cardiology Dep, National Cardiovascular Center, Japan (Scholarship of Japan Society of Ultrasonics in Medicine)

Cardiology Dep, Strong Memorial Hospital, University of Rochester, Rochester, New York, USA (Scholarship of Paul N. Yu Fellowship)

Fulltime Employments

1994 – 1998	Chairman, Department of Medicine, Chang Gung Memorial Hospital, Keelung.
1997 – 2003	Chairman, Department of Medicine, Chang Gung Memorial Hospital, Linkou, Taoyuan.
2001 – 2003	Vice-Superintendent, Chang Gung Memorial Hospital, Keelung.
2003 – 2016	Superintendent, Chang Gung Memorial Hospital, Keelung.
2016 – present	Director of Board, Chang Gung Medical Foundation.
2017 – present	Chairman, Chang Gung Steering Committee.
2017 – present	Superintendent, Chang Gung Memorial Hospital, Linkou, Taoyuan.

Academic Appointments

1999 – present	Professor of Medicine, Chang Gung Memorial Hospital.
2004 – present	Professor of Medicine, Chang Gung Medical College, Chang Gung University.

Opening Guest 開幕致詞

Yang Chih Shih(施養志), Ph.D.

Counselor

Ministry of Health and Welfare, Taiwan



Academic Qualifications

1985-1989 Ph.D: Department of Food Science, Rutgers, State University, USA

Present Appointments

- present Counselor, Ministry of Health and Welfare
- present Adjunct Professor, Department of Food Science, Fu Jen Catholic
- present Executive Director, AOAC International, Taiwan Section
- present Director, Agricultural Chemical Society of Taiwan
- present Managing Director, Agricultural Technology Research Institute
- present Director, Taiwan Association for Food Science and Technology

Previous Appointments

2011-2014 Director, Division of Research and analysis, TFDA

Opening Guest 開幕致詞

Ming Hsun Liu(劉明勳)

Chief Executive Officer

Center for Drug Evaluation, Taiwan

Tel:886-2-81706000

Email: mhliu941@cde.org.tw



Education & Training

2007	Elite Leadership Program John F. Kennedy School of Government, Harvard Kennedy School, USA
1994	Master of Pharmacy and Health Sciences Long Island University, NY, USA
1989	Bachelor of Department of Pharmacy Kaohsiung Medical College, Taiwan

Summary of Career

2020.03~now	Chief Executive Officer Center for Drug Evaluation
2018.10~2020.02	Director, Division of Medicinal Products Food and Drug Administration, Ministry of Health and Welfare
2016.7~ 2018.10	Director, Office of Public Relations Ministry of Health and Welfare
2013.7~ 2016.7	Senior Specialist, Department of Medical Affairs, Ministry of Health and Welfare
2009.12~2013.7	Senior Specialist, Bureau of Medical Affairs Department of Health
2004.11~2009.12	Section Chief, Bureau of Medical Affairs Department of Health
2000.7~2004.11	Section Chief, Centers for Disease Control Department of Health
1998.10~2000.7	Specialist, Office of Public Relations Department of Health
1996.12~1998.10	Specialist, NHI Medical Expenditure Negotiation Committee
1996.7~1996.12	Specialist, Bureau of Pharmacy Department of Health
1995.2~1996.7	Researcher, Bureau of Medical Affairs Department of Health

Moderator 主持人

Chin Fu Hsiao (蕭金福), Ph.D.

Investigator

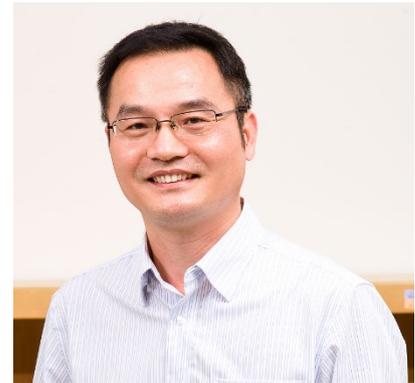
Institute of Population Health Sciences

National Health Research Institutes, Taiwan

35 Keyan Rd. Zhunan Town Miaoli 350, Taiwan

Tel: 037-246166 ext. 36106

Email: chinfu@nhri.org.tw



Education

University of Wisconsin-Madison, Wisconsin, U.S.A.: **Ph.D.** in Statistics, August 1997.

National Central University, Taiwan, R.O.C.: **M.S.** in Mathematics, June 1989.

National Central University, Taiwan, R.O.C.: **B.S.** in Mathematics, June 1987.

Experience

10/2011–Present	Investigator Institute of Population Health Sciences, National Health Research Institutes
8/2014 –8/2020	Deputy Director, Institute of Population Health Sciences, National Health Research Institutes
1/2011 – 7/2014	Director, Division of Clinical Trial Statistics, Institute of Population Health Sciences, National Health Research Institutes
8/2012–Present	Adjunct Professor, National Yang Ming University
8/2011–Present	Adjunct Professor, National Chiao Tung University
2/2006–Present	Adjunct Associate Professor, National Taiwan University
9/2004–9/2011	Associate Investigator, Division of Biostatistics and Bioinformatics, Institute of Population Health Sciences, National Health Research Institutes
2/2001–9/2004	Assistant Investigator, Division of Biostatistics and Bioinformatics, National Health Research Institutes

Moderator 主持人

Chyong Huey Lai (賴瓊慧), M.D.

Vice Superintendent

Linkou Chang Gung Memorial Hospital, Taiwan

Distinguished Professor

Chang Gung University College of Medicine, Taiwan



Dr. Chyong-Huey Lai is Professor and Vice Superintendent of Chang Gung Memorial Hospital, and Distinguished Professor of Chang Gung University College of Medicine, Taiwan. She was President of Taiwan Medical Women's Association (2014-2017). Dr. Lai obtained her M.D. degree from College of Medicine, National Taiwan University in 1982. She was President of the Taiwan Association of Gynecologic Oncologists (2002-2004) and a Council Member of International Gynecologic Cancer Society (2002-2006). Dr. Lai served the founding President of Asian Gynecologic Oncology Group (AGOG) 2005 to 2015, and has continued her service as Honorary Chairperson and Advisor of the AGOG since November 2015. Dr. Lai served the founding President of Taiwanese Gynecologic Oncology Group since April 2021. She serves several editorial boards, such as "Gynecologic Oncology" (2005 till present), Biomedical Journal (1996 till present), Journal of Formosan Medical Association (since 2014), and "International Journal of Gynecological Cancer" (2001-2008). Dr. Lai served the founding President of Taiwanese Gynecologic Oncology Group since April 2021. Dr. Lai's areas of research are cervical cancer prognosis, screening, HPV molecular epidemiology, molecular imaging, genomic medicine, and gynecologic cancer biology and therapeutics. She received Excellence Award from the National Science Council, Taiwan in 2007 and 2010, respectively, Outstanding Professionalism Award, Ministry of Health and Welfare, Taiwan in 2018, Medical Doctor's Role Model Award of Taiwan Medical Association, and We Innovators Award in 2020, respectively for her contribution in medical research. She serves several editorial boards, such as "Gynecologic Oncology" (2005 till present), Biomedical Journal (1996 till present), Journal of Formosan Medical Association (2014-2020), and "International Journal of Gynecological Cancer" (2001-2008).

Moderator 主持人

Churn Shiouh Gau (高純琇), Ph.D.

Director

Preparatory Office of International Research Platform of Regulatory Science and Administration for Medicinal Products, Taiwan



Dr. Gau is now the adjunct professor and the director of the Platform for Research and Inspiration in Regulatory Science, School of Pharmacy, National Taiwan University, and the distinguished senior specialist at the Ching-Kang Foundation for pharmacy Promotion. Dr. Gau also serves as the project director for the Office of Sustainable Platform for Big Data in Health, a program sponsored by the Ministry of Health and Welfare, Taiwan in 2021.

Dr. Gau had been the Chief Executive Director of Center for Drug Evaluation (CDE), Taiwan for 9 years, from April 1, 2011 to Feb. 29, 2020. CDE was established by Department of Health (DOH, now MOHW) in 1998, to assist the technical evaluation for market approval of drugs and medical devices. Dr. Gau was appointed as the Deputy Executive Director of CDE from June 2006 to Aug. 2009.

Dr. Gau received her Ph.D. degree in Pharmaceutics from the School of Pharmacy, University of Wisconsin-Madison, USA, in 1992. After that she returned to the School of Pharmacy, National Taiwan University (NTU) as a faculty member. During Aug. 1996 to July 2000, she was appointed as the Director of the Department of Pharmacy, NTU Hospital, one of the largest university-affiliated medical centers in Taiwan.

Prior to joining CDE, Dr. Gau served as expert/advisor in many Committees for MOHW, specializing in the evaluation of new drug application, assessment of drug safety, and accreditation of teaching hospital. Dr. Gau had led the projects for establishing the National ADR Reporting System in Taiwan for many years. Dr. Gau's researches focus on the use of claim database of the National Health Insurance program of Taiwan to study the prescription pattern of drug utilization, the adherence of drug usage to the professional practice guidelines, and the association of adverse reactions and clinical outcomes with the drug used. She has published more than sixty research papers in the fields of pharmaceutical sciences, drug safety, and pharmaceutical regulation in internationally recognized medical journals.

Moderator 主持人

Tsang Wu Liu (劉滄梧), M.D.

Investigator

National Institute of Cancer Research, NHRI, Taiwan



Education

1974-1981 M.D., Medical College National Taiwan University

Academic Appointments

- 2020.01 – present Investigator & Attending Physician, National Institute of Cancer Research, NHRI, Taiwan
- 2014.08 – present Deputy Director, National Institute of Cancer Research, NHRI, Taiwan
- 2002.07 – present Director, Taiwan Cooperative Oncology Group, NICR, NHRI, Taiwan
- 2006.03 – 2019.12 Associate Investigator & Attending Physician, National Institute of Cancer Research, NHRI,
- 1996.02 – 2006.02 Assistant Investigator & Attending Physician, National Institute of Cancer Research, NHRI, Taiwan
- 1996.05 – 1997.08 Research Associate, Department of Pharmacology, School of Medicine, Yale University, USA

Hospital Appointments

- 2008.01 – present Adjunct Attending Physician, National Taiwan University Hospital, Taiwan
- 1996.02 – 2007.12 Adjunct Attending Physician, Taipei Veterans General Hospital, Taiwan
- 1989.07 – 1996.01 Director, Resident and Fellow Training Program, Koo Foundation Sun Yat-Sen Cancer Center, Taiwan
- 1989.07 – 1996.01 Senior Staff, Medical Oncology, Koo Foundation Sun Yat-Sen Cancer Center, Taiwan

Professional Appointments and Activities

- 2017.01 – present Member, National Health Insurance Dispute Mediation Committee, MOHW
- 2016.01 – 2019.12 Chairman, The subcommittee for Review and Approval of Orphan Drugs, Committee for the Review and Examination of Rare Diseases and Orphan Drugs, FDA, MOHW
- 2008.01 – present Board member & council member, Asian Oncology Society (AOS) (formed from Asian Clinical Oncology Society)
- 2005.1 – present Member and Principal Investigator, Accreditation of Cancer Care Program, Health Promotion Administration, Ministry of Health and Welfare
- 2015.01 – 2016.12 Member, Central Board of Cancer prevention and Control, Executive Yuan
- 2011.05 – 2015.05 President, The Taiwan Oncology Society
- 2008.09 – 2011.08 Head, Department of Research Planning and Development, National Health Research Institutes
- 2005.08 – 2008.12 Chairman, Drug Evaluation Committee, the Bureau of Pharmaceutical Affairs, Department of Health
- 2000.07 – 2006.06 Executive Secretary, Medical Ethics Committee, National Health Research Institutes

Moderator 主持人

Yung Chang Lin(林永昌), M.D.

Director

Clinical Trial Center

Linkou Chang Gung Memorial Hospital, Taiwan

Email: yclinof@adm.cgmh.org.tw



Education

1980-1987, Bachelor of Medicine, Taipei Medical College, Taipei, Taiwan

Post-Graduate Education

July 1989 - June 1992	Resident, Department of Internal Medicine, Chang Gung Memorial Hospital (CGMH)
July 1992 - June 1993	Clinical Fellow, Division of Medical Oncology, Department of Internal Medicine, CGMH
July 1993 - June 1995	Fellow, Department of Medical Oncology, Division of Medicine, UT MD Anderson Cancer Center, Houston, USA

Academic Appointment

August 1995 - 1998	Clinical lecturer, Chang Gung University.
August 2002 -2011	Clinical Assistant professor, Chang Gung University
August 2011-	Clinical Associate professor, Chang Gung University

Employment Record

2018-	Director, Clinical Trial Center
2014 -2018	Deputy Director, Clinical Trial Center
2013 -2020	Director, Cancer Center, CGMH LinKou branch
2011 Feb-2017 June	Director, Division of Hematology/Oncology, Department of Internal Medicine, CGMH, LinKou
July 1995 -	Attending Physician, Division of Medical Oncology, Department of Internal Medicine, CGMH, LinKou

IRB Member/Staff

2000-	Member of Chang Gung Medical Foundation IRB
2003-	Member of Joint IRB
2010-	Secretary, Chang Gung Medical Foundation IRB

Moderator 主持人

Chee Jen Chang (張啟仁), Ph.D.

Distinguished Professor

Graduate Institute of Clinical Medical Sciences;

Department of Biomedical Sciences;

Clinical Informatics and Medical Statistics Research Center;

Research Services Center for Health Informatics

Chang Gung University, Taiwan



Professor Chang is a biostatistics-trained methodologist, expert in design and analysis of clinical trial and HTA research and development, focus on methodologies, harmacoeconomics modeling and big data analysis. He is a Distinguished Full Professor in Graduate Institute of Clinical Medical Sciences; Department of Biomedical Sciences; Director of Clinical Informatics and Medical Statistics Research Center; and Research Services Center for Health Informatics in Chang Gung University, Taiwan.

Professor Chang receives his PhD in Statistics from University of Iowa in USA. Then he became a faculty member in Department of Epidemiology and Social Medicine at Albert Einstein College of Medicine, Yeshiva University in New York City where he served as a faculty in teaching, research and research services in many clinical related researches.

During his service in AECOM, he helped to establish the General Clinical Research Center and Biostatistical Core of Cancer Center. In 1999, he returned to his birth country in Taiwan and helped to establish Clinical Trial Center in National Taiwan University Hospital. Later in 2006, he was invited to Chang Gung University as a Full Professor and continue his career in teaching and research. He also established a RCT/HTA master program in 2019 to educate the master students who are interested in pursuing their career in these areas.

His interests cover the areas in methodology development and study design of Randomized Clinical Trials (RCT), modeling approaches in pharmaceoeconomics (PE), real world data/evidence (RWD/RWE) derivations in health economics and outcome research (HEOR), which is applicable to health technology assessment (HTA) process of pharmaceutical industries and government agency. He also serves in many government committee members related to new drug approval in TFDA and health insurance reimbursement in NHIA. He was the president of Taiwan Society for Pharmacoconomics and Outcome Research (TaSPOR), 2012 ~ 2017, and the chairperson of ISPOR, Taiwan chapter. Now, he is the chair-elect for ISPOR Asia Consortium advisory board.

Prof. Chang is a statistical reviewer of many peer review journals and advisor editorial board. He has published more than 250 papers as author or co-author in many peer-reviewed journals.

Keynote Speaker 主題演講人

Shein Chung Chow(周賢忠), Ph.D.

Professor

Department of Biostatistics and Bioinformatics,
Duke University School of Medicine, USA



Shein-Chung Chow, Ph.D. is currently a Professor at the Department of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, North Carolina, USA. Dr. Chow is also a special government employee (SGE) appointed by the United States Food and Drug Administration (FDA) as an Oncologic Drug Advisory Committee (ODAC) voting member and Statistical Advisor to the FDA. Between 2017 and 2019, Dr. Chow was on-leave for FDA as Associate Director of the Office of Biostatistics responsible for statistical methodology research within FDA. Dr. Chow was the Editor-in-Chief of the Journal of Biopharmaceutical Statistics (1992-2020) and the Editor-in-Chief of the Biostatistics Book Series at Chapman and Hall/CRC Press of Taylor & Francis Group. He was elected Fellow of the American Statistical Association in 1995 and an elected member of the ISI (International Statistical Institute) in 1999. Dr. Chow has published more than 320 methodology papers and 32 books including Design and Analysis of Clinical Trials, Adaptive Design Methods in Clinical Trials, and most recently Innovative Methods for Rare Diseases Drug Development.

Speaker 主講人

Toshimitsu Hamasaki, Ph.D.

Research Professor

Biostatistics Center and the Department of Biostatistics and
Bioinformatics, George Washington University, USA



Toshimitsu Hamasaki is a Research Professor of the George Washington University (GWU) Biostatistics Center and the Department of Biostatistics and Bioinformatics. He is the Associate Director of the Statistical and Data Management Center (SDMC) for the Antibacterial Resistance Leadership Group (ARLG), a collaborative clinical research network that prioritizes, designs, and executes clinical research to reduce the public health threat of antibacterial resistance. Prior to joining GWU, he worked at Shionogi, Pfizer, Osaka University, and National Cerebral and Cardiovascular Center. His research interests include the design, monitoring, analyses, and reporting of clinical trials. He is the author of more than 200 peer-reviewed publications and four textbooks on statistical methods in clinical trials including "Sample Size Determination in Clinical Trials with Multiple Endpoints" and "Group-Sequential Clinical Trials with Multiple Co-Objectives".

Dr. Hamasaki is the Editor-in-Chief of *Statistics in Biopharmaceutical Research*, an Official Publication of the American Statistical Association (ASA). He also currently serves as an Editor for *Statistical Communications in Infectious Diseases* and an Editorial Board Member for *Contemporary Clinical Trials*. He served as an Associate Editor or Editor for several journals including *Statistics in Biopharmaceutical Research*, *Journal of Biopharmaceutical Statistics*, *Japanese Journal of Statistics and Data Science*, *CHANCE*, and *Journal of the Japanese Society of Computational Statistics*. He is co-chair of the Society for Clinical Trials (SCT) Program Committee. He was the chair of the ASA Committee on International Relation in Statistics, a member of the Steering Committee for the Adaptive designs CONSORT Extension (ACE) Project, an extension to the CONSolidated Standards of Reporting Trials (CONSORT) Statement for adaptive clinical trials, and a member of Implementation Working Group on ICH-E5 Guideline "Ethnic Factors in the Acceptability of Foreign Clinical Data" as a representative of Japan Pharmaceutical Manufacturers Association.

Dr. Hamasaki is an elected member of International Statistical Institute (ISI) and a fellow of the ASA. He received the Distinguished Article Award from the Japanese Society of Computational Statistics and Hida-Mizuno Prize from the Behaviormetric Society of Japan.

Speaker 主講人

Chin Fu Hsiao (蕭金福), Ph.D.

Investigator

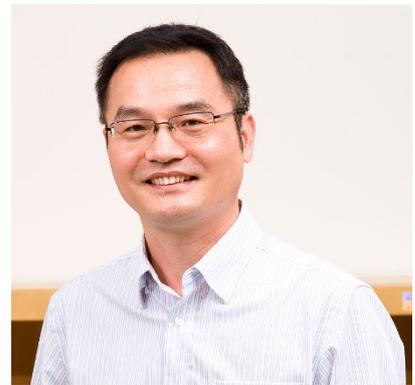
Institute of Population Health Sciences

National Health Research Institutes, Taiwan

35 Keyan Rd. Zhunan Town Miaoli 350, Taiwan

Tel: 037-246166 ext. 36106

Email: chinfu@nhri.org.tw



Education

University of Wisconsin-Madison, Wisconsin, U.S.A.: Ph.D. in Statistics, August 1997.

National Central University, Taiwan, R.O.C.: M.S. in Mathematics, June 1989.

National Central University, Taiwan, R.O.C.: B.S. in Mathematics, June 1987.

Experience

10/2011–Present	Investigator Institute of Population Health Sciences, National Health Research Institutes
8/2014 –8/2020	Deputy Director, Institute of Population Health Sciences, National Health Research Institutes
1/2011 – 7/2014	Director, Division of Clinical Trial Statistics, Institute of Population Health Sciences, National Health Research Institutes
8/2012–Present	Adjunct Professor, National Yang Ming University
8/2011–Present	Adjunct Professor, National Chiao Tung University
2/2006–Present	Adjunct Associate Professor, National Taiwan University
9/2004–9/2011	Associate Investigator, Division of Biostatistics and Bioinformatics, Institute of Population Health Sciences, National Health Research Institutes
2/2001–9/2004	Assistant Investigator, Division of Biostatistics and Bioinformatics, National Health Research Institutes

Keynote Speaker 主題演講人

Haruko Yamamoto, M.D., Ph.D.

Chief Medical Officer, Associate Executive Director
Pharmaceutical and Medical Devices Agency, Japan



Since graduating from Osaka University School of Medicine, Dr. Haruko Yamamoto has worked for many years at the National Cardiovascular Center as a specialist in neurology, notably cerebrovascular accidents (acute stroke) and higher brain dysfunction. While playing an active role as a medical doctor on the front lines, Dr Yamamoto directed the research and development of new drugs and medical devices, and the creation of innovation. She also contributed widely to the promotion of the development of new drugs and medical devices in the planning, management, and education of clinical trials and clinical research in her role as Director, Center for Advancing Clinical and Translational. Since October 2020, she has been working for Pharmaceutical and Medical Devices Agency, the Japanese regulatory agency, as the Chief Medical Officer and the Associate Executive Director. She has been one of the 210 Council Members of the Science Council of Japan since October 2020. She received a Ph.D. from Osaka University School of Medicine.

Speaker 主講人

Chien Feng Li (李健達), M.D., Ph.D.

Chair

Department of Medical Research, Chi Mei Medical Center, Taiwan



Education

1995-2002 Kaohsiung Medical University, Kaohsiung, Taiwan: M.D. in Medicine

2009-2012 National Sun Yat-sen University, Kaohsiung, Taiwan: Ph.D. in Biomedical Sciences

Positions and Employment

2002-2007	Resident, Department of Pathology, Chi Mei Medical Center, Taiwan
2007-2009	Attending physician, Department of Pathology, Chi Mei Medical Center, Taiwan
2009-2019	Chief, Division of Clinical Pathology, Department of Pathology, Chi Mei Medical Center, Taiwan
2010-2013	Adjunct attending physician, National Institute of Cancer Research, National Health Research Institutes, Taiwan
2010-Present	Principal Investigator, Translational Research Laboratory of Human Cancers, Department of Medical Research, Chi Mei Medical Center, Taiwan
2012-2015	Assistant professor, Department of Biotechnology, Southern Taiwan University of Science and Technology, Taiwan
2013-2018	Joint-Appointment Assistant Investigator, National Institute of Cancer Research, National Health Research Institutes, Taiwan
2015-2018	Associate Professor, Department of Biotechnology, Southern Taiwan University of Science and Technology, Taiwan
2017-2021	Chair, Department of Pathology, Chi Mei Medical Center, Taiwan
2018-Present	Joint-Appointment Associate Investigator, National Institute of Cancer Research, National Health Research Institutes, Taiwan
2018-2019	Professor, Department of Biotechnology, Southern Taiwan University of Science and Technology, Taiwan
2019-Present	Joint-Appointment Professor, Institute of Medical Science and Technology, National Sun Yat-sen University
2020-Present	Joint-Appointment Investigator, National Institute of Cancer Research, National Health Research Institutes, Taiwan

2021-Present Chair, Department of Medical Research, Chi Mei Medical Center, Taiwan

Other Experience and Professional Memberships

2004- United States and Canadian Academy of Pathology
2015- International Society of Bone and Soft Tissue Pathology
2019- American Associations for Cancer Research

Honors

2006 IACP best abstract award
2009 Best research paper (Taiwan Academy of Pathology)
2011 Outstanding poster award, Asia-Pacific Congress on Pancreas and Biliary Tract Cancer, 14th TCOG Annual Meeting & 2010 International Conference on Translational Cancer Research
2012 IACP best abstract award (corresponding author)
2012 National Innovation Award (Teamed with National Cheng-Kung University)
2014 IACP best abstract award (corresponding author)
2014 Young Investigator (Encouragement) Award, Japanese Society of Medical Oncology (JSMO)
2014 Travel Award, Japanese Society of Medical Oncology (JSMO)
2014 National Innovation Award (Teamed with Kun Shan University)
2015 Best Poster Award (Multi-national Alliant Gastro-Intestinal Cancer Symposium, 2015)
2015 Travel Award (Multi-national Alliant Gastro-Intestinal Cancer Symposium, 2015)
2015 National Innovation Award (Teamed with Kun Shan University)
2015 National Innovation Award (Teamed with National Cheng-Kung University)
2016 Academic Research Award-Wu-Da-You Memorial Award
2016 Outstanding Alumni Award, National Sun Yat-sen University
2020 Young Investigator Outstanding Cancer Research Award, Taiwan Oncology Society

Journal Editorial Board (SCI)

2010-Present Editorial board, Oncology letters (Spandidos publication)
2018-Present Associate Editor-in-Chief, Cancer Management of Research (Dove Medical Press)
2020-Present Associate Editor, Frontiers in Cell and Developmental Biology (Frontiers Media S.A.)
2020-Present Associate Editor, Frontiers in Oncology (Frontiers Media S.A.)
2020-Present Academic Editor, Medicine (Lippincott Williams & Wilkins)
2021-Present Editorial board, International Journal of Molecular Sciences (MDPI)

Grant Review (International)

2015,2018,2020 Ministry of Health, Italy
2015 Netherlands Organisation for Scientific Research (NWO), Netherlands

Speaker 主講人

Guei Feng Tsai (蔡貴鳳), Ph.D.

Statistical Team Leader

Center for Drug Evaluation, Taiwan

Email: gftsai@cde.org.tw



Education

Ph.D. Statistics Oregon State University, USA

MS Biometry Division, Dep. of Agronomy National Taiwan University

BS Department of Agronomy National Taiwan University

Work Experience

2014 – Current Statistical Team Leader, Division of New Drugs, Center for Drug Evaluation, Taiwan

2006 – 2014 Statistical Reviewer, Division of New Drugs, Center for Drug Evaluation, Taiwan

2005 – 2006 Post-doc fellow, Department of Statistics, Northwestern University, USA

Key Skills

Clinical trial design

Interpretational skills

Sample size calculation

Consultation

Statistical inference and modeling

Regulatory guidance knowledge

Speaker 主講人

Wen Yi Shau (邵文逸) M.D., Ph.D.

Senior Medical Director of Taiwan
Pfizer Inc.



Work Experience

- 2015-present Senior Medical Director of Taiwan, Pfizer Inc.
- 2014-2016 PEH (Pfizer Essential Pharma Business) Medial Lead of Taiwan & APAC Mature Market (Taiwan, Hong Kong & Singapore), Pfizer Inc.
- 2012-2015 Medical Director of Taiwan, Pfizer Inc.
- 2008-2012 Principal Researcher, Health Technology Assessment, Center for Drug Evaluation, Taiwan.
- 2005-2007 Epidemiology Director of Asia Pacific Region, GlaxoSmithKline Pharmaceuticals R&D.
- 2003-2005 Medical Director, GlaxoSmithKline Pharmaceuticals Taiwan Branch.
- 2001-2003 Clinical Development Manager, GlaxoSmithKline Pharmaceuticals Taiwan Branch.
- 1992-1993 Resident, department of surgeon, Hospital of Kaohsiung Medical College, Kaohsiung.
- 1990-1991 Resident, department of surgeon, Kee-Long Naval Hospital, Kee-Long.

Profession experience

- 2019-present Adjunct associate professor, Graduate Institute of Clinical Pharmacy, College of Medicine, National Taiwan University.
- 2012-present Adjunct associate professor, Graduate Institute of Clinical Medicine, College of Medicine, National Taiwan University.
- 2002-2012 Adjunct assistant professor, Graduate Institute of Clinical Medicine, College of Medicine, National Taiwan University.
- 1998-2001 Teaching assistant, Graduate Institute of Clinical Medicine, College of Medicine, National Taiwan University.

Education

- 1995-2000 Ph.D., Graduate Institute of Epidemiology, College of Public Health, National Taiwan University.
- 1994-1996 Postgraduate Training Program in Applied Epidemiology, Field Epidemiology Training Program (FETP) of ROC, also certificated by Centers for Disease Control and Prevention, USA.
- 1994-1995 M.Ph., Graduate Institute of Epidemiology, College of Public Health, National Taiwan University.
- 1983-1990 M.D., Department of Medicine, Kaohsiung Medical College.

Research interest

Epidemiology and Clinical research methodology, Pharmacoeconomic, Health care Database analysis.

Speaker 主講人

Ya Lei Wang (王亞蕾), M.D.

Senior Reviewer

Center for Drug Evaluation, Taiwan

E-mail: ylwang448@cde.org.tw



Current Position

Section Chief, Division of new drugs.

Professional Experience

- 2021 - now Senior Reviewer. Center of Consultation, Center for Drug Evaluation (CDE), Taiwan.
- 2018 - 2021 Section Chief. Division of new drugs, Center for Drug Evaluation (CDE), Taiwan.
- 2013 - 2018 Medical Reviewer. Division of new drugs, Center for Drug Evaluation (CDE), Taiwan.
- 2013 - now Adjunct Physician, Department of Pediatric, Far Eastern Memorial Hospital.
- 2010 - 2012 Research Fellow in Neonatology. Department of Pediatric, National Taiwan University Hospital.
- 2007 - 2010 Resident and Chief Resident. Department of Pediatric, National Taiwan University Hospital.

Highest Education

- 2000-2007 Medical Doctor. Department of Medicine, College of Medicine, National Taiwan University.