

台灣臨床試驗資訊平台更新說明

TAIWANCLINICALTRIALS.TW

資深推廣經理

蘇福墩

諮詢輔導中心

2020/9/23

2020 TCTs 新版上線



精進臨床試驗能量 及國際躍升計畫

推動臨床試驗 發展計畫

優化臨床試驗環境
增加臨床試驗
執行力

促進國內產業發展
提升國際臨床試驗競爭力

鼓勵醫師執行臨床試驗
加強相關人才的培育

更新目標

友善搜尋環境
增加台灣能見度

UI/UX以
使用者為中心

獨創性、互動式、
專業性

RWD相容於各式
瀏覽器與行動裝置



台灣臨床試驗資訊平台改版架構

卓越亮點

- 國家健康資料
- 臨床試驗資訊
- 法規架構

TCTC

- 聯盟成員
- 各聯盟成果
- 聯盟服務

未來新增

- PI資料庫
- 民眾衛教



臨床試驗中心

- 試驗中心簡介
- 重點領域
- 相關成果/認證

c-IRB

- 機制介紹
- 主副審醫院
- 統計與訊息

其它

- e-learning
- 民眾專區
- 相關聯結
- 最新消息

Taiwanclinicaltrials.tw



INTRODUCTION

TAIWAN SPOTLIGHT

CLINICAL TRIAL CENTERS

TCTC

c-IRB

RESOURCES

e-LEARNING



TAIWAN CLINICAL TRIALS

TaiwanClinicalTrial.tw is an information platform that provides the public, academic, and industry with comprehensive information about clinical trials in Taiwan.

受試者招募廣告



受試者招募廣告-申請



支援與服務






支援與服務

平台簡介 申請資訊 臨床試驗中心 TCTC c-IRB 友善連結 政策專區 學習平台

相關協會

相關協會 臨床試驗受理機構 相關連結

 台灣藥物臨床研究協會 Taiwan Clinical Research Association	台灣藥物臨床研究協會(TCRA) Taiwan Clinical Research Association http://www.tcrs.org.tw/?lang=en
 臺灣製藥工業同業公會 Taiwan Pharmaceutical Industry Association	臺灣製藥工業同業公會(TPMA) Taiwan Pharmaceutical Manufacturer's Association http://www.tpma.org.tw/index.php?lang=en
 台灣藥品行銷暨管理協會 Taiwan Pharmaceutical Marketing & Management Association	台灣藥品行銷暨管理協會(TPMMA) Taiwan Pharmaceutical Marketing & Management Association http://www.tpmma.org.tw/
	台北市西藥代理商同業公會(TPADA) Taipei Pharmaceutical Agents and Distributors Association http://www.tpada.org.tw/

臨床試驗受託機構

相關協會

臨床試驗受託機構

相關連結



台灣醫健維康生技顧問有限公司
A2 Healthcare Taiwan Corporation

台灣醫健維康生技顧問有限公司

A2 Healthcare Taiwan Corporation

<http://www.a2healthcare.com.tw/>



美商安美睿生技有限公司

Amarex Taiwan, LLC

<https://www.amarex.tw.com/home.cn>



亞法貝德生技股份有限公司
AlfaBeta Clinical Research Co., Ltd.

亞法貝德生技股份有限公司

AlfaBeta Clinical Research Co., Ltd.

<http://www.alfabetacro.com/>



倍思大生技股份有限公司
Bestat Pharmaservices Corp.

倍思大生技股份有限公司

Bestat Pharmaservices Corporation

<http://www.bestat.com.tw/>



WHY TAIWAN ?

- Excellent Clinical Trial Centers & IRBs
- High Quality Trials
- Globally Harmonized Regulations
- Expedited Review Process for MRCTs
- Outstanding Healthcare System
- Professional Consultation Service through Center for Drug Evaluation



TaiwanClinicalTrials

Taiwan Profile

- Population : 23.60 million
- Land Area : About 36,000 km²
- Capital City : Taipei
- Health System : Universal healthcare system through National Health Insurance (NHI) that covers 99.84% of the population.

Clinical Trial Centers Inspected by International Regulatory Institutions

*GCP inspection result with no major and critical findings.

Northern Taiwan	
US FDA*	National Taiwan University Hospital
	Taipei Veterans General Hospital
	Taipei Chang Gung Memorial Hospital
EMA	Hidexia General Hospital
	Taipei Medical University Hospital
	Taipei Veterans General Hospital
PMDA*	Linkou Chang Gung Memorial Hospital
	National Taiwan University Hospital
Central Taiwan	
US FDA*	Chung Shan Medical University Hospital
	Taichung Veterans General Hospital
	China Medical University Hospital
PMDA*	Chung Shan Medical University Hospital
Southern Taiwan	
US FDA*	Kaohsiung Medical University Chungcho Memorial Hospital
	National Cheng Kung University Hospital
	Kaohsiung Chang Gung Memorial Hospital
	Kaohsiung Veterans General Hospital

International Regulatory Institutions

- Taiwan FDA/TFDA



Globally First Approved New Drugs

GIOTRIF

- Afatinib
- EGFR TKI
- Approved for NSCLC
- Taiwan participation:
 - Phase I trials: 81%, 17%
 - Phase II trials: 21%, 18%
- C.H. Yang (NTHU): Global chairman

ONIVYTE

- Liposomal irinotecan
- Approved for metastatic pancreatic cancer
- Taiwan participation:
 - Phase I trials: 55%
 - Phase II trials: 23%
- L.T. Chen (NCKUH):
 - Global chairman (Phase II)
 - Corresponding author of Phase III NAPOLI-1 primary trial's publication in The Lancet

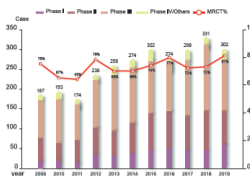
Top1 Patient Recruitment in Asia

- TVGH - ENGAGE-AF-TIMI-48
- NTUH - NCT02719743, KATHERINE, HIMALAYA, NCT01970865
- TMUH - AEGEAN, NCT02089087
- CMUH - NCT01888432, NCT01580639, NCT03171155
- NCKUH - NCT01494506

Health Databases for Efficient Clinical Research

- **NHI Research Database** : Over 20 years of data collection through NHI
- **Taiwan Stroke Registry (TSR)** : >40,000 stroke patients registered
- **Taiwan Cancer Registry (TCR)** : Nationwide population-based cancer registry system since 1979

- Cancer, Diabetes, Hepatology, Nephrology Databases
- Kaohsiung Medical University Chungcho Memorial Hospital
- Cancer, Cardiology, Endocrinology, Rheumatology Databases
- National Cheng Kung University Hospital
- Brain Tumor, Dermatology, Gynecology, Oncology Databases
- Linkou Chang Gung Memorial Hospital



Taiwan has demonstrated its ability in participating in multiregional clinical trials (MRCTs). The percentage of MRCTs has an average of 72% within recent years.

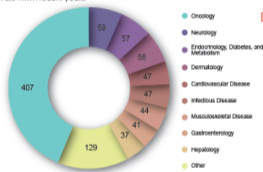


Table 2. The Number of INDs Approved by Therapeutic Area (N=432, 2015-2019)

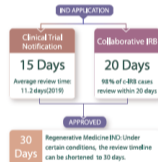
Globally Harmonized Regulations

- Follow ICH Guidelines
- ICH Regulatory Member
- Participated in more than 20 expert working groups
- GCP/PICS/ GMP Compliance
- Medical device trials follow ISO 14155

High Quality Medical Institutions & IRBs



Expedited Review Process



Outstanding Academic Accomplishments

Many Taiwan PI have remarkable publications in influential international journals due to their participation in important clinical trials.

* Selective publications: 2019-2020, N Engl J Med, and The Lancet

Organization	PI	Drug/Study	Therapeutic Area	Journal
TVGH	Chen-Gu, Chiang	Dapagliflozin/NCT03081124	HRF	N Engl J Med. 2019; 381(21): 1999-2008
NCKUH	Wu-Chou, Su	Fembrolumab/KEYNOTE-042	NSCLC	Lancet. 2019; 393(10185): 1819-1829
	Chio-Jui, Yan	Ramucicab/REACH-2	HCC	Lancet Oncol. 2019; 20(2): 202-209
NTUH	Chun-Hsiang, Huang	Treatumab/KATH-016	Breast Cancer	N Engl J Med. 2019; 380: 417-428
	An-Hsi, Chang	Ibraxo-400	HCC	N Engl J Med. 2020 in press
CMUH	Yan-Hou, Chen	US-401/NCT02089144	HV	N Engl J Med. 2019; 380(14): 1439-1446
TMUH	Chen-Yuan, Chiang	STRAM	MDR-IR	N Engl J Med. 2019; 380(13): 1201-1213
	Chung-T, Hsu	Afrezza/EXTEND	Stroke	N Engl J Med. 2019; 380(19): 1799-1803
CMUH	Su-Peng, Yan	ECHELON-2	Lymphoma	Lancet. 2019; 393(10145): 229-240



Scan QR code for more info of Taiwan Clinical Trials



Oncology



Li-Yuan, Bai
M.D., Ph.D.

China Medical University Hospital

- Director - The Division of Hematology and Oncology, China Medical University Hospital


Highlights

- DSMB committee (Phase I Study of HC-6004 in Combination With S-FU and Cetuximab as First-line Treatment in Patients With Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck)
- Leading PI (Phase I Trial of Efficacy S-1, Leucovorin and Gemtuzumab (GG21) in Elderly Patients with Locally Advanced or Metastatic Pancreatic Adenocarcinoma)
- Leading PI (Phase II Study of Neoadjuvant Irinotecan (at 80, 160, 240, 320, 400mg) with S-FU and Leucovorin in Squamous Cell Carcinoma SCC of Head & Neck and Esophagus after Prior Platinum-based Chemotherapy or Chemoradiotherapy)

Research Areas of Interest
Gastric cancer, pancreatic cancer, Biliary tract cancer, neuroendocrine tumor, Gastrointestinal stromal tumor, lymphoma

>70 >70

Oncology



Ann-LS, Cheng
M.D., Ph.D.

National Taiwan University Hospital

- Distinguished Professor - Department of Internal Medicine, National Taiwan University College of Medicine
- Superintendent - National Taiwan University Cancer Center Hospital


Highlights

- Prof. Cheng has been the Global leading PI (Globalw150 - EYENOTE-240 - CENTRAL, APRC, RESOLVE, ...) and Distinguished member in many global trials.
- He contributed significantly in all first-line treatment of advanced hepatocellular carcinoma(HCC) - sorafenib, lenvatinib, and the combination of apixotamab and lenvatinib (MORAVI, New England Journal of Medicine, 2020, DOI:10.1056/NEJMOA1911965)

Research Areas of Interest
Medical Oncology, HCC

>170 >460

Oncology



Tzu-Yi, Chao
M.D., M.D.

Taipei Medical University Shuang Ho Hospital

- Chief - Department of Medical Affairs, Shuang Ho Hospital, Taipei Medical University
- Chief and Professor - Division of Hematology/Oncology, Shuang-Ho Hospital, Taipei Medical University

Highlights

- Participated in over 120 investigations ranging from Phase I to Phase IV studies since 1997.
- Successful trials include capecitabine (Prelado) in the treatment of ACC, trabectedin (Brentuximab) in HDN for HD and CD20-CD30/CD22 stain, gefitinib (Daxid) in SFGC, etc., etc.
- Serving in the Asia-Pacific regional steering committee of Moxetin study. Also has been the steering committee member of Asia-Pacific breast (adjuvant I and II) studies.
- Currently involved in the trials of prevention and treatment of hepatitis B recurrence after chemotherapy in lymphoma and breast cancer patients.

Research Areas of Interest
Hematology and Oncology, Translational studies

>100 >200

Oncology



Chao-Hua, Chiu
M.D.

Taipei Veterans General Hospital

- Director - Division of Thoracic Oncology, Department of Chest Medicine, Taipei Veterans General Hospital
- Executive Secretary - Human Research Protection Center, Taipei Veterans General Hospital

Highlights

- Successfully managed the accreditation process of the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in 2018 and 2019.
- Actively participates in clinical trials as a senior investigator, lung cancer

Research Areas of Interest
Lung cancer

>70 >40

Oncology



Tzai-Yun, Chen
M.D.

National Cheng Kung University Hospital

- Director - Clinical Trial Center, National Cheng Kung University Hospital

Highlights

- Early phase drug development

Research Areas of Interest
Herzule Oncology, Stem Cell Transplantation and Coagulation, Cancer treatment and consultation, Hematological Diseases

>50 >70

Oncology



Ming-Feng, Hou
M.D.

Kaohsiung Medical University Chung-Ho Memorial Hospital

- Superintendent - Kaohsiung Medical University Chung-Ho Memorial Hospital

Highlights

- Specialize in breast cancer diagnosis, surgery, chemotherapy, and molecular oncology.
- The Third President of the Breast Cancer Society of Taiwan.
- Dr. Hou's research group joint in International breast cancer research with Academic Society and 70 service General Hospital, and the related result was published in Nature.

Research Areas of Interest
Breast Cancer

>40 >250



Hepatology



Ting-Tsang, Cheng
M.D.

National Cheng Kung University Hospital

- Distinguished Professor - Internal Medicine, Medical College, National Cheng Kung University
- Director - Biotechnology Center of Hepatology, National Cheng Kung University

Highlights

- Great contribution to hepatitis medication
- Global leading PI for one trial of Entecavir+AC+BBV Asia-Pacific Steering Committee Members

Research Areas of Interest
Hepatitis, Hepatocellular Carcinoma, Virology, Gastroenterology

>60 >190

Hepatology



Wen-Juan, Jeng
M.D., Ph.D.

Chang Gung Memorial Hospital, Linkou Branch

- Associate Professor, Attending Physician - Department of Gastroenterology and Hepatology, Chang Gung Memorial Hospital, Linkou
- Assistant Professor - Chang Gung University, College of Medicine

Highlights

- Dr. Jeng has been main PI for BBV phase II and III trials for the treatment of hepatitis B.
- Editorial board member of global HEPATOITB study and member for TAIL, EASL and AASLD Subcommittee member of AASLD during 2019-2022.

Research Areas of Interest
Hepatitis B, Viral hepatitis, Clinical hepatology

>10 >70

Hepatology



Wen-Long, Cheng
M.D., Ph.D.

Kaohsiung Medical University Chung-Ho Memorial Hospital

- Vice Superintendent - Kaohsiung Medical University Chung-Ho Memorial Hospital
- Chief Editor - The Kaohsiung Journal of Medical Science

Highlights

- Dr. Cheng is a reviewer and member of editorial board of several scientific journals, and the Chief Editor of the Kaohsiung Journal of Medical Science, and World Journal of Hepatology.
- He was the past President of the Taiwan Association for the Study of the Liver in 2020 and 2011.

Research Areas of Interest
Hepatobiliary and pancreatic diseases, viral hepatitis particularly HBV and HCV, Liver fibrosis, hepatocellular carcinoma

>120 >450

Hepatology



Jia-Hong, Kao
M.D., Ph.D.

National Taiwan University Hospital

- Chief - Division of Gastroenterology and Hepatology, Department of Internal Medicine, National Taiwan University Hospital
- Lit-Ching Biological Professor - Graduate Institute of Clinical Medicine, National Taiwan University College of Medicine


Highlights

- Prof. Kao has conducted many global and local phase I and II trials for the treatment of hepatitis B, such as pegylated interferon and nucleos(t)ide analogues (e.g. tenofovir, entecavir, pegylated interferon plus ribavirin and a novel DAA for HCV).
- He joined several early phase clinical trials for the cure of HBV and treatment of NAFLD.
- Steering commit of AASLD low and high-dose AASLD annual meeting in 2012 with nearly 4000 international and local delegates.

Research Areas of Interest
Viral hepatitis, Hepatology, Gastroenterology

>70 >560

Hepatology



Long-Bin, Jeng
M.D.

China Medical University Hospital

- Superintendent - China Medical University Hospital, Organ Transplantation Center
- CEO - China Medical University Hospital, Cell Therapy Center
- CEO - China Medical University Development Committee of CMU and CMUH


Highlights

- Global leading PI of steering committee
- TAGI member around the world
- Global expert for entering worldwide recruitment by clinical trial world evidence
- Support Carven liver transplantation indication in Japan.
- International speaker at international congresses
- Fund and corresponding author in international journals
- Pre-surgery program for Asian liver transplantation team

Research Areas of Interest
General surgery, Surgery of hepatobiliary pancreatic system Transplantation: Liver, Kidney, pancreas and small bowel transplantation Cell Therapy

>20 >340

Hepatology



Ming-Pung, Yu
M.D., Ph.D.

Kaohsiung Medical University Chung Ho Memorial Hospital

- Senior Vice President - Kaohsiung Medical University
- Academic Editor - PLOS ONE
- Attending Physician - Hepatobiliary Section, Department of Internal Medicine, Kaohsiung Medical University Hospital

Highlights

- Dr. Yu is a board certified internist and gastroenterologist. Specializes in Hepatology He has published more than 100 articles in peer-reviewed journals and 10 books.
- Editorial roles in PLOS ONE, World Journal of Hepatology, and Korean Journal of Hepatology
- Editorial Board Member of "Hepatology" and "The Journal of Infectious Diseases"
- Decision for major international journals such as The Lancet, Annals of Internal Medicine, Clinical Microbiology Reviews, Gastroenterology, Hepatology, Gut, Journal of Hepatology, Clinical Infectious Diseases, Thrombosis, Genome Medicine, and Journal of Infectious Diseases Gastroenterology Hepatology, Gut, Journal of Hepatology, Clinical Infectious Diseases, Thrombosis, Genome Medicine, Thrombosis, Scientific Reports and Journal of Infectious Diseases.

Research Areas of Interest
HBV, HCV, NAFLD, NAHG, cirrhosis, liver cancers, therapeutic approach of liver disease

>60 >320

臨床試驗人才培育相關計畫



藥品臨床試驗教育
訓練及受試者權益
促進計畫



精進臨床試驗
管理能力計畫



推動臨床試驗
發展計畫

台灣臨床試驗教育訓練中心

單一平台
資源集中

知識與學分
最佳選擇

廠商、醫事人員
便利&效率

推動力道UP





台灣臨床試驗教育訓練中心

Center for Clinical Trial Training in Taiwan

最新消息

[更多消息 >](#)[2020-08-26](#)

本中心將於109年8月31日AM9:00~PM18:00實施維護作業

[2020-04-20](#)

取得證書所需條件

[2019-12-17](#)

新手須知-線上平台使用教學

[2020-04-29](#)

107年度藥品臨床試驗線上課程將於2020年5月20日下架，請有興趣...

[2020-04-20](#)

註冊會員後，須透過電子郵件認證才能登入本中心備修課程

More information



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More information



Center for Clinical Trial
Training in Taiwan



謝謝大家