



TaiwanClinicalTrials

TAIWAN

EXPLORE THE POTENTIAL OF ASIA

ABOUT TAIWAN

- Population : 23.41 million
- Land Area : 36,193 km² (13,974 mi²)
- Capital City : Taipei



Universal Healthcare System

National Health Insurance covers >99% of the population.



ICH Regulatory Member

Participated in >20 expert working groups.



QUALIFIED INFRASTRUCTURES



424 Medical Institutions



143 Clinical Trial Sites



22 Medical Centers

Table 1. Number of IND Applications Submitted by Year, 2013-2022

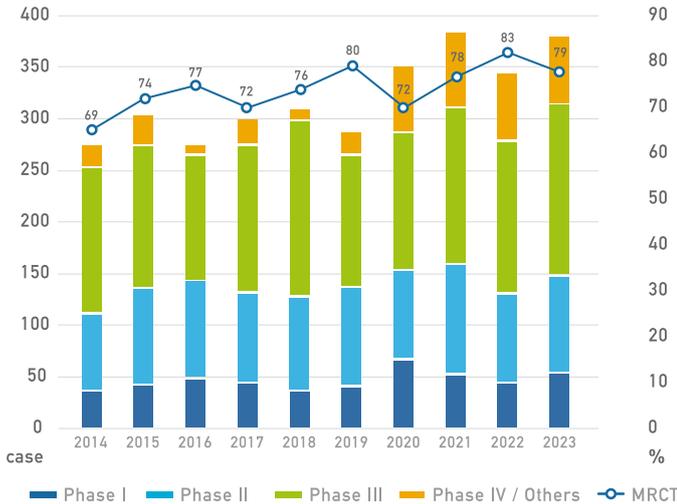
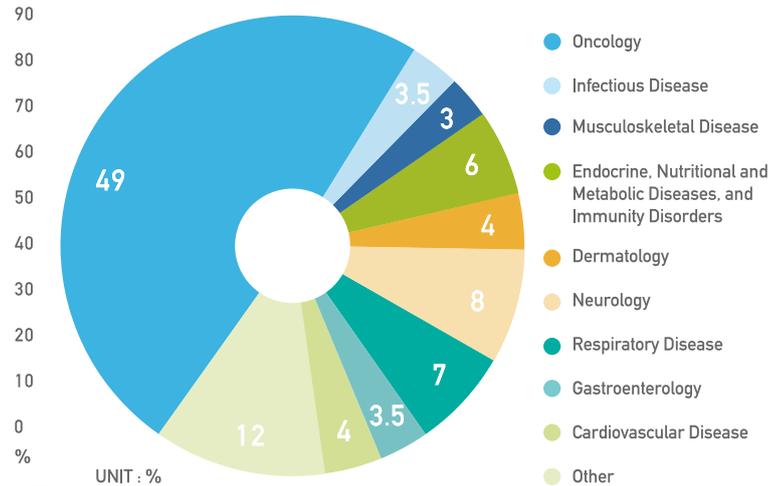


Table 2. Percentage of IND Applications Submitted by Therapeutic Area, 2023



INTERNATIONAL ACCREDITATIONS FOR IRBs



DECENTRALIZED CLINICAL TRIAL (DCT) APPLICABLE

Guidelines on the Implementation of Decentralized Elements in Clinical Trials with Medicinal Products (Taiwan FDA, June 2023): Including trial recruitment, remote monitoring, investigational product delivery, utilization of digital system, etc.



EXPEDITED REVIEW PROCESS



Regenerative Medicine IND

30 Days

Under certain conditions, the review timeline can be shortened to 30 days.





OUTSTANDING PRINCIPAL INVESTIGATORS

Taiwan is home to globally recognized PIs, steering committee, or advisory board members in pivotal or major MRCTs. Visit Taiwan Principal Investigator Database (TPIDB) for more information: <https://tpidb.taiwanclinicaltrials.tw/>



ACADEMIC ACCOMPLISHMENTS

Selected publications: 2023-2024, Lancet, JAMA, N Engl J Med.
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Organization	PI	Drug/Study	Therapeutic Area	Journal
NTUH	Jyh-Ming Liou	Levofloxacin/NCT03148366	Helicobacter pylori.	Lancet Gastroenterol Hepatol. 2023 Mar;8(3):228-241
	Yen-Shen Lu	Bevacizumab/NCT02185352	ER+/HER2-Meta 1st line	JAMA Oncol. Online., Dec 21, 2023
CMUH	Li-Yuan Bai	Pembrolizumab/NCT04003636	Biliary Tract Carcinoma	Lancet. 2023 Jun3;401(10391):1853-1865
	Chen-Yuan Lin	Tislelizumab/NCT03783442	Esophageal Squamous Cell Carcinoma	Lancet Oncol. 2023 May;24(5):483-495
	Wen-Yuan Lin	Tirzepatide/NCT04660643	Maintenance of Weight Loss in Adults With Obesity	JAMA. 2024 Jan 2;331(1):38-48
	Hsi-Chin Wu	Enfortumab Vedotin/NCT04223856	Urothelial cancer	N Engl J Med. 2024 Mar 7;390(10):875-888
CKUH	Chen-Yuan Lin	Selpercatinib/NCT04211337	Thyroid Cancer	N Engl J Med. 2023 Nov6;389(20):1851-1861
	Chia-Jui Yen	Erdafitinib/NCT04083976	Solid tumours	Lancet Oncol., 2023 Aug 24(8), 925-935.
	Chia-Jui Yen	Pembrolizumab/NCT04003636	Biliary tract cancer	Lancet. 2023 Jun 401(1391),1853-1865
KMUH	Wei-Pang Chung	Trastuzumab deruxtecan (DS-8201a)/NCT03529110	Breast cancer	Lancet. 2023 Jan 401(10371),105-117
	Yen-Hsu Chen	Rezafungin/NCT03667690	Candidaemia	Lancet. 2023 Jan 401(10370), 49-59
CGMH	Jen-Yu Hung	Amivantamab/NCT04538664	Non-small-cell lung cancer (NSCLC)	N Engl J Med. 2023 Oct 389(22), 2039-2051
	Tsai-Sheng Yang	Camrelizumab plus rivoceranib/ NCT03764293	Hepatocellular carcinoma	Lancet. 2023 Sep 402(10408), 1133-1146
	Hung-Ming Wang	Toripalimab/NCT03581786	Nasopharyngeal carcinoma	JAMA. 2023 Nov 330(20), 1961-1970

ROBUST PARTNERSHIPS

The Taiwan government works closely with the biotechnology industry and academia to support clinical trials and facilitate the development process.

Taiwan Clinical Trial Consortium (TCTC)

The TCTC was funded by the Taiwan Ministry of Health and Welfare, bringing together 12 disease-specific consortiums involving 300+ experienced principal investigators and medical professionals.

TaiwanClinicalTrials.tw

The Taiwan Clinical Trials website provides up-to-date comprehensive clinical trial information, including regulatory information, health statistics, and clinical trial centers.

Taiwan Principal Investigator Database (TPIDB)

The TPIDB is a public resource that contains information on clinical trials approved by the TFDA, combining 2,000+ PIs, 5,000 MDs, and operation site data.



TaiwanClinicalTrials.tw
www.taiwanclinicaltrials.tw



Taiwan Principal Investigator Database, TPIDB
tpidb.taiwanclinicaltrials.tw



Ministry of Health and Welfare
www.mohw.gov.tw



Taiwan Food and Drug Administration
www.fda.gov.tw



Center for Drug Evaluation Taiwan
www.cde.org.tw