



TaiwanClinicalTrials

MAXIMIZE YOUR CLINICAL TRIAL SUCCESS WITH TAIWAN

ABOUT TAIWAN

- Population : 23.37 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



422 Medical Institutions



143 Clinical Trial Sites



25 Medical Centers

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

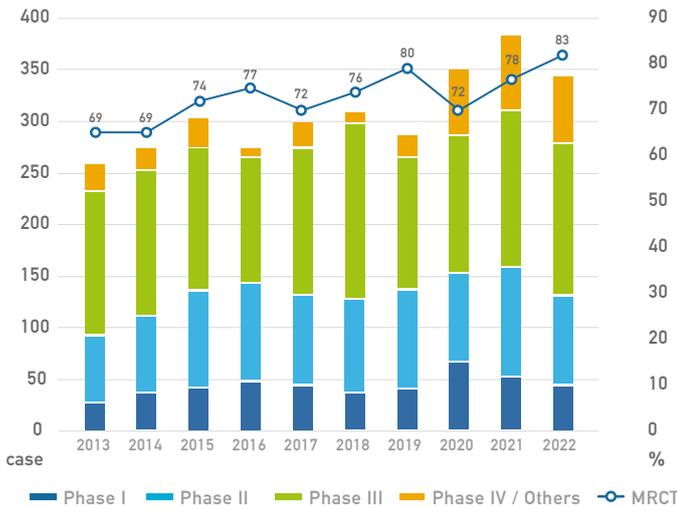
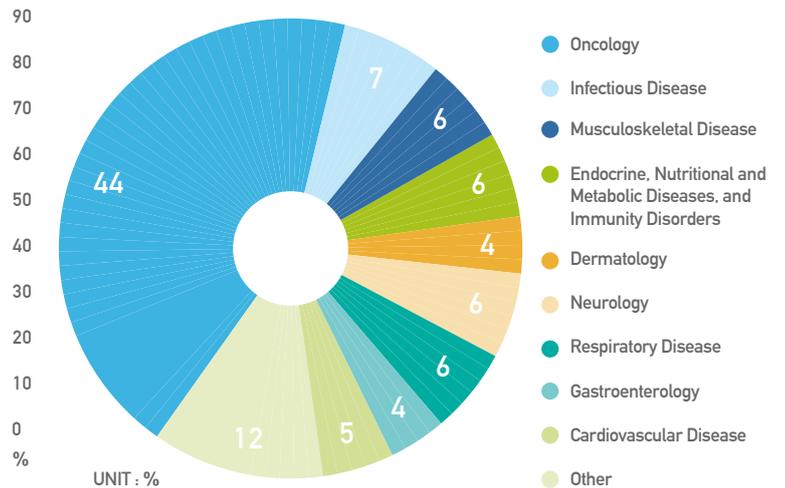


Table 2. Percentage of IND Applications Submitted by Therapeutic Area, 2021-2022



GLOBALLY RECOGNIZED QUALITY

INTERNATIONAL RECOGNIZED ACCREDITATIONS FOR IRBs



EXPEDITED REVIEW PROCESS





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: 2022-2023, Lancet, JAMA, N Engl J Med.

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Organization	PI	Drug/Study	Therapeutic Area	Journal
TVGH	Chern-En Chiang	Dapagliflozin / NCT03619213	HFpEF	N Engl J Med. 2022 Sept 387(12), 1089-1098
NTUH	Li -Min Huang	EV71vac / NCT03865238	Enterovirus 71 vaccine	Lancet. 2022 Apr 30;399(10336), 1708-1717
CMUH	Su-Peng Yeh	AG-120 / NCT03173248	Leukemia	N Engl J Med. 2022 Apr 386(16), 1519-1531
NCKUH	Wei-Pang Chung	T-DXd / T-DM1 / NCT03529110	HER2-Positive MBC	Lancet. 2023 Jan 401(10371), 105-117
CGMH	Cheng-Hsun Chiu Shin-Ru Shih	EV71vac/ NCT03865238	Enterovirus 71 vaccine	Lancet. 2022 Apr 30;399(10336), 1708-1717

INNOVATIVE VACCINE DEVELOPMENT

Enterovirus 71 (EV71) has been a major concern among pediatric infectious diseases. With the collaborations of major clinical trial centers, the success of local EV71 vaccines demonstrates Taiwan's ability to conduct clinical trials and its dedication to developing new, life-saving drugs.

EnVAX-A71 / NCT05099029

A Phase III, Multiple-center, Double-blind, Randomized, Placebo-controlled Study to Evaluate the Efficacy, Immunogenicity, and Safety of an Adjuvanted Inactivated Enterovirus 71 (EV71) Vaccine in Healthy Infants and Children.



Licensure Approved by TFDA* February 2023

Envacgen / NCT03865238

A Phase 3, Prospective, Randomized, Double-blind, Placebo-controlled, Multi-region Study to Evaluate the Efficacy, Safety, and Immunogenicity of Inactivated EV71 Vaccine Produced in Vero Cells With Adjuvant in Infants and Children.



Licensure Approved by TFDA* April 2023

*Taiwan Food and Drug Administration (TFDA)

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
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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