

# TAIWAN 2022 CLINICAL TRIAL IN THE PRIME



## TAIWAN PROFILE

- Population : 23.37 million
- Land Area : 36,193 km<sup>2</sup> (13,974 mi<sup>2</sup>)
- Capital City : Taipei
- Universal Healthcare System



**ICH Regulatory Member**

Participated in > 20 expert working groups



**National Health Insurance (NHI)**

Covers 99.96% of the population

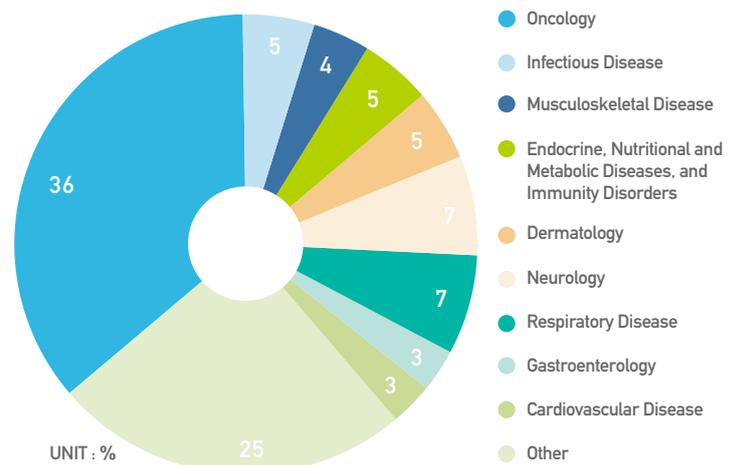


**78%** of the approved clinical trials in Taiwan are MRCTs.

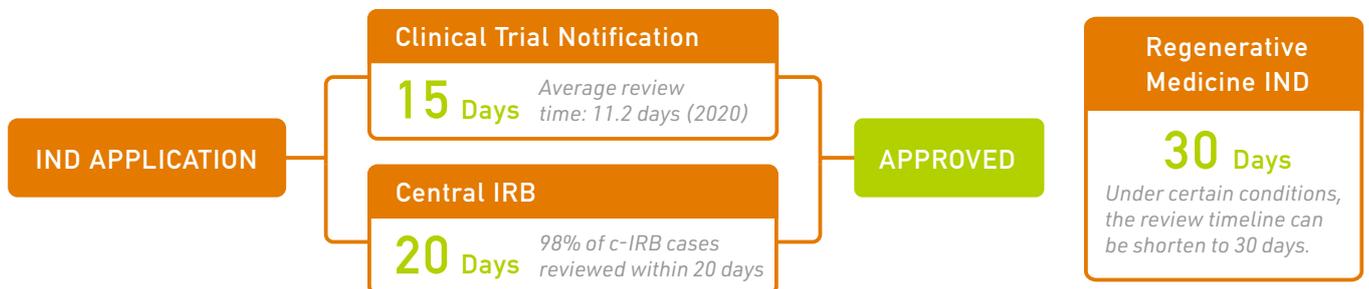
Table1 . Approved IND Cases in Taiwan by Year, 2011-2021 After COVID-19



Table2 . The Percentage of IND Approval by Therapeutic Area, 2016-2021



## EXPEDITED REVIEW PROCESS



## OUTSTANDING HEALTHCARE SYSTEM



**422**

Qualified Medical Institutions



**143**

Qualified Clinical Trial Sites



**23**

Qualified Medical Centers

### Real-World Data (RWD) Databases

**NHI Research Database**

Over 20 years of data collection through NHI

**Taiwan Stroke Registry (TSR)**

>140,000 stroke patients registered

**Taiwan Cancer Registry (TCR)**

Nationwide population-based cancer registry system since 1979

# GLOBALLY RECOGNIZED QUALITY



## PARTICIPATION IN TAIWAN COVID-19 VACCINE DEVELOPMENT

Major clinical trial centers have participated in the development of Taiwan's local vaccines.

**Participations**

NTUH NCKUH  
CGMH TMUH  
CMUH TVGH  
KMUH AND OTHERS

**MVC-COV1901 COVID-19 Vaccine / NCT04695652**  
Double-blinded, Randomized, Placebo-controlled  
**3854** subjects  
Good Safety Profile  
Elicits Promising immunogenicity responses  
*Lancet Respiratory Medicine* : 2021 Dec;9(12):1396-1406.

**2021 July: TFDA EUA**  
EUA: Emergency Use Authorization

## ACADEMIC ACCOMPLISHMENTS

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

Selected publication: 2020-2022, NEJM, Lancet oncology, JAMA

Organization	PI	Drug/Study	Therapeutic Area	Journal
CMUH	Li-Yuan, Bai	Nivolumab /NCT02746796	Gastric cancer	The Lancet Oncology, 23(2), 234-247
		Ramucirumab or merestinib/NCT02711553	Metastatic biliary tract cancer	The Lancet Oncology, 22(10), 1468-1482
	Su-Peng, Yeh	Ivosidenib and azacitidine/NCT03173248	Acute Myeloid Leukemia with an IDH1 Mutation	New England Journal of Medicine, 386(16), 1519-1531
		Azacitidine and Venetoclax /NCT02993523	Acute Myeloid Leukemia	New England Journal of Medicine, 383(7), 617-629
TVGH	Chern-En, Chiang	Dapagliflozin / NCT03036124	HFrEF	JAMA, 323(14), 1353-1368
NTUH	Shu-Min, Hsieh	Remdesivir /NCT04292730	COVID-19	JAMA, 2020 Sep 15;324(11), 1048-1057
	Li-Min, Huang	EV71vac/ NCT03865238	Enterovirus 71	Lancet, 2022 Apr 30;399(10336), 1708-1717
KMUH	Li-Tzong, Chen	Erdafitinib/NCT02365597	Urothelial Cancer	The Lancet Oncology, 23(2), 248-258
CGMH	Cheng-Hsun, Chiu Shin-Ru, Shih	EV71vac/ NCT03865238	Enterovirus 71	Lancet, 2022 Apr 30;399(10336), 1708-1717

## TAIWAN PRINCIPAL INVESTIGATOR DATABASE(TPIDB) & OUTSTANDING PRINCIPAL INVESTIGATORS

TPIDB contains information about all the clinical trials conducted and approved by TFDA, concatenated with more than a thousand principal investigators, M.Ds, and clinical trial sites data.



Major hospital recommended Outstanding PIs as listed.



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