

# 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

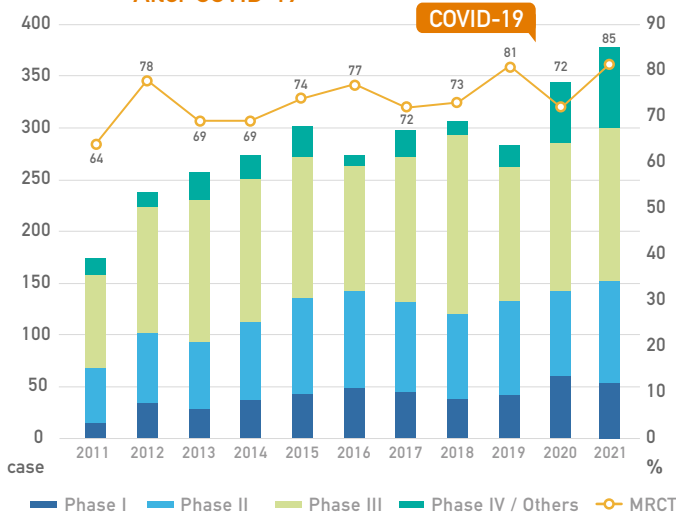
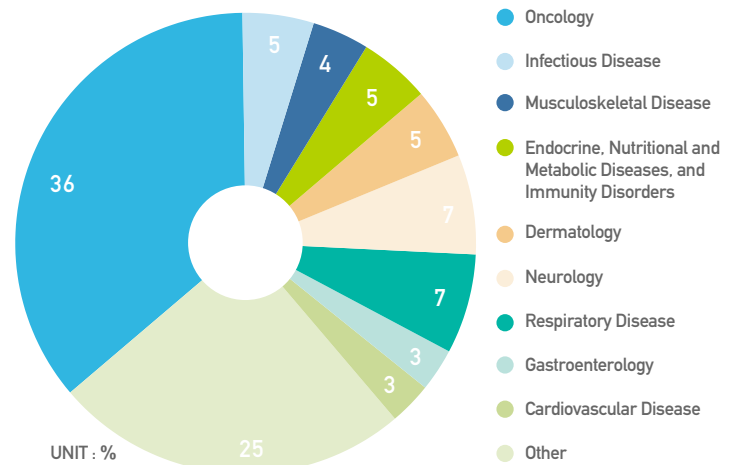
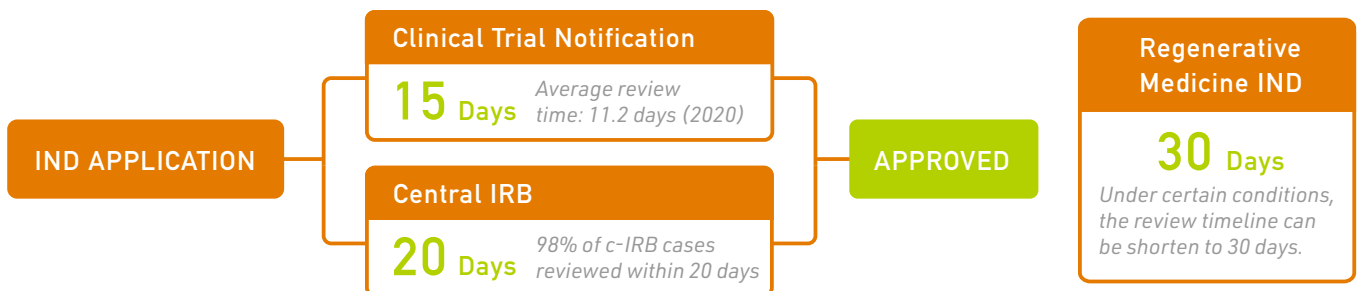


Table2 . The Percentage of IND Approval by Therapeutic Area, 2016-2021



## 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.

