

TAIWAN 2021 YOUR CLINICAL TRIAL SOLUTION



TAIWAN PROFILE

- Population : 23.57 million
- Land Area : 36,193 km² (13,974 mi²)
- Capital City : Taipei
- Universal Healthcare System



ICH Regulatory Member

Participated in > 20 expert working groups



National Health Insurance (NHI)

Covers 99.84% of the population



72% of the approved clinical trials in Taiwan are MRCTs.

Table1 . Approved IND Cases in Taiwan by Year, 2010-2020

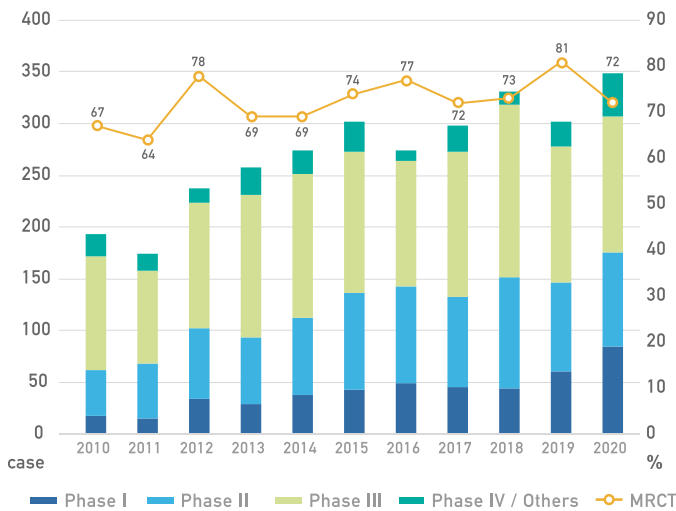
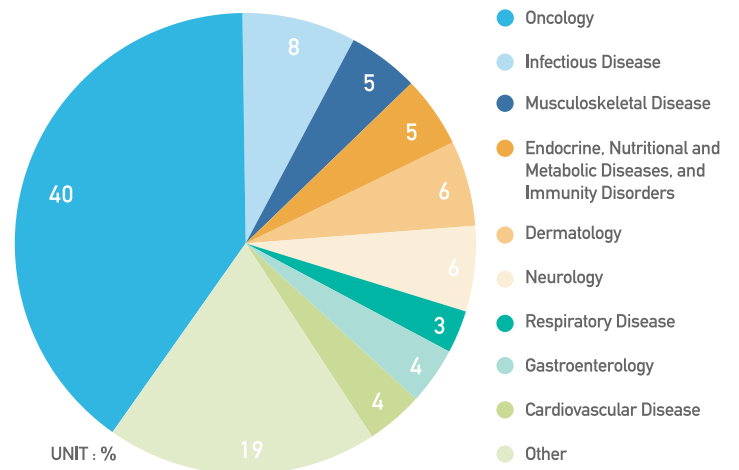
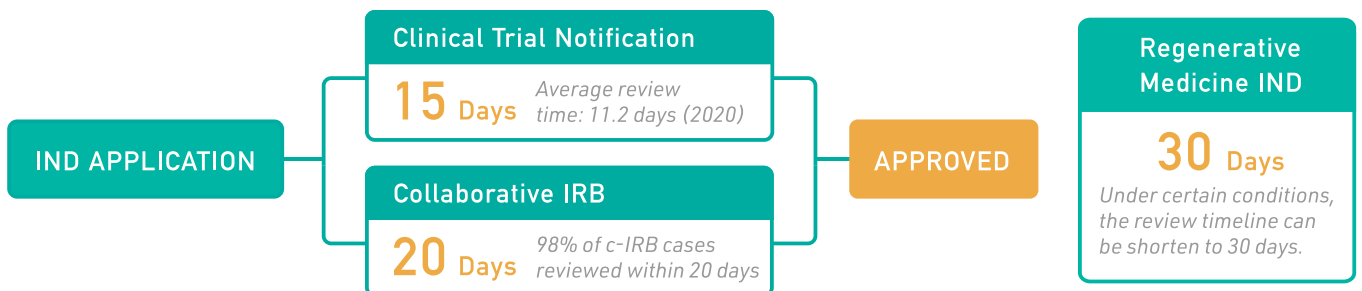


Table2 . The Percentage of IND Approval by Therapeutic Area, 2016-2020



EXPEDITED REVIEW PROCESS



OUTSTANDING HEALTHCARE SYSTEM



426

Qualified Medical Institutions



149

Qualified Clinical Trial Sites



22

Qualified Medical Centers

Real-World Data (RWD) Databases

NHI Research Database

Over 20 years of data collection through NHI

Taiwan Stroke Registry (TSR)

>150,000 stroke patients registered

Taiwan Cancer Registry (TCR)

Nationwide population-based cancer registry system since 1979

GLOBALLY RECOGNIZED QUALITY

12
AAHRPP
Accredited
Organizations

24
SIDCER-FERCAP
Recognized
ECs/IRBs

13
JCI Gold Seal
of Approval
Entities



Globally First Approved New Drugs

GIOTRIF

- Afatinib • EGFR TKI • Approved for NSCLC
- Taiwan participation:
 - Phase II trials: **81%** & **17%** of trial population were from Taiwan.
 - Phase III trials: **21%** & **18%** of trial population were from Taiwan.
- Global chairman: C.H. Yang, M.D., Ph.D (National Taiwan University Hospital)

ONIVYDE

- Liposomal irinotecan • Approved for metastatic pancreatic cancer
- Taiwan participation:
 - Phase II trial: **55%** of trial population were from Taiwan.
 - Phase III trial: **22.8%** of trial population were from Taiwan.
- Global chairman: L.T. Chen, M.D., Ph.D (National Cheng Kung University Hospital) (Phase II)
- Corresponding author of Phase III NAPOLI-1 primary trial's publication in *The Lancet*.



Top 1 Patient Recruitment in Asia

- TVGH - ENGAGE AF-TIMI 48
- TMUH - AEGEAN, NCT02089087

- NTUH - NCT02719743, KATHERINE, HIMALAYA, NCT01970865
- CMUH - NCT01888432, NCT01580839, NCT03171155



- NCKUH - NCT01494506

ACADEMIC ACCOMPLISHMENTS



Many Taiwan PIs 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	Chern-En, Chiang	Dapagliflozin/NCT03036124	HFrEF	<i>N Engl J Med.</i> 2019; 381(21): 1995-2008
NCKUH	Wu-Chou, Su	Pembrolizumab/KEYNOTE-042	NSCLC	<i>Lancet.</i> 2019; 393(10183): 1819-1830
	Chia-Jui, Yen	Ramucirumab/REACH-2	HCC	<i>Lancet Oncol.</i> 2019; 20(2): 282-296
NTUH	Chiun-Sheng, Huang	Trastuzumab/KATHERINE	Breast Cancer	<i>N Engl J Med.</i> 2019; 380: 617-628
	Ann-Lii, Cheng	Atezolizumab plus Bevacizumab/IMbrave 150	HCC	<i>N Engl J Med.</i> 2020; 382(20): 1894-1905
KMUH	Yen-Hsu, Chen	UB-421/NCT02369146	HIV	<i>N Engl J Med.</i> 2019; 380(16): 1535-1545
TMUH	Chen-Yuan, Chiang	High-dose moxifloxacin(main)/STREAM	MDR-TB	<i>N Engl J Med.</i> 2019; 380 (13): 1201-1213
CMUH	Chung-Y, Hsu	Alteplase/EXTEND	Stroke	<i>N Engl J Med.</i> 2019; 380(19):1795-1803 <i>Lancet.</i> 2019; 394(10193):139-147
	Su-Peng, Yeh	Brentuximab vedotin/ ECHELON-2	Lymphoma	<i>Lancet.</i> 2019; 393(10168): 229-240

More Information >

TAIWAN
CLINICAL TRIALS



www.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