

WHY TAIWAN ?

- Excellent Clinical Trial Centers & IRBs
- High Quality Trials
- Globally Harmonized Regulations
- Expedited Review Process for MRCTs
- Outstanding Healthcare System
- Professional Consultation Service through Center for Drug Evaluation



TaiwanClinicalTrials

Taiwan Profile

- Population : 23.60 million
- Land Area : About 36,000 km²
- Capital City : Taipei
- Health System : Universal healthcare system through National Health Insurance (NHI) that covers 99.84% of the population.

Clinical Trial Centers Inspected by International Regulatory Institutions

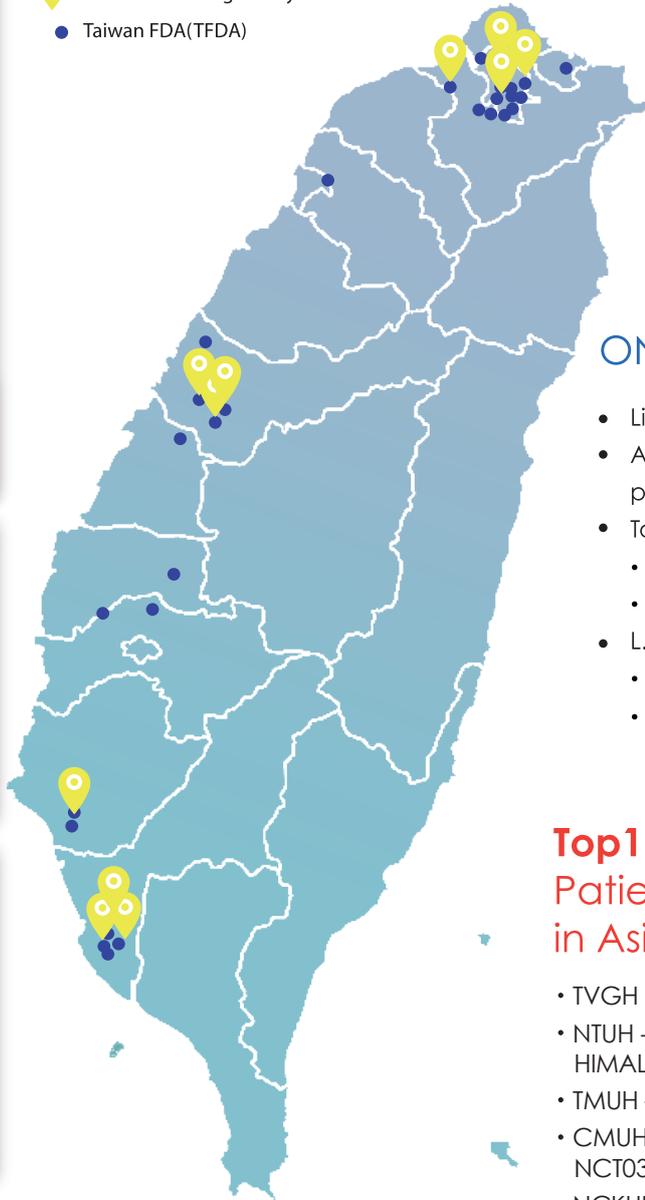
*GCP inspection result with no major and critical findings.

Northern Taiwan	
US FDA*	National Taiwan University Hospital
	Taipei Veterans General Hospital
	Taipei Chang Gung Memorial Hospital
	Tri-Service General Hospital
	Taipei Medical University Hospital
EMA	Taipei Veterans General Hospital
	Linkou Chang Gung Memorial Hospital
PMDA*	National Taiwan University Hospital
	Taipei Medical University Hospital

Central Taiwan	
US FDA*	Chung Shuan Medical University Hospital
	Taichung Veterans General Hospital
PMDA*	China Medical University Hospital
	Chung Shuan Medical University Hospital

Southern Taiwan	
US FDA*	Kaohsiung Medical University Chung-Ho Memorial Hospital
	National Cheng Kung University Hospital
	Kaohsiung Chang Gung Memorial Hospital
	Kaohsiung Veterans General Hospital

International Regulatory Institutions
 ● Taiwan FDA(TFDA)



Globally First Approved New Drugs

GIOTRIF

- Afatinib
- EGFR TKI
- Approved for NSCLC
- Taiwan participation:
 - Phase II trials: 81%, 17%
 - Phase III trials: 21%, 18%
- C.H. Yang (NTUH): Global chairman

ONIVYDE

- Liposomal irinotecan
- Approved for metastatic pancreatic cancer
- Taiwan participation:
 - Phase II trial: 55%
 - Phase III trial: 23%
- L.T. Chen (NCKUH):
 - Global chairman (Phase II)
 - Corresponding author of Phase III NAPOLI-1 primary trial's publication in *The Lancet*

Top1 Patient Recruitment in Asia

- TVGH - ENGAGE-AF TIMI-48
- NTUH - NCT02719743, KATHERINE, HIMALAYA, NCT01970865
- TMUH – AEGEAN, NCT02089087
- CMUH - NCT01888432, NCT01580839, NCT03171155
- NCKUH - NCT01494506

Health Databases for Efficient Clinical Research

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

Cancer, Diabetes, Hepatology, Nephrology Databases	Kaohsiung Medical University Chung-Ho Memorial Hospital
Cancer, Cardiology, Endocrinology, Rheumatology Databases	National Cheng Kung University Hospital
Brain Tumor, Dermatology, Gynecology, Oncology Databases	Linkou Chang Gung Memorial Hospital

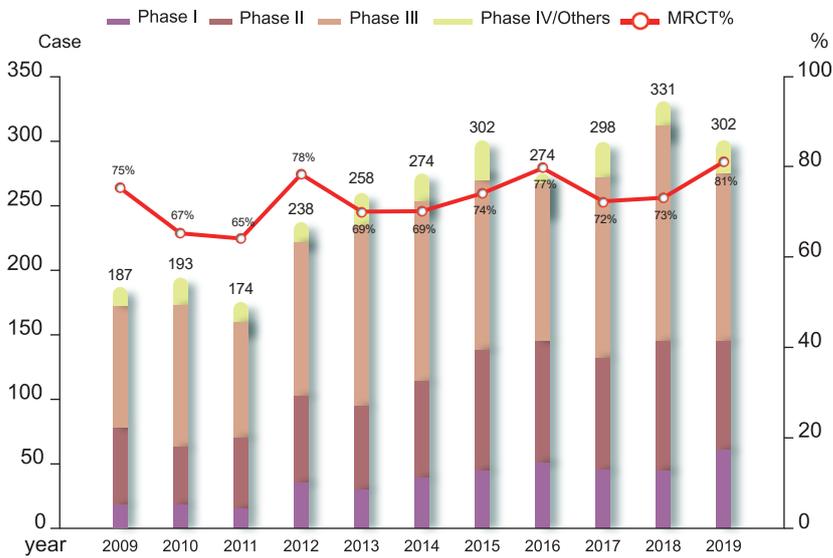


Table 1. Approved INDs in Taiwan by Year

Taiwan has demonstrated its ability in participating in multiregional clinical trials (MRCTs). The percentage of MRCTs has an average of 72% within recent years.

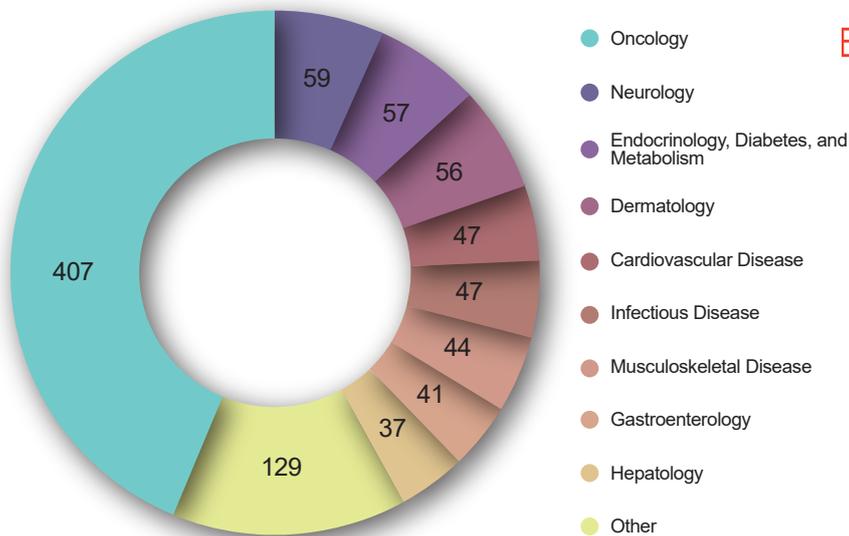


Table 2. The Number of IND Approval by Therapeutic Area [N=924], 2017-2019

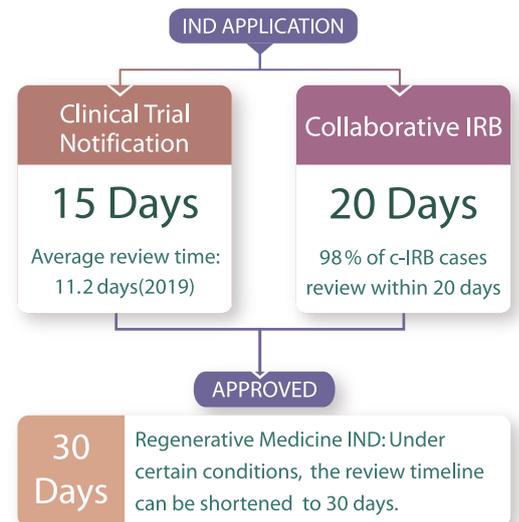
Globally Harmonized Regulations

- Follow ICH Guidelines
- ICH Regulatory Member
- Participated in more than 20 expert working groups
- GCP, PIC/S GMP Compliance
- Medical device trials follow ISO 14155

High Quality Medical Institutions & IRBs



Expedited Review Process



Outstanding 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	Chem-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	IMbrave050	HCC	<i>N Engl J Med.</i> 2020 in press
KMUH	Yen-Hsu, Chen	UB-421/NCT02369146	HIV	<i>N Engl J Med.</i> 2019; 380(16): 1535-1545
TMUH	Chen-Yuan, Chiang	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	ECHELON-2	Lymphoma	<i>Lancet.</i> 2019; 393(10168):229-240

