



Taiwan

TRPMA Established in 2012

Research-based Biopharma Cluster

Covering NCEs, Biologics, Regenerative Medicines, Medical Devices

Platform for

Government-academia-industry Collaborations

Motivate Innovation

Consolidate resources, capitals and talents

Alliance with International Partners



Biopharma Industry in Taiwan

Taiwan Pharma Industry Value Chain

Drug Research

Pre- Clinical

IND

Clinical Trial

NDA

Manufacturing and Marketing

Academia Sinica
NHRI
ITRI
Universities

**Lead-Compound Optimization
Pharmacology Studies**

Academia Sinica, NHRI, DCB, ITRI,

Toxicology Studies

ATRI, GreenLink, Level Biotech,
Medgaea, SuperLab, Vita
Genomics

National Clinical Trial Centers

National Center of Excellence for Clinical
Trial and Research, TCTC

CRO

A2 Healthcare, AlfaBeta, Amarex, Bestat,
Clinipace, CMIC, Covance, EffPha, EPS, IQVIA,
Linal, Mithra Biotech, Novotech, QPS, PPC,
PAREXEL, StatPlus, TTMC, VCRO

BA/BE CRO/ Lab

Mithra Biotech, PPC, Rosetta Pharmamate,
AdvPharma, QPS

- 30 API GMP Manufacturers
- 144 PIC/S GMP Manufacturers
- 9 PIC/S GMP Pilot Plant Facility
- 28 GDP Distributors

DNA Sequencing

ACT Genomics, Genomics, Vita Genomics, Missionbio, PURIGO

Laboratory Animals

National Lab Animal Center, LEVEL Biotech,
BioLASCO

CDMO

Mycenax, EirGenix, OEP, TaiwanBio, etc.

Academia Sinica



Chi-Huay Wong, Ph.D., President,
Robert Robinson Award 2012 Winner



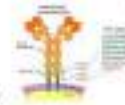
Yuan-Tsong Chen, M.D., Ph.D.
Institute of Biomedical Sciences

Mycozyme®
Pompe Disease
Glyzyme, 2006.



Chiaag, Tee Wee Ph.D.
Genomic Research Center

Xolair®, Novartis
Anti-Cem®,
Fountain BioPharma, 泉盛生技



Updated Oct, 2024

2024 TRPMA Members

26 New Drugs



22 Regenerative Medicines



7 Innovative Medical Devices



R&D Projects Worldwide



Taiwan New Drugs Approved in Global Markets

Company	Product	Indication	Approved Year/ Region
TaiGen Biotechnology	Taigexyn [®]	Community Acquired Pneumonia	(oral) 2014/TW, 2016/CN (iv) 2020/TW, 2021/CN
Panion & BF Biotech	Nephoxil [®]	Hyperphosphatemia caused by chronic kidney disease	2014/JP ,2014/US, 2015/TW, 2015/EU,2022/KR
PharmaEngine	Onivyde [®]	Pancreatic cancer	2015/TW, 2015/US, 2016/EU, 2016/AU, 2017/CA, 2017/KR, 2018/SG, 2020/JP, 2022/CN
Lumosa Therapeutics	Naldebain [®]	Long-acting Analgesic for Moderate to Severe pain	2017/TW, 2020/SG, 2021/TH, 2022/MY, 2023/UA
TaiMed Biologics	Trogarzo [®]	HIV-1	2018/US, 2019/EU
PharmaEssentia	Besremi [®]	Polycythemia Vera (PV)	2019/EU, 2020/TW, 2020/CH, 2021/IL, 2021/KR, 2021/US, 2023/JP
Oneness Biotech	Fespixon [®]	Diabetic foot ulcer	2021/TW, 2021/MO, 2023/SG, 2023/MA

- 2 Biosimilar: Mycenax TuNex[®], Eirgenix Eirgasun[®]
- 6 505b(2): TAHO Pharmaceuticals Ondansetron OD Film, Orient PHARMA Methydur[®], PhytoHealth Oraphine[®], Foresee Pharmaceuticals CAMCEVI[™], Handa Pharmaceuticals Tascenso[®] ODT, Orient PHARMA Tonvasca[®]

Taiwan successfully developed COVID-19 Vaccine



MVC COVID-19 Vaccine

EUA

Phase 3

Taiwan 2021 WHO Solidarity Trial Vaccines 2021
Paraguay 2022 (Colombia, Mali, Philippines)



Envacgen®

Marketed

Enterovirus A71 Vaccine Taiwan, 2023



MVC FLU Quadrivalent

Marketed

pre-filled syringe injection Taiwan, 2023

Government Funding for COVID-19 Vaccine

Developer	Government Funding
Moderna	\$1B for vaccine development, \$1.5B for initial supply
Pfizer/BioNTech	\$1.95B (United States)
Johnson & Johnson	\$456M for development, \$1B for initial supply
AstraZeneca	\$1.2B
Medigen	\$16M (Taiwan)
Source : Taiwan CDC, Clarivate, 2021	

ELIXCYTE®

向榮生技脂肪幹細胞製劑
Adipose-Derived Stem Cell



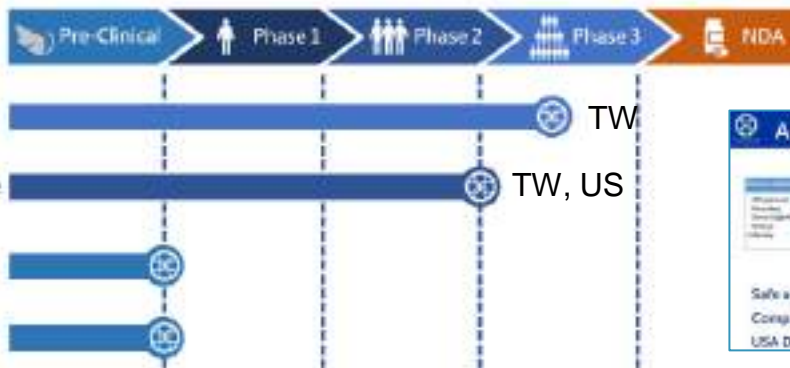
Pipeline

Knee Osteoarthritis

Chronic Kidney Disease

Retinal Degeneration

Chronic Wound



UnicoVial®

The ideal cryotube & drug container for biologics

US FDA Drug Master File

TFDA Class 2 Medical Device

🏆 National Innovation Award



VOIS

VOCAL IMPLANT SYSTEM

For Unilateral vocal fold paralysis

Developed by



Europe

- CE Certificate (Dec 2019)
- Reimbursement countries



Japan

- Looking for Marketing Partners
- Health Reimbursement Negotiation

US

- Clinical Trials

Taiwan

- Market Approval 2023



Australia

- Market Approval 2022
- Reimbursement Negotiation

ASEAN

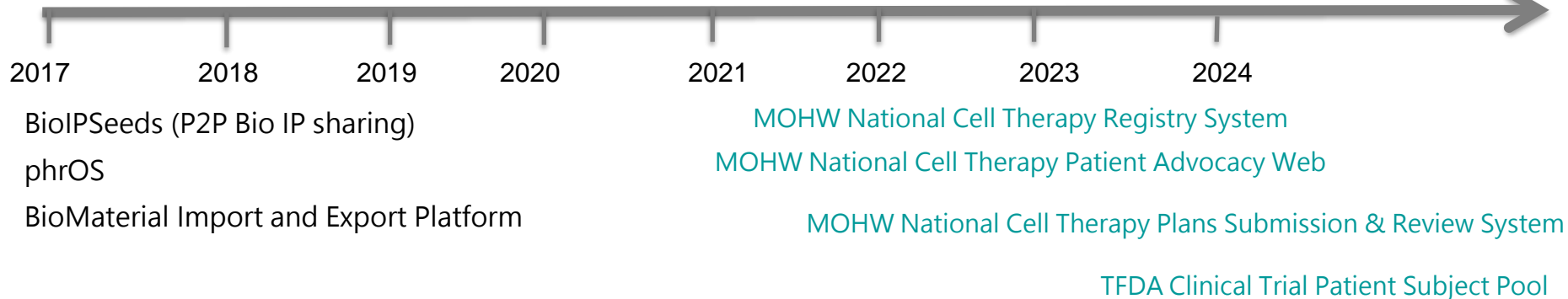
- Market Approval: Malaysia, Indonesia, Singapore, Vietnam



EC-CERTIFICATE



TRPMA Digital Team



National Platform for Bio-Material Import/Export



Bio-Material Import Platform
<https://biom.tw>



Cell Therapy Patient Resource Web
<https://celltherapy.mohw.gov.tw>



MOHW- National Cell Therapy Treatment Plans Submission & Review System



TRPMA Research Projects

- GMP Regulations and Compliance Issues for Nucleic Acid and Advanced Therapy Products, Taiwan FDA Research Project, 2024
- Design and Development of a Digital Submission and Review System for Specific Medical Techniques in Cell Therapies, Taiwan MOHW Project, 2024
- Design and Development of a Patient Registry System for Cell Therapies, Taiwan MOHW Projects, 2020-2024
- Design and Development of a Cell Therapy Education Website, Taiwan MOHW Project, 2020-2022
- Consultation Program for GTP Guidances for CPUs in Taiwan, TFDA Research Project, 2020
- Study on International Regulations for ATMPs, Taiwan FDA, 2019
- Strategies for Vaccine Industry Development in Taiwan, Taiwan CDC Research Project, 2018
- Design and Development of the Biomaterials Importation and Exportation Platform, Executive Yuan, Taiwan, 2018-2024
- PHR-OS, a Blockchain-based Personal Health Record Operational System, Co-developed with Taipei Medical University, 2017
- Comparative Study of National Strategies for Promoting Biopharma Industry between Taiwan and South Korea, Executive Yuan, Taiwan, 2016

Thank You and Welcome to Visit TRPMA!!



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