

# Taiwan Innovative BioPharma Industry

---

Carol Cheng  
Chief Operating Officer, TRPMA  
Nov 4, 2024



# 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

# Biopharma Designated as Taiwan's Core Strategic Industry

PIC/S GMP, 2013

144 PIC/S GMP Plants



Biopharma Industry  
Development Act

Market Value USD 44B



Clinical Trial Excellency



Digital Health

BioBank



# 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-Huey Wong, Ph.D. President,  
Robert Robinson Award 2015 Winner



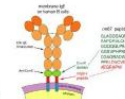
Yuan-Tsong Chen, M.D., Ph.D.  
Institute of Biomedical Sciences

Myozyme®  
Pompe Disease  
Gzyme, 2006.



Chang, Tse Wen Ph.D.  
Genomic Research Center

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



Updated Oct, 2024

# 2024 TRPMA Members

## 26 New Drugs



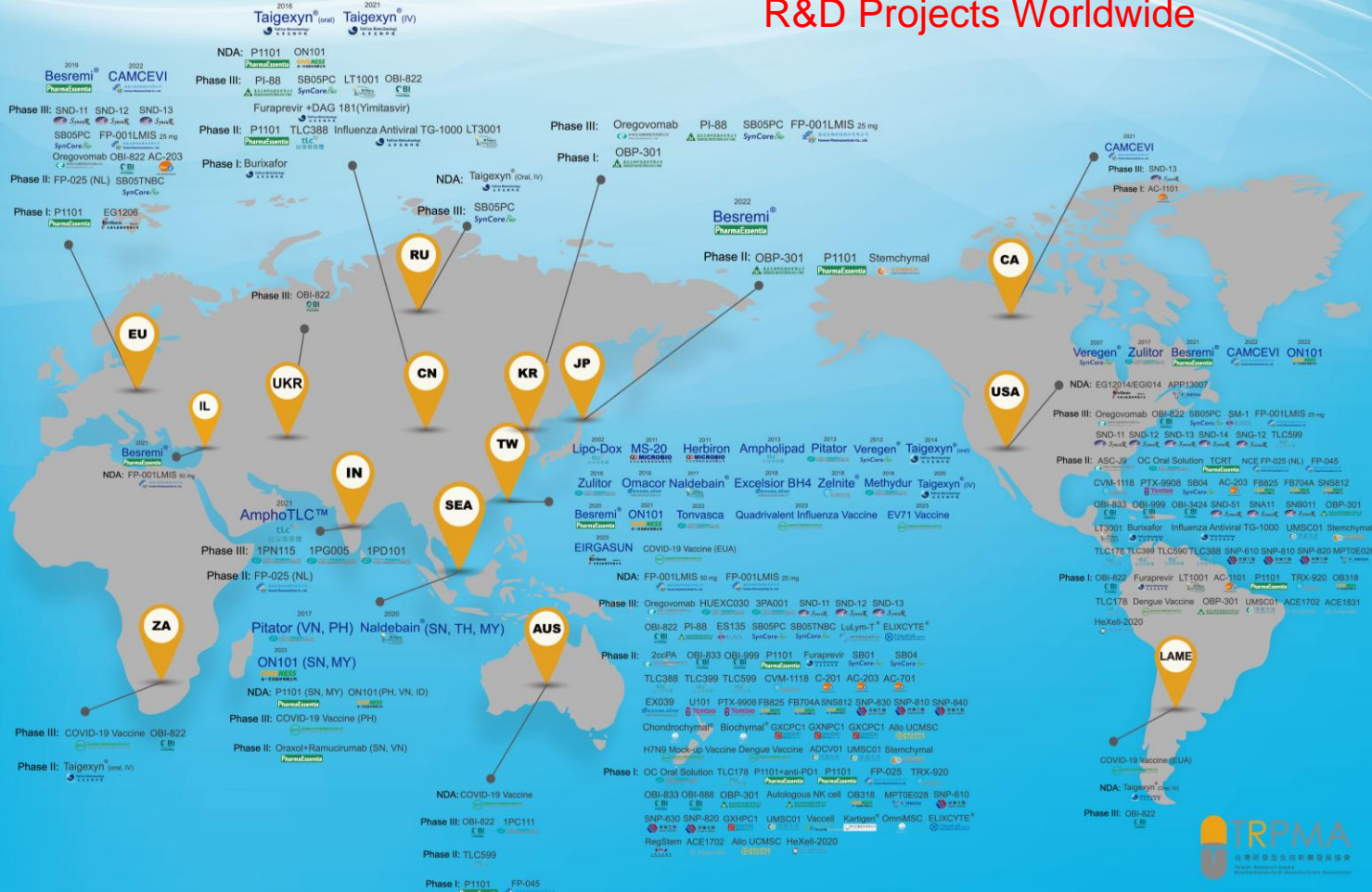
## 22 Regenerative Medicines



## 7 Innovative Medical Devices



# R&D Projects Worldwide



# Taiwan New Drugs Approved in Global Markets

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

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



# 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
<b>Moderna</b>	\$1B for vaccine development, \$1.5B for initial supply
<b>Pfizer/BioNTech</b>	\$1.95B (United States)
<b>Johnson &amp; Johnson</b>	\$456M for development, \$1B for initial supply
<b>AstraZeneca</b>	\$1.2B
<b>Medigen</b>	\$16M (Taiwan)

Source : Taiwan CDC, Clarivate, 2021

# ELIXCYTE®

向榮生技脂肪幹細胞製劑  
Adipose-Derived Stem Cell



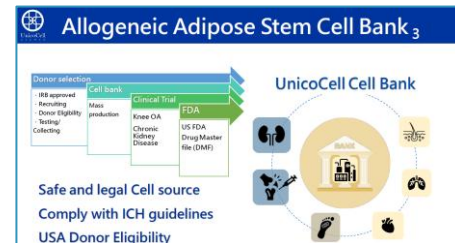
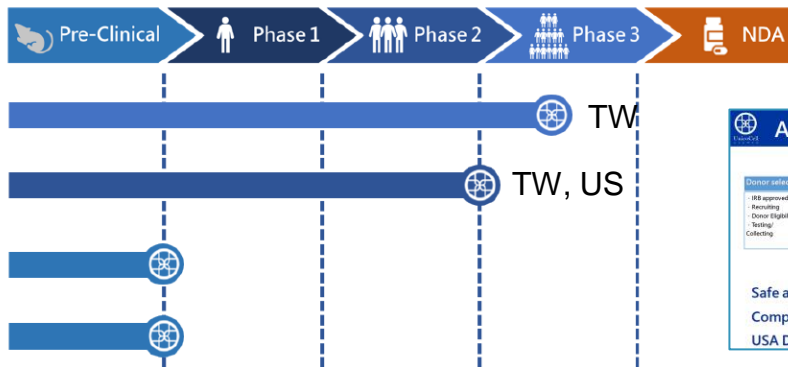
## Pipeline

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



- ✓ Medical Device
- ✓ USFDA Drug Master File
- ✓ Ultra-low temperature storage
- ✓ Tamper-evident capping
- ✓ Convenient for clinical use
- ✓ Easy to transport

# 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 (Full quality assurance system)

This is to certify that the company

**APrevent Biotech GmbH**  
In Lehen 24  
8000 Pöchlarn  
Austria

has implemented and maintains a full quality assurance system which applies to the products of every stage from design to final controls.

Through an audit, documented as a report, performed by DQS Multisystemaudit GmbH, it was verified that the management system fulfils the requirements of

**Annex II – excluding Section 4 of Council Directive 90/42/EEC concerning medical devices**

with respect to the following medical device:

Device family	Device	Class
VOIS Implant System	VOIS-1	IIIb
	VOIS-2	IIIb
	VOIS-3	IIIb
	VOIS-4	IIIb

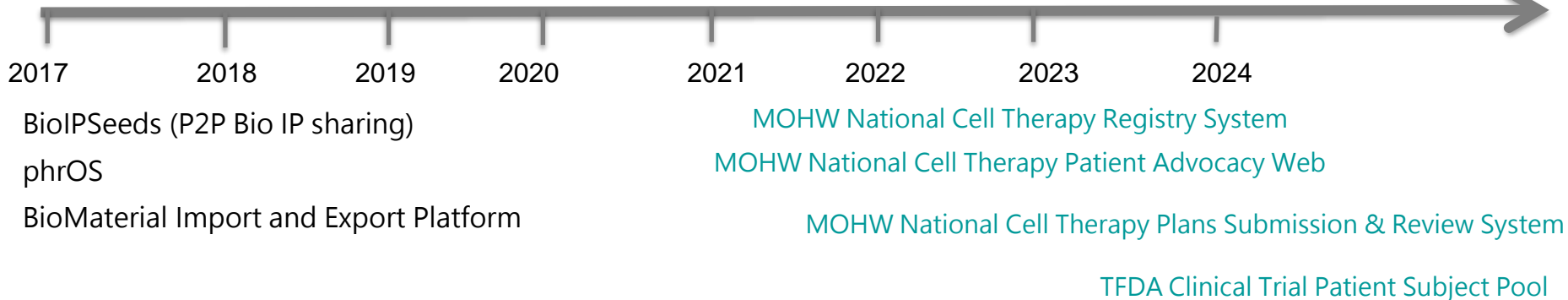
The manufacturer is subject to surveillance according to Article 18, Section 5. The CE marking with the notified body identification number (20201) may be affixed to the devices listed in the certificate. An EC Design Declaration Certificate according to Article 10, Section 4 is required for class II devices covered by this certificate. The certificate is in the case of class III devices (a) in cases previously placed on the market in a specific condition by the approval of a manufacturer concerned with mounting and maintaining these conditions. The certificate is in the case of class IIIb devices (b) in cases with a measuring function) limited to the scope of production concerned with the conformity of the products with the regulatory requirements.

Certificate registration no. 523984 MDD  
Certificate unique ID: 121700000  
Effective date: 2019-12-20  
Expiry date: 2024-05-24  
Finalised on March: 2019-12-20

DQS Multisystemaudit GmbH  
Signature: *[Signature]*  
Title: Notary seal  
Official seal: *[Seal]*

VOIS Implant System is a notified body according to Council Directive 90/42/EEC concerning medical devices with the identification number 20201.

# 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!!




台灣研發型生技新藥發展協會  
Taiwan Research-based  
Biopharmaceutical Manufacturers Association

1F, No 465-1, Sec. 6, Chung-hsiao E.  
Rd., Taipei City 11557, TAIWAN

+886-2-27831262

[trpma@trpma.org.tw](mailto:trpma@trpma.org.tw)



<https://trpma.org.tw/cmn>

