

The Development of Regenerative Medicine and Regulatory issues in Taiwan

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OUTLINES

1. **The role of regenerative medicine & cell therapy in the precision health industry**
2. **Implementation results of the Program Project of Regenerative Medicine**
3. **Current status of the regenerative medicine industry after special implementation in Taiwan**
4. **Future collaboration between Taiwan and Japan**

Missions of Institute for Biotechnology and Medicine Industry (IBMI)



Integrate resources and promote the healthcare industry

Policy Think Tank

- Act for the Development of Biotech and New Pharmaceuticals Industry
- Cross-Strait Cooperation Agreement on Medicine and Public Health Affairs
- The Human Biological Database Management Act

- Symbol of National Quality (SNQ) certification system
- National Quality Awards
- **National Innovation Awards**

Award & Certification

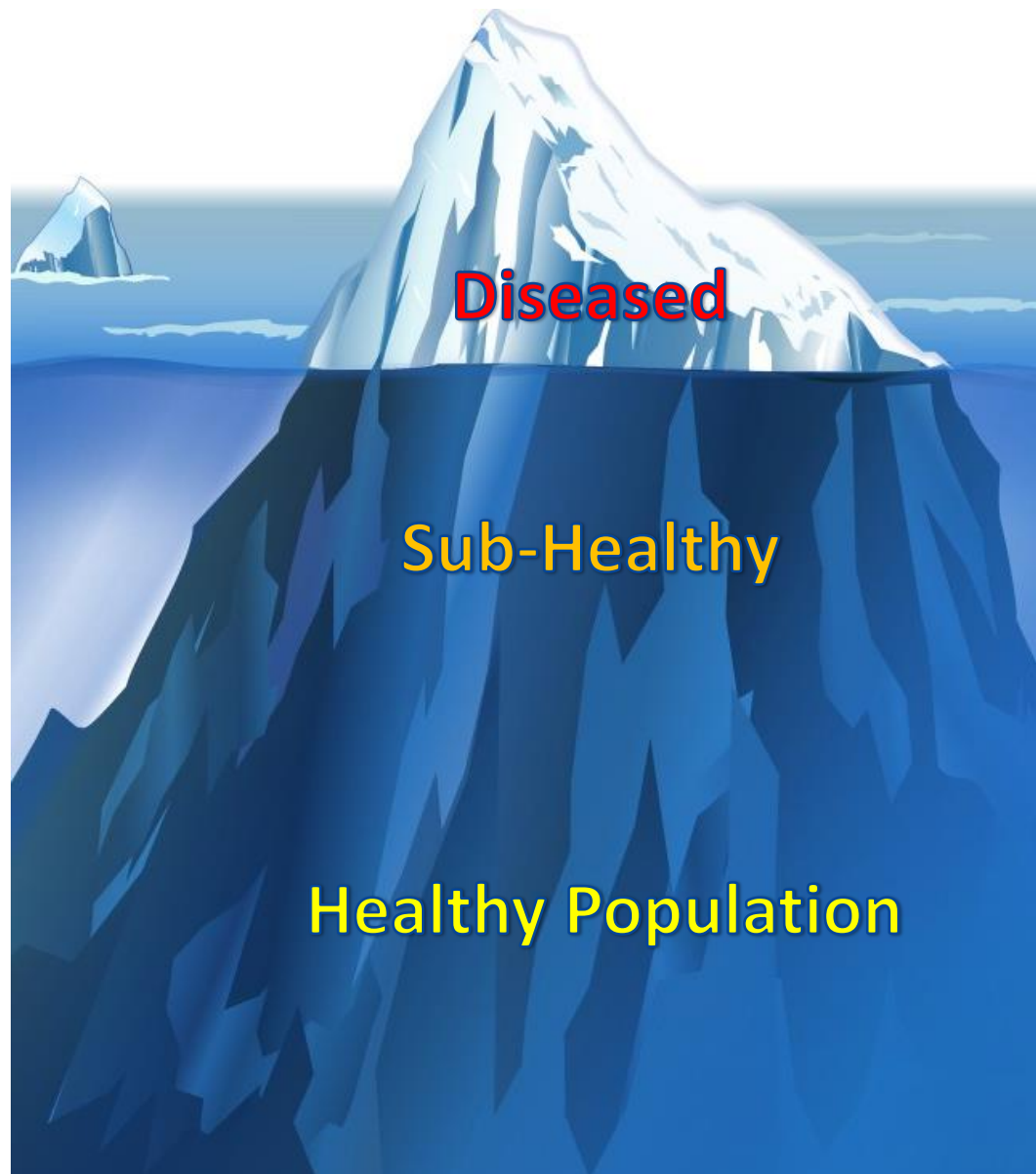
Global Partnering Platform

Taiwan Healthcare⁺
Taiwan Healthcare⁺ Expo

Biomedical Angel Fund
Star-up investment

Start-up Incubation

Precision Medicine and Precision Health



【 Precision Medicine 】

Precision Diagnosis : NGS, Liquid Biopsy, Medical AI, POC devices , Digital Imaging Equipment *etc.*

Precision Treatment : Targeted Therapy, **Cell Therapy**, Immunotherapy, Surgical Robot, *etc.*

Medical Care: Smart Hospital, Smart healthcare, *etc.*

【 Precision Health 】

Risk Assessment : Genetic risk, Behavioral Patterns, family history *etc.*

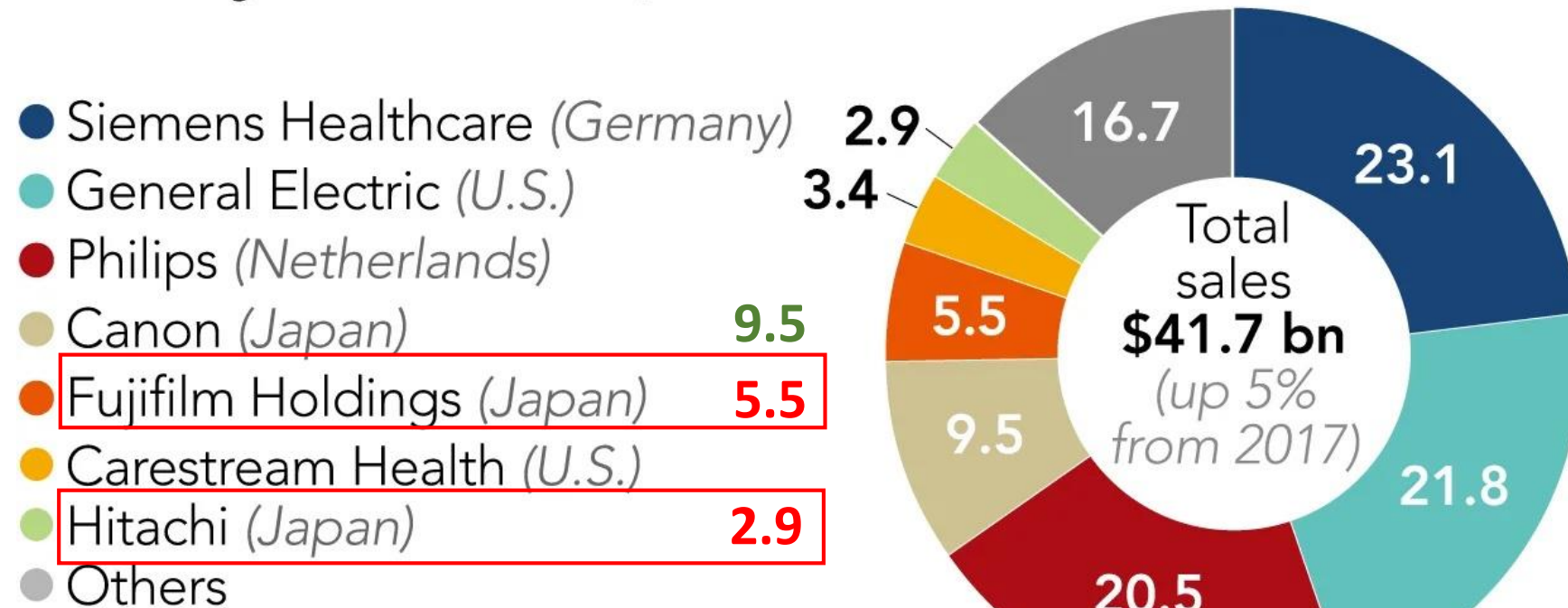
Precision Prevention : Personalized Health Check 、 AI for Early Detection, Home Screening, Tele Health Consulting Services *etc.*

Health Promotion: Lifestyle, Environmental Adjustments, Personalized Diet, Sport and Exercise, Microbiota, Homecare and Wearable Devices, Health Management, *etc.*

Fujifilm Healthcare acquires Hitachi Diagnostic Imaging

on 31 March 2021 for 179 billion yen

Diagnostic imaging equipment global market share by sales (2018, in percent)



Source: Evaluate

8.4 + 9.5 = 17.9 (Japan)

a complete and integrated portfolio of diagnostic products and services, including CT, MRI, X-ray, AI, PACS, endoscopy and ultrasound systems.

Healthcare Innovation by cross-industry collaborations

Taiwan is a total solution provider



Key drivers of Taiwan's
healthcare industry

Advanced Medical Care



High Quality R&D and MFG



Strong ICT and Elec. Tech.



Program Project of Regenerative Medicine (2017-2021)



- 1: **3D printing of meniscus and articular cartilage cup for the clinical application**
(Hung, Shih-Chieh, China Medical University)
- 2: **Advanced Translation of Cellular Reprogramming Technologies in Regenerative Medicine** (Lee, Oscar, National Yang-Ming University)
- 3: **Application of Stem Cell Tissue Engineering of Tracheal Regenerative Medication** (Chen, Jin-Shing, National Taiwan University)
- 4: **Harnessing Stem Cell Properties for Regenerative Medicine and Development of Stem Cell-related Theranostics**
(Yu, John, Chang Guan Medical Foundation)
- 5: **Development of systemic safety allograft pcMSCs/SB cell product for unmet medical needs of diabetics, decubitus, severe burn and Multiple Sclerosis**
(Huang, Rita Yen-Hua, Taipei Medical University)
- 6: **Taiwan Heart Tissue Chip Project**
(Hsieh, Patrick Ching-Ho, Institute of Biomedical Sciences, Academia Sinica)

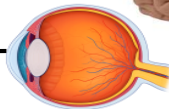
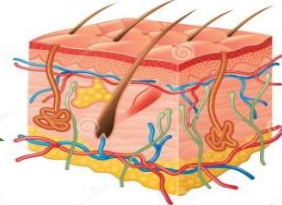


- 1: **Regenerative Medicine Initiative Program at NHRI**
(Lin, Shaw-Fang, National Health Research Institutes)
- 2: **Management Mechanism for Regenerative Medicine Industry**
(Shih, Chung-Liang, Department of Medical Affairs, Ministry of Health and Welfare)

Research Targets of 6 Program Teams

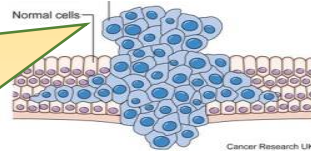
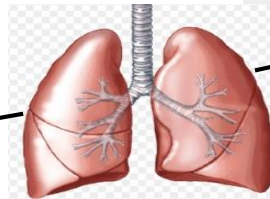
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Development of systemic safety allograft pcMSCs/SB cell products for unmet medical needs of diabetics, decubitus, severe burn and Multiple Sclerosis
(Huang, Rita Yen-Hua, Taipei Medical University)



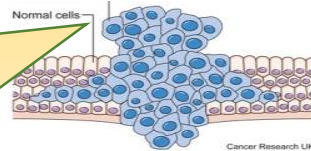
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Advanced Translation of Cellular Reprogramming Technologies in Regenerative Medicine
(Lee, Oscar, National Yang-Ming University)



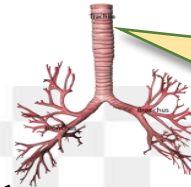
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Harnessing Stem Cell Properties for Regenerative Medicine and Development of Stem Cell-related Theranostics
(Yu, John, Department of Medical Research, Chang Gung Medical Foundation)



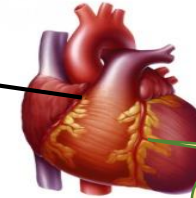
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Application of Stem Cell Tissue Engineering in Tracheal Regenerative Medication
(Chen, Jin-Shing, National Taiwan University)



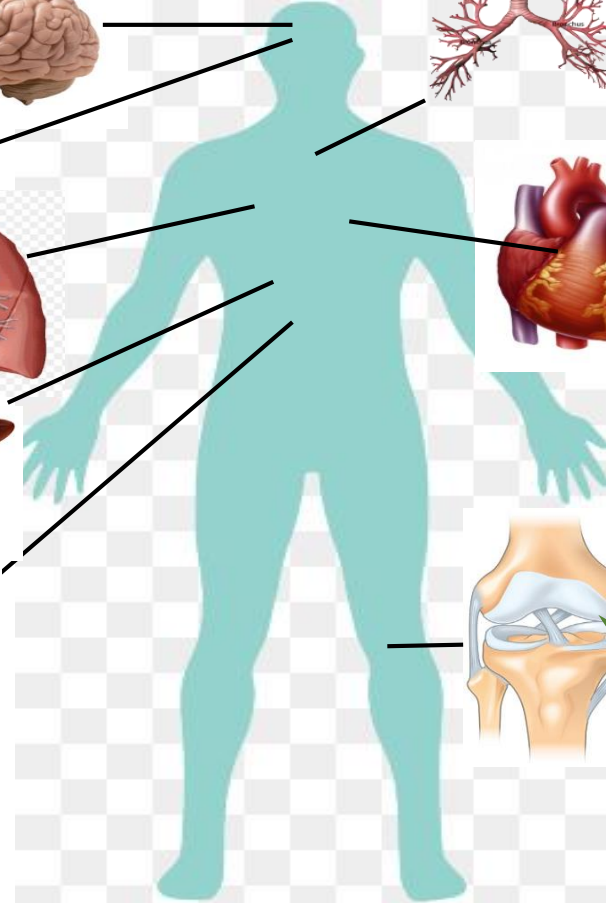
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Taiwan Heart Tissue Chip Project
(Hsieh, Patrick Ching-Ho, Institute of Biomedical Sciences, Academia Sinica)



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3D-printed meniscus and articular cartilage cup translate to patients
(Hung, Shih-Chieh, China Medical University)



Contributions from the Department of Medical Affairs, Ministry of Health and Welfare:

- (1) Four symposia with experts on the development of regenerative medicine industry and industry-academia cooperation models were held on November 22, 2017; January 17, March 15, and April 24, 2018, respectively. Experts were invited from the fields of industry, medicine, and definition and management of the regulations of regenerative medicine in various countries. Suggestions were collected from industry and medical professionals on the overall management structure of regenerative medicine in Taiwan.
- (2) On June 8th and July 13th, 2018, 2 sessions of regenerative medicine management symposia were held to invite experts in the fields of medicine, law, and patient groups to discuss the direction of the technology management for the regenerative medicine.
- (3) To Analyze and compare the current status and management systems of the regenerative medicine industry in Japan, the United States, and the European Union. The item is included in the "**Administrative Measures for the Implementation or Use of Specific Medical Technology Inspection and Testing Medical Instruments**", so that cell therapy can be applied for patients in need. This approach was issued and implemented on September 6, 2018.
- (4) Completed the research and analysis of the regenerative medicine industry and one copy of the report on regulations and recommendations.
- (5) The International Forum on Global Trends in Regenerative Medicine were held on December 18, 2018, and foreign guests from the United Kingdom, the United States, Japan, and South Korea were invited to Taiwan to exchange experience in industry-academia cooperation.

Early Approval for Regenerative Medicine Products in Japan

Process of the Development So Far



Development Process of introducing Early Approval System

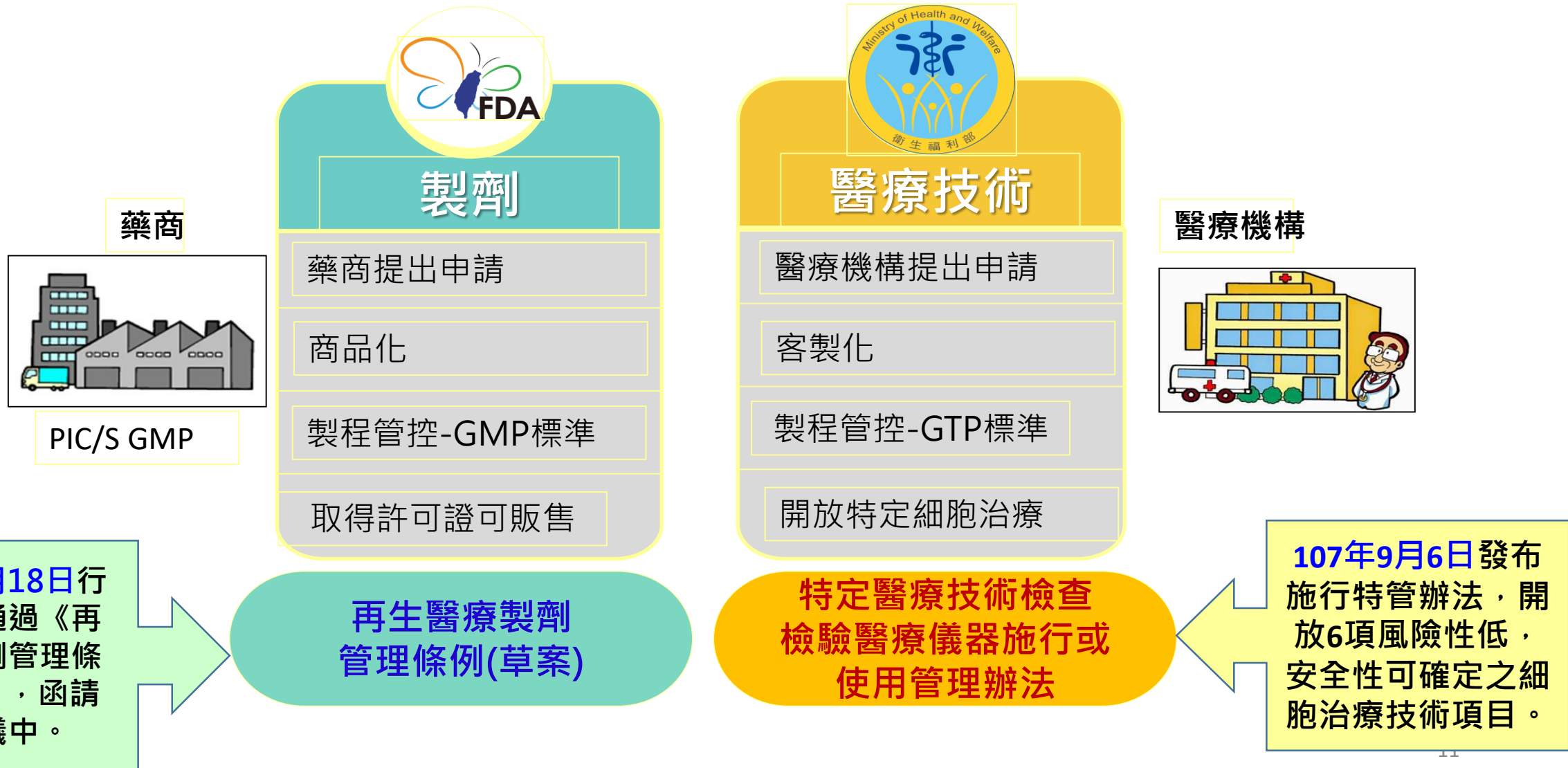


- Drastic reduction in the treatment period and number of patients with '**Early Approval System**' .
- Insurance is listed at '**Early Approval**' stage.

Cited from:

<https://www.healios.co.jp/en/regenerative-medicine/>

Management Framework of Regenerative Medicine and Regulation Adjustment in Taiwan



Status of Taiwan's Regenerative Medicine Industry and R&D Capacity (after the releasing of the special implementation)

Medical

1. The General Hospital of the Tri-Services: May 3, 2019, was approved by the Ministry of Health and Welfare to establish an autoimmune cell therapy center.
2. E-Da Hospital: Cooperated with Sangu to conduct a trial of autologous chondrocytes in the treatment of knee cartilage defects.
3. Taicheng Stem Cell Center of National Taiwan University Hospital: cooperated with Novartis for CAR-T therapy, and proceeded the first phase of clinical trials in 2020.

Industrial

1. Products from 50 cell biotechnology companies have proceeded the clinical trials.
2. Stem cell related clinical trials are the most common, followed by immune cell therapy.
3. The therapeutic targets are mainly knee joints, cancer, and neurological diseases.

ITEM	Company	Medical Collaborators
Immune cell therapy	訊聯、尖端醫、麗寶生醫、宣捷、生寶、永生、再生緣、基亞、長聖、沛爾、鑫品、仲恩、諾華、長春藤、媚登峰	台大附醫、馬偕、長庚、中醫大附醫、慈濟、台北榮總
MSC therapy	國璽	慈濟、越南7家綜合醫院
Vectors	啟弘生技、生技開發中心、宇越生醫	長庚
Cell sheet	三顧 (口腔黏膜上皮細胞層片)	義大附醫
Gene therapy* (Kindness Therapy)	百健	高醫大、台大、榮總、長庚、馬偕

Business Landscape in Taiwan: Regenerative Medicine

	Storage & Banking	Scaling & Manufacturing	Gene & Cell Therapy	Lab Services
Company				
Focus Area	<p><u>Cell types:</u></p> <ul style="list-style-type: none"> • Cord blood • ADSCs • MSCs • Immune cells • PBSCs • Amniotic fluid stem cells • Oral stem cells 	<ul style="list-style-type: none"> • CIK, DC, NK, DC-CIK, Gamma-Delta T cells • Chondrocytes for Cartilage • Adipose stem cells • Bone marrow mesenchymal stem cells • Exosomes 	<p><u>Cells, products / applies</u></p> <ul style="list-style-type: none"> • ELIXCYTE® / CKD • Autologous adipose stem cells / brain stroke • Immunotherapy / cancer • Amniotic fluid stem cells / osteogenesis imperfecta • Umbilical cord blood stem cells / chronic spinal cord injury 	<ul style="list-style-type: none"> • Stem cell culture medium • Growth factor, R-proteins • Biomimetic carrier • Automated cell isolation and culture system

Note: the list provides merely the information on companies, products and/or services relevant to regenerative medicine
Source: corporate websites, compiled by IBMI & RBMP; last updated Aug, 2022

Potential Collaboration and Partnership Opportunities between Japan and Taiwan

- ***Biomaterials and Bio-information***
- ***Training program for Young Talents***
- ***Pre-Clinical and Clinical Trials***
- ***Harmonization on the Regulations for Regenerative Medicines***

TAIWAN
Where innovations are shaping a new era of intelligent healthcare

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Over **1800 biotech** companies
Best healthcare system in the world
Top-ranked life science research institutes and universities
Most influential ICT & electronics industry in the world
Growing number of **emerging biotech startups**

Health	Pharma	Electronics
Medical	Biotech	IT

Endless Potential & Opportunities

Thank you for your attention!

Healthcare[®] EXPO · TAIWAN 台灣醫療科技展

2-5 December 2021, Taipei

Medical AI Application



Inno Zone



Trade Visitor & Professional
31,000

- 28% Healthcare Related
- 16% Trade & Investment
- 15% Digital Tech & ICT
- 15% Medical Devices
- 14% Academia, R&D
- 12% Life Sciences & Others

Diagnostics, Pharmaceuticals & Cell Therapy

Predict, prevent, or precisely treated.

Diagnostics lays the foundation of making a clinical decision. The latest development and advancement- both for individual health and commercial use- were on display, ranging from digital pathology, liquid biopsy, bone marrow counting to cell manufacturing & storage.



- IVD devices, microfluidic chips
- Cancer screening, pharmacogenomic testing
- Cell products & cell therapy services
- CRO, CMO & CDMO
- Lab apparatus, reagents, workflow automation

Onsite + Online

*Expand Healthcare Markets &
Businesses in APAC*

Healthcare⁺ Expo 1 – 4 December 2022, Taipei
Healthcare⁺ B2B 1 August 2022 – 31 July 2023