# The ACTO Times

Asian Cellular Therapy Organization

VOL. 3
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**SPOTLIGHT**
Taiwan CGT Update

**2026 ACTO**
Annual Meeting

- Regional CGT Regulation
- Academic Highlight
- Special Topic
- CGT in Industry View

**2026 NEW YEAR EDITION**

The ACTO Times
Asian Cellular Therapy Organization

# 2026 NEW YEAR EDITION

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## SPECIAL TOPIC



## CGT IN INDUSTRY VIEW





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# Greetings
## The ACTO Chairperson



Dear ACTO Members and Supporters,
We are pleased to distribute the Volume 3 Issue 1 of The ACTO Times 2026 New Year Edition. Thank you for your continuous support of the journal as well as the overall activities of ACTO.

ACTO annual meetings have already been held 16 times in many cities, and the 17th Annual Meeting will be held in Jakarta from August 27–29, organized by the Indonesian team under the guidance of the Meeting President, Dr. Amin Soebandrio. We would like to encourage you not only to participate in the meeting but also to submit your abstracts.
By doing so, you will have the opportunity to compete for the Best Abstract Award. As in previous years, the Best Abstract will be selected by members of the Abstract Review Committee, and the award will be presented during the meeting with support from the ACTO Headquarters Office.
Another important announcement is that the 18th Annual Meeting in 2027 will be held in Niigata City, Japan, organized by Prof. Shuji Terai of Niigata University. The exact date and venue will be announced at a later time.

At present, several issues remain regarding the clinical use of exosomes. From what I have learned through clinical studies conducted at Duke University and IGR (France), dendritic cell (DC)-derived exosomes can transfer information to various immune-related cells when they carry the appropriate biological signals. However, even DC-derived exosomes are not effective if they do not contain the proper information, such as antigen-specific signals.

Another important point to emphasize is the regulatory process for such new materials and therapies. Any material administered to humans must have sufficient safety data and preliminary evidence of efficacy. In addition, the research protocol must be reviewed by an appropriate ethics committee and submitted to the relevant local regulatory agency. Our two studies were reviewed by the US FDA and were approved for clinical trials. In those studies, we proposed methods to evaluate the safety and efficacy of exosomes derived from dendritic cells.

Today, we are concerned that there are many clinical applications of exosomes being conducted without the proper involvement of regulatory authorities. The situation is similar to the time when we published an appeal regarding cell therapy in 2010 (Cell therapy medical tourism: Time for action, Cytotherapy, 2010; 12: 965–968).

I strongly believe that our members will follow the appropriate regulatory processes when conducting new studies. The ACTO Regulatory Committee members will be ready to support your new ideas and initiatives.

Best regards,

Chairperson, Asian Cellular Therapy Organization (ACTO)
Akihiro Shimosaka, Ph.D.

# Editor's Column

## The ACTO Times Editor-in Chief

Dear readers and friends of The ACTO Times,

As we welcome the New Year 2026, I would like to extend my warmest greetings and sincere appreciation to everyone who has supported The ACTO Times. Your continued engagement through reading, submitting manuscripts, reviewing, and sharing our work has been essential to our progress and momentum.

As Editor-in-Chief, I am thrilled to share one of our most meaningful milestones: The ACTO Times has been granted an ISSN (3105-6539). This achievement strengthens the journal's identity and visibility and marks an important step toward our long-term development and international recognition.

We are also encouraged by the continued growth in readership. Under the leadership of Chairperson Professor Shimosaka and the Advisory Board, our latest readership and website traffic report shows steady increases in visits and engagement.

This reflects rising interest in the topics we publish and the value our community finds in the journal. We are grateful for this trust, and we will continue to enhance the quality, relevance, and accessibility of our content.

In 2026, we are pleased to welcome new leadership and expertise to our team. We are honored to introduce Professor Kenneth Kaushansky, MD, MACP, as a new member of our Editorial Advisory Board. He is Dean and Distinguished Professor Emeritus of the Renaissance School of Medicine at Stony Brook University and the former Editor-in-Chief of Blood. We are also delighted to welcome Dr. WH Chen, President of the Taiwan Association of Cellular Therapy (TACT), as our new Vice President in Taipei. Their experience, insight, and commitment will further strengthen our editorial direction and expand our academic and professional network.

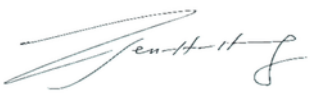
In this New Year 2026 edition, The ACTO Times is pleased to present special highlights that reflect both important policy progress and regional scientific collaboration. We feature timely perspectives on Taiwan's Regenerative Medicine Act, focusing on its significance for clinical translation, regulatory readiness, and the future development of regenerative therapies in Taiwan. We also highlight ACTO Indonesia 2026 as a key platform for exchange and partnership across Asia, and we look forward to sharing emerging research, strengthening cross-border collaboration, and advancing shared standards and innovation in the field.

Looking ahead, 2026 will be a year of continued progress and innovation for The ACTO Times. We will further expand our academic scope and strengthen our publishing practices, with particular attention to emerging directions such as AI and cell and gene therapy (CGT). We also look forward to engaging with the broader community at ACTO Indonesia 2026, where we hope to build closer collaborations across Asia.

Thank you again for being part of The ACTO Times community. We look forward to working together with all of you.

With best wishes for a successful and inspiring 2026,

Sincerely,



**Yen Hua Huang, PhD**
Editor-in-Chief, The ACTO Times
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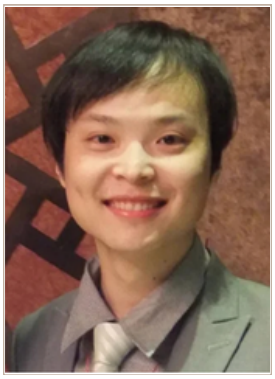

## Yung-Che Kuo, Ph.D.
Taipei

Kuo is an Assistant Research Fellow, TMU Research Center of Cell Therapy and Regeneration Medicine member and TMU Research Center of Thoracic Medicine. He is also a Director of Core Laboratory of Good Tissue Practice (GTP), Taipei Medical University, Taipei, Taiwan.

## Josephine MD, Ph.D.
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Jojo is a lecturer at the Department of Parasitology, Faculty of Medicine, Public Health, and Nursing at Universitas Gadjah Mada (UGM). Her research interests include dengue infection, parasitology, immunology, and medical education.

## D. Renovaldi, M.Sc
Jakarta

Reno is a PhD Student in International PhD Program in Medicine, Taipei Medical University. His research focuses on molecular medicine especially related to tumor niche / microenvironment and their role in cancer therapy.

## Nova, MD, Ph.D.
Yogyakarta

Nova is a faculty member in the Pediatric Surgery Division, Department of Surgery, Universitas Gadjah Mada (UGM), Indonesia. His research interests include stem cell biology, organoid technology, and translational applications of regenerative medicine in pediatric surgery.

## Karen Kitchley, M.Sc
Madurai

Karen is a PhD student at the Taipei Medical University. Her research focuses on exosomal therapy on hepatocellular carcinoma and exploring their mechanism of action.


## Yu-Xiu Lin, M.Sc
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Tony is a PhD student at the Graduate Institute of Pharmacology, National Taiwan University College of Medicine. His research focuses on MSC culture and therapy, specifically exploring their role in regenerative medicine.

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# UNVEILING THE TIMELESS TAPESTRY

## THE CHRONICLE OF ACTO THROUGH TIME

**ACTO, the Asian Cellular Therapy Organization**, serves as a dedicated platform for fostering the growth and progress of cellular therapy in the Asian context. It aims to respond more dynamically to the specific challenges and opportunities found in the diverse healthcare and research landscape across Asia.

ACTO is dedicated to driving advancements in cell and gene therapy (CGT), including research, clinical applications, industry collaborations, and global regulation. It seeks to facilitate collaborative environment where professionals, researchers, industry leaders, and regulatory agencies can come together to share knowledge, experiences, and innovations in CGT.

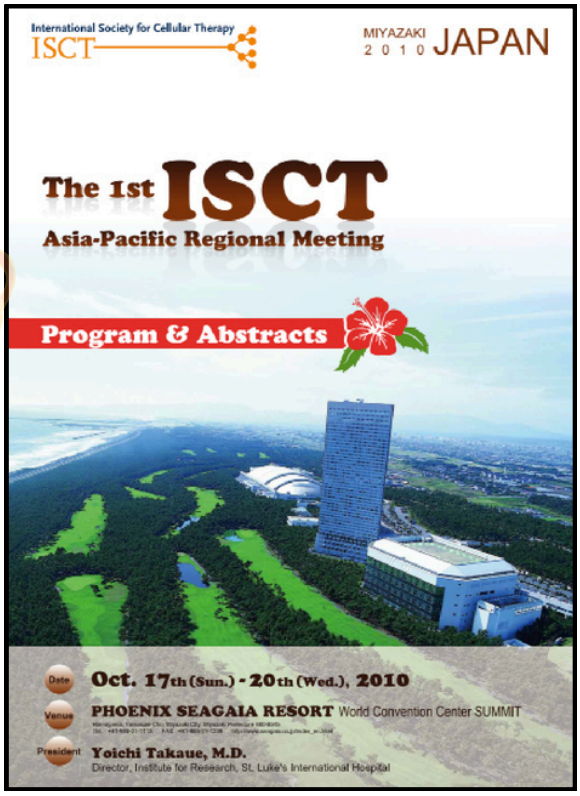
By doing so, ACTO envisions creating a comprehensive ecosystem that accelerates the translation of CGT research into practical applications, benefiting patients and contributing to the broader field of regenerative medicine. Through its activities, publications, and events, ACTO aims to play a crucial role in shaping the future of cellular therapy in Asia and contributing to the global discourse on regenerative medicine.

Since its establishment stemming from the ISCT Asian Regional Meeting, ACTO has evolved into a dynamic organization with a broad presence covering 15 regional territories, including Bangladesh, China, India, Indonesia, Iran, Japan, Jordan, Israel, Korea, Malaysia, Taiwan, Thailand, Singapore, Vietnam, and Pakistan. The expansion of ACTO into these territories not only amplifies the impact of CGT initiatives but also facilitates the exchange of knowledge and expertise across borders.

This collaborative approach aligns with ACTO's overarching mission to create a vibrant and interconnected network dedicated to advancing CGT within the diverse landscape of Asia.

The inclusion of these 15 regional territories served by ACTO highlights the varied landscapes, healthcare systems, and research environments across Asia. It demonstrates ACTO's recognition of the importance of tailoring CGT initiatives to the unique needs, challenges, and opportunities specific to each region.

Looking ahead, the ACTO organization remains committed to its regional focus, striving to further expand its presence and influence to better serve the diverse needs of the Asian CGT community.



# PRELUDE

## NAVIGATING THE UNIQUE DYNAMICS OF CGT IN ASIA

*In the vibrant landscape of CGT. "The ACTO Times" unfolds as a chronicle attuned to the distinctive characteristics that define the Asian population. This prelude invites readers into a realm where the convergence of a large and diverse populace, intricate gene backgrounds, evolving regulations, and culture-related intricacies shape the narrative of CGT in Asia.*


### Large Population Dynamics

Asia, with its colossal and diverse population, charts a path for CGT that is both unprecedented and dynamic. "The ACTO Times" embarks on a journey to unravel how the sheer scale of population diversity influences research, clinical applications, and the industrial landscape of CGT.

### Gene Background Diversity

Within the mosaic of Asian societies lie rich variations in gene backgrounds. This prelude delves into the intricacies of genetic diversity, exploring how the tapestry of genes across Asian populations influences the trajectory of CGT, from personalized medicine to targeted therapies.

### Culture-Related Pre-Clinical Research

Cultural contexts weave through the fabric of pre-clinical research. This publication uncovers the cultural nuances influencing the design and execution of pre-clinical studies, shedding light on how diverse cultural perspectives impact the trajectory of CGT research in Asia.

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### Manufacturing and Industry Evolution

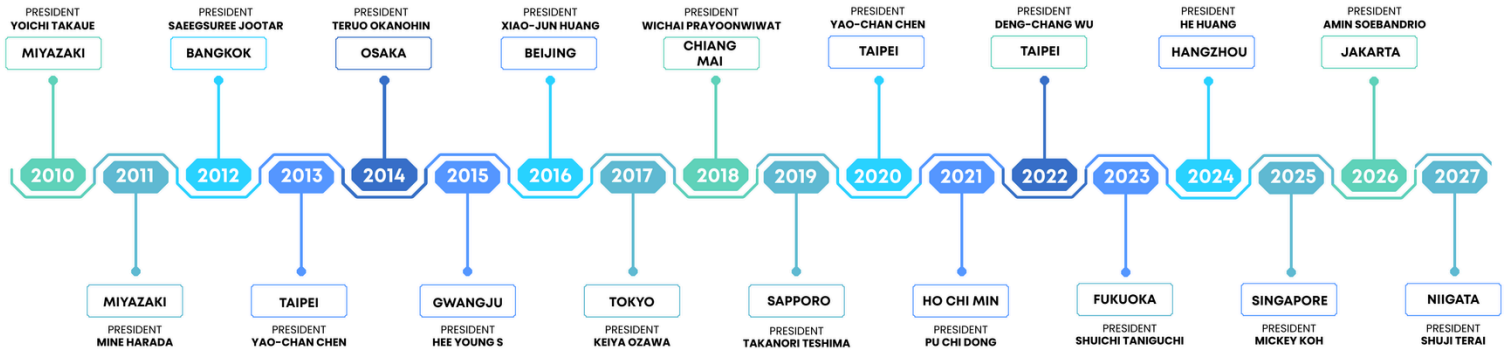
The industrial heartbeat of cellular therapy in Asia is a testament to innovation and growth. "The ACTO Times" investigates how manufacturing practices, deeply entwined with cultural norms, contribute to the dynamic evolution of the CGT industry in this expansive region.

### Regulatory Frontiers

The diverse regulatory frameworks and rich cultural tapestry across Asian regions stand as influential forces shaping the intricate process of CGT in the region. In navigating this dynamic landscape, each nation brings its own set of regulations, reflecting unique perspectives on ethical considerations, patient safety, and research practices.

# OUR JOURNEY THROUGH TIME

IMAGE FROM CANVA.COM



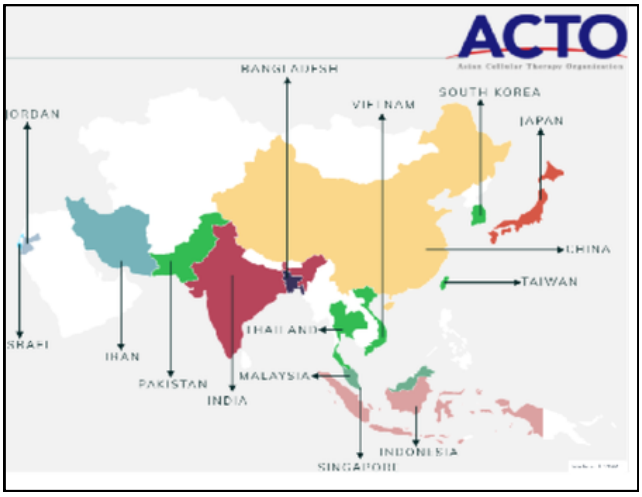

Over the years, the ACTO meetings became a cornerstone for professionals in the field, providing a platform for networking, sharing knowledge, and forging international partnerships. As the organization evolved, reflecting the dynamic landscape of CGT in the Asia-Pacific region.

The ACTO meeting was started from the first International Society of Cellular Therapy (ISCT) Asian-Pacific Regional Meeting 2010 in Japan. The primary objective of this gathering is to facilitate the exchange of knowledge and expertise among researchers, clinicians, business professionals, and regulators in the realm of CGT.

The focus is on advancements in equipment and treatments, encompassing areas such as expansion or modification for transplantation, immunotherapy, regenerative medicine, and gene therapy.

In many Asian regions, there has been limited exploration of expertise in innovative cellular therapy and the development of equipment for clinical purposes. Additionally, there is a notable absence of well-established regulatory guidelines for approval processes, which are crucial for fostering new ideas in clinical applications.

These challenges pose significant hurdles to the progress of our research initiatives. The intention is that this meeting will serve to improve communication among Asian professionals and foster collaborations with their Western counterparts, thereby contributing to overcoming these obstacles.




As of the present moment, the Asian Cellular Therapy Organization (ACTO) has seen the enthusiastic engagement of 15 regional territories in its annual meetings. This collective involvement underscores the organization's commitment to fostering collaboration and knowledge exchange among diverse regions within the realm of CGT. Joining ACTO provides an opportunity for regions to contribute their unique insights, experiences, and expertise to the ongoing discourse in CGT. As we embrace a spirit of inclusiveness, our shared journey towards scientific and medical advancements becomes even more robust and impactful.

Editorial Office
The ACTO Times

Vijetha Karen Kitchley, M.Sc.
International PhD Program in Cell Therapy and Regenerative Medicine
Taipei Medical University

# The ACTO Times website performance report

## OVERALL TRAFFIC

Over the past three years, the ACTO Times website has demonstrated steady visibility and international reach, with a notable peak in engagement during 2025.

Between January 2024 and February 2026, the website recorded 2.6K total views and 1.1K visitors, reflecting consistent interest and returning readership. Engagement remains modest but meaningful, with 3 likes and 1 comment, indicating early-stage audience interaction and potential for growth.


## GEOGRAPHIC REACH

The ACTO Times audience is international, with strong engagement across Asia and North America.
This distribution reflects regional leadership in regenerative medicine and growing global interest.


## KEY INSIGHTS

- 2025 marked a significant growth period.
- Scientific and therapy-focused articles drive readership.
- Organic search and professional networks are major traffic drivers.
- Audience reach is strongest in Asia-Pacific and expanding globally.

## CONCLUSION

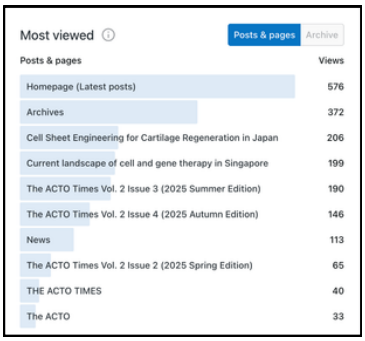
**The ACTO Times website** continues to strengthen its role as a specialized information platform for regenerative medicine and cell therapy. The significant growth observed in 2025 demonstrates increasing visibility, improved discoverability, and rising interest in the publication's scientific content. Readers are particularly drawn to clinically relevant and region-focused articles, confirming the value of providing timely updates on advancements across Asia and beyond.

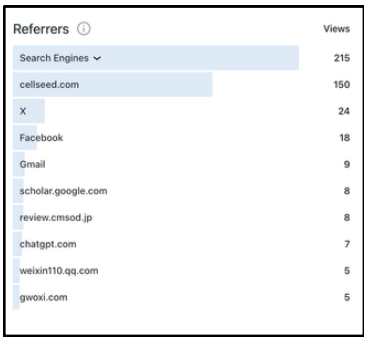
Traffic patterns indicate that search engines and professional networks are key drivers of readership, while the geographic distribution highlights strong engagement in Taiwan, Japan, and other Asia-Pacific regions, with expanding international reach. Although interaction metrics such as likes and comments remain limited, they signal an opportunity to further cultivate reader engagement and community participation.

Sustaining growth will depend on continuing to publish high-quality, relevant content, improving search optimization, strengthening academic and institutional partnerships, and expanding outreach through digital and professional channels. With strategic development, ACTO Times is well positioned to broaden its global impact and become a leading regional voice in regenerative medicine discourse.

## MOST VIEWED CONTENT & TRAFFIC SOURCE

Readers primarily access the homepage and archival materials, suggesting users explore both current updates and past issues. Scientific and regional therapy updates clearly attract sustained interest. Search engines are the primary gateway to the site, confirming strong discoverability through organic search. Academic and professional referrals indicate relevance within scientific and clinical communities.



Thai-Yen Ling, Ph.D.
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IMAGE FROM CANVA.COM

# Before and after "The Stone Age": Taiwan dual regenerative medicine acts

**2018 "Special Regulation" (特管辦法): Establishing a "controlled opening" clinical framework through subordinate regulations, and gradually moving toward dedicated legislation**

Taiwan's dual regenerative medicine laws were officially implemented on January 1, 2026. Looking back at Taiwan's legislative journey in regenerative medicine, the amended "Regulations Governing the Implementation or Use of Specific Medical Techniques, Examinations, Tests, and Medical Instruments" commonly known as the "Special Regulation" (特管辦法), formally announced by the Ministry of Health and Welfare (MOHW) on September 6, 2018, was a pivotal starting milestone. When confronted with patients' urgent needs, where "time is life," waiting solely for the completion of primary legislation was clearly too slow to meet the moment.

Against this backdrop, the then Director General of the Department of Medical Affairs, Minister Chung Liang Shih, proposed an innovative approach after careful deliberation. He used the Special Regulation, originally issued in 2003 with only 11 articles, as a regulatory foothold and established a manageable clinical governance framework through substantial amendments.

On September 6, 2018, the MOHW officially promulgated a comprehensively revised Special Regulation, expanded to 34 articles. Appendix Table 3 specifies six cell therapy items permitted for clinical use, with an initial focus on autologous cells, based on their higher safety and more predictable efficacy.

At the same time, the regulation broadened cancer indications beyond end-stage solid tumors to include patients with stage I to stage III disease who had failed standard treatments, as well as certain hematologic malignancies. This allowed cell therapy to enter clinical practice under a controllable regulatory framework. The policy message was clear. In the face of unmet medical needs, regulators may choose to open access, but the opening must be controlled. Speed can be pursued, but only on the premise of safety, quality, transparency, and traceability.

**The "Stone Age"**

2018 Special Regulation represented a ground-breaking leap in Taiwan's healthcare governance and in the development of the biotech and medical sectors, particularly the cell therapy industry.

Minister Shih played an indispensable role in advancing this regulatory framework. This initiative not only benefited patients but also catalyzed rapid growth in Taiwan's biotech and medical ecosystem, especially in cell therapy.

Because Minister Shih's surname "石" corresponds to "stone" in English, people in the medical and biotech industries who are familiar with this history often use September 6, 2018, as a dividing line, calling the period before it "Before the Stone Age" and the period after it "The Stone Age."

The term symbolizes the beginning of a new era in medicine and conveys respect and appreciation for Minister Shih's contributions to building Taiwan's regenerative medicine system.

**From the Special Regulation to Taiwan's Dual Regenerative Medicine Laws**

As the number of cases accepted under the Special Regulation grew rapidly, governance tools also needed to be upgraded. In May 2022, the MOHW submitted draft bills for the dual regenerative medicine laws to the Executive Yuan for review. The institutional design focused on establishing dedicated funds, creating a national-level cell bank, and using mechanisms such as conditional approvals to shorten development timelines and accelerate market entry.

After multiple rounds of review at different stages, including 2018, 2023, and May 2024, the bills were finally passed on third reading by the Legislative Yuan on June 4, 2024. Going forward, new technologies and products involving "genes, cells, and their derivatives" for the treatment, repair, or replacement of human cells, tissues, and organs will be regulated under two separate legal instruments, the Regenerative Medicine Act and the Regenerative Medicinal Products Management Act. The goal is to provide new options for patients who respond poorly to existing treatments, while also driving domestic innovation and industrial development in regenerative medicine.

**Taiwan's Dual Regenerative Medicine Laws in 2026: Significance and Challenges**

The implementation of the dual laws in 2026 is not merely an upgrade of the Special Regulation into higher-level legislation. More importantly, it expands the governance scope of regenerative medicine, moving from clinical pilot use, data accumulation, and risk control toward a complete closed loop that covers product development, scaled manufacturing, and market regulation.

Looking ahead, the real challenge lies not in the laws taking effect per se, but in whether the system can be implemented in a high-quality and sustainable manner. Key questions include whether real-world data generated after conditional approvals can be comprehensively collected and rigorously analyzed, whether long-term follow-up and adverse event reporting will be faithfully executed, whether review capacity and industry support can be strengthened in parallel, and whether National Health Insurance decisions can strike a transparent and consistent balance between cost effectiveness and equitable access.

2026 is not only the first year of implementation for Taiwan's dual regenerative medicine laws, but also a key milestone in Taiwan's transition from research to broader clinical adoption, and from isolated cases to an affordable and well regulated market. The term "The Stone Age" will become widely recognized and will be met with deep appreciation and gratitude.

# Welcome New Advisory Board Member
## Prof. Kenneth Kaushansky MD, MACP

*"It is my great honor to join the Board of the Asian Cellular Therapy Organization. It has been a pleasure to have watched the organization grow from its first meeting in 2010 in Japan to its current roster of over a dozen countries and regions. I am particularly impressed with ACTO's stated pillars: fostering international translational research, helping to inform national and global regulatory agencies, promote collaboration amongst scientific and clinical entities, encouraging commercialization strategies of cellular therapies, and helping to educate principal investigators, lab directors, technologists and clinicians. It is not hyperbole to state that cellular therapies, or "living drugs" as some refer to them, represent an exciting and promising approach to solve so many of the serious disorders of human health. It is clear that medicine has become quite complex, especially true for cellular therapies, and medical problem solving is best approached as a "team sport". As such, ACTO provides the perfect platform to bring together Asian basic and clinical scientists, the regulators and the commercial entities, all of whom are vital to bringing new cellular therapies from conception to treating patients.*

*As a new member of the Board, I was asked to provide a brief personal introduction to the members and participants of ACTO. My journey in medicine began as an undergraduate biochemistry student and medical student at the University of California at Los Angeles. I became fascinated with how the various cells, tissues and organs of human beings function, and why they stop working during various disease states.*

*I fell in love with hematology when as a second-year resident in Internal Medicine one of my mentors, Dr. Clem Finch, shared with me his belief that at that time (and I believe, still today) we understood the biochemistry of hematological diseases better than all other disciplines of medicine. That, coupled with the beauty of a blood or marrow smear, hooked me on hematology for life.*


**Kenneth Kaushansky MD, MACP**
Dean and Distinguished Professor Emeritus,
Renaissance School of Medicine,
Stony Brook University

*Another important epiphany came as a second-year medical student, when on the first day of our pharmacology course, Dr. Don Catlin shared that while 99% of all drugs at the time had been discovered by pure serendipity, one day, he mused, we will understand our diseases well enough that we will be able to rationally design drugs to treat human illness. I then mused, what a great career making rational drug discoveries might be. The third insight was shared by my mentor, Dr. John Adamson, when he introduced me to hematopoiesis and stem cell biology, and along with another mentor, Dr. Earl Davie, launched my career as a physician-scientist studying the role of growth factors in the development of the mature cells of the blood derived from hematopoietic stem cells.*

*"Chance favors the prepared mind", a phrase coined in 1854 by Louis Pasteur, is one of my favorite observations in all of science. So much so that I placed that quote at the entrance to the new translational cancer center building I launch while serving as Senior Vice President for Health Sciences and Dean of the Renaissance School of Medicine at Stony Brook University in New York. But during my life as a biology watcher, I have also learned that sometimes it is an observation in a seemingly unrelated field that sheds critical light on your particular scientific problem. Having cloned and characterized several hematopoietic growth factors, including thrombopoietin, which was dependent on a study that appeared in the virology literature, my scientific attention turned almost entirely towards the hematopoietic stem cell, for two reasons. Somewhat surprisingly, thrombopoietin turned out to be one of only two proteins absolutely essential for hematopoietic stem cell survival (the other being stem cell factor), and secondly. that my primary clinical interest was in patients with myeloproliferative neoplasms, clonal malignancies of the hematopoietic stem cell. From this work we discerned that thrombopoietin and its receptor in one way or another is critically involved in the pathogenesis of a majority of patients with myeloproliferative neoplasms.*

*Over my career I have witnessed rational drug and cellular design applied to nearly every aspect of my clinical and research experience. Hence, my great interest in participating in ACTO, an organization devoted to bringing "living drugs" to human disease. I am also strongly attracted to the ACTO educational pillar. In addition to my numerous roles as a medical educator at the three universities I have called my professional home, the University of Washington, the University of California at San Diego, and Stony Brook University, I have led both the educational and scientific programs of the annual meeting of the American Society of Hematology, have served as Editor-in-Chief of the journal Blood, and for the past 20 years as lead editor of Williams Hematology, about to launch its 11th edition. And now having transitioned to Distinguished Professor and Dean Emeritus at Stony Brook, I now serve as Distinguished Visting Professor at Chang Gung University in Taiwan, sharing insights with students into the future of medicine in Taoyuan one month each year. In short, having visited Asia well over a dozen times, and now my strong affection for so many Asian countries, I cannot wait to join my good friends, Chair of ACTO, Professor Akihiro (Sam) Shimosaka, and Editor-in-Chief of ACTO Times, Dr. Yen-Hua (Rita) Huang, and all the other distinguished members and participate as a member of the Board of the Asian Cellular Therapy Organization."*

# Welcome New ACTO Vice President Taipei
## Dr. Wannhsin Chen

**Dr. Wannhsin Chen** is a distinguished scientist and leader in stem cell research and regenerative medicine, with more than 30 years of experience spanning fundamental stem cell biology, translational research, therapeutic product development, and regulatory advancement. She currently serves as President of the Taiwan Association for Cellular Therapy (TACT) and Vice President & Chief Technology Officer of Hexun Biosciences Co., Ltd., where she leads innovative programs in cell therapy and extracellular vesicle (EV)-based therapeutic development.

**Dr. Wannhsin Chen**
whsin.chen@hexunbio.com

Dr. Chen received her Ph.D. through the joint program of Academia Sinica and the National Defense Medical College in Taiwan. After completing her doctoral training, she joined the Biomedical Engineering Research Laboratories at the Industrial Technology Research Institute (ITRI), where she played a pioneering role in advancing stem cell science and translational biotechnology in Taiwan. During her tenure at ITRI, Dr. Chen led the establishment of Taiwan's first human embryonic stem cell (hESC) lines, laying a critical foundation for pluripotent stem cell research in Taiwan. She also contributed to the development of multiple pluripotent stem cell culture and differentiation platforms, such as feeder-free culture system and iPSC platform, etc.

In the field of regenerative medicine, Dr. Chen has been deeply involved in bridging laboratory discoveries to clinical applications. She led the development of a clinical-grade mesenchymal stem cells (MSCs)-based investigational product for acute myocardial infarction, including GTP-compliant manufacturing process development, regulatory documentation, and submission to the Taiwan Food and Drug Administration (TFDA) for clinical trial approval. Following TFDA approval and technology transfer, she continued to support the partner company in conducting the clinical trial.

In 2024, Dr. Chen transitioned to industry leadership as Vice President and CTO of Hexun Biosciences Co., Ltd. In this role, she oversees research strategy, product development, regulatory submissions, and clinical translation. Under her leadership, a clinical-grade MSC product targeting vascular diseases has entered patient enrollment, and two additional investigational programs have received U.S. FDA authorization, with plans to initiate trials in Taiwan upon TFDA approval.

Dr. Chen has been actively engaged in the international cell therapy community since the early stages of her career, participating in activities of the International Society for Cell & Gene Therapy and the Asia Cellular Therapy Organization (ACTO), where she previously served as an industry member representative. Through decades of translational research and product development, she has developed a strong appreciation for the importance of regional collaboration. In recent years, while advancing cell therapy programs and navigating multi-jurisdictional regulatory pathways, Dr. Chen has recognized that closer cooperation among Asian countries can significantly accelerate clinical translation. She believes that harmonizing regulatory frameworks, leveraging complementary national strengths, and fostering cross-border scientific and industrial partnerships will enable Asia to achieve faster and more impactful progress in regenerative medicine.

Through ACTO's organizational framework, Dr. Chen aims to promote regulatory dialogue, technical collaboration, and strategic alignment among Asian countries. By integrating diverse expertise across research, clinical medicine, manufacturing, and regulation, she envisions building a coordinated regional ecosystem that accelerates the realization and responsible advancement of clinical applications of cell therapies throughout Asia.

Dr. Chen has published more than 40 scientific papers and holds over 20 granted patents worldwide. In addition to her scientific achievements, she is a founding member and current President of TACT, a founding member of the Taiwan Society for Stem Cell Research (TSSCR), a certified instructor for Ministry of Health and Welfare (MOHW)-approved cell therapy physician training programs, and a former member of the TFDA Regenerative Medicine Consulting Committee, where she contributed actively to policy development and regulatory science. Through her integrated roles in scientific innovation, industrial translation, and regulatory policy, Dr. Chen remains committed to advancing safe, effective, and globally harmonized cell therapy development. She believes that strong collaboration across Asia—supported by ACTO's leadership and collective expertise—will unlock the full therapeutic potential of cellular therapies for patients throughout the region and beyond.

# Welcome Message
# President of 2026 ACTO Annual Meeting

*Distinguished colleagues, esteemed guests, and partners across Asia and beyond,*

**Prof. dr. Amin Soebandrio WK, Ph.D. SpMK(K)**
**President of 2026 ACTO Annual Meeting**

It is an honour and privilege to welcome you to the 17th Annual Meeting of the Asian Cellular Therapy Organization (ACTO), taking place in Jakarta, Indonesia, on August 26–28, 2026. This year marks a pivotal moment for our region as we work collectively to accelerate the growth of and strengthen Asia's leadership in the global cellular therapy landscape.

Our theme, "Advancing Research & Clinical Translation of Cell-Based Therapies: Academician, Business, Community, and Government," reflects ACTO's commitment to bridging discovery, policy, clinical application, and societal impact. ACTO remains the platform where science meets regulation, innovation meets clinical need, and collaboration evolves into real-world solutions.

As a clinician, I witness the urgent need for safe, effective, and accessible cell therapies daily. ACTO 2026 is designed to bring us closer to meeting those needs by convening researchers, clinicians, policymakers, and industry leaders in a shared space for knowledge exchange and strategic dialogue.

The discussions and interactions throughout this meeting aim to spark new insights, strengthen regional collaboration, and open pathways for advancing cell-based therapies across the Asia region. Over the course of three days, ACTO 2026 will feature high-level scientific exchanges, in-depth regulatory conversations, and opportunities to explore innovations emerging from academia and industry alike. Participants will also have the chance to engage in laboratory visits that connect scientific progress with its practical implementation and further reinforce the multidisciplinary spirit that defines ACTO.

We cordially invite you to be part of this momentum. Your perspectives, experience, and collaboration will shape meaningful progress for patients and communities across the region. On behalf of the organizing committee, I look forward to welcoming you to ACTO 2026 in Jakarta.

Sincerely,
**Prof. dr. Amin Soebandrio WK, Ph.D., SpMK(K)**
**President of the 2026 Asian Cellular Therapy Organization (ACTO) Annual Meeting**

# Welcome from Indonesia



## 17th annual meeting of ACTO

### "Advancing Research & Clinical Translation of Cell-Based Therapies: Academician, Business, Clinician, and Government"

***Welcome to the 17th Annual Meeting of the Asian Cellular Therapy Organization (ACTO), organized in collaboration with the Indonesian Stem Cell Association (ASPI).***

Since its establishment, the ACTO Annual Meeting has served as a premier scientific platform advancing cellular therapy and regenerative medicine across Asia. Over the years, the meeting has been successfully hosted in more than 15 cities across Asian countries, bringing together leading scientists, clinicians, industry innovators, and regulatory stakeholders to foster collaboration and accelerate clinical translation.


The 17th Annual Meeting of the Asian Cellular Therapy Organization (ACTO), in collaboration with the Indonesian Stem Cell Association (ASPI), will be held on 26–28 August 2026 in Jakarta, Indonesia. The meeting will bring together experts in cellular therapy, regenerative medicine, and translational biomedical science to discuss recent scientific developments, clinical applications, and regulatory perspectives shaping the future of cell-based therapies in the Asia-Pacific region.

**Location : Hotel Borobudur Jakarta**
**Meeting date : 26–28 August 2026**
Includes exclusive site visits to cell therapy production facilities

**Programme Highlights :**

- Advancing research and clinical translation of cell-based therapies
- Multidisciplinary sessions involving academicians, clinicians, industry, and government
- Scientific, regulatory, clinical, and public sessions
- Organization and networking meetings

**Register here:**
bit.ly/EarlyRegistrationACTOASPI2026

**More information :**
https://aspindonesia.co.id/17th-annual-meeting-acto-

# SPOTLIGHT
# Taiwan CGT Update

Dr. Chung-Liang Shih, MD., Ph.D.
Minister, Ministry of Health and Welfare, Taiwan

IMAGE FROM CANVA.COM

## Taiwan's journey from the "Regulations of Special Medical Techniques" framework to the "Regenerative Medicine Dual Acts": building a full life-cycle system to institutionalize and scale regenerative medicine

*Today, I would like to use this space in ACTO Times to share Taiwan's experience through a simple timeline of how our regenerative medicine policy moved from a pilot phase to a more complete, institutionalized system, and why we officially brought the Regenerative Medicine Dual Acts into force on January 1, 2026.*

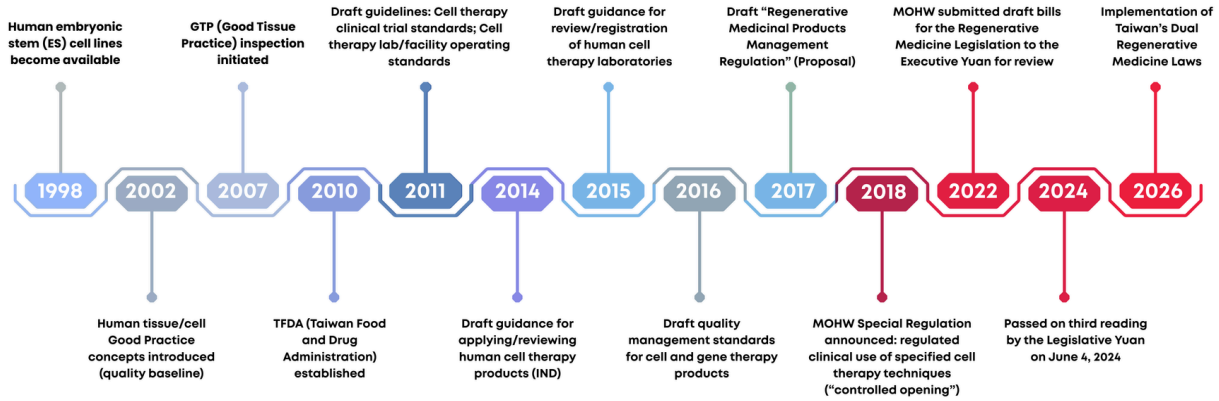
**Dr. Chung-Liang Shih, MD., Ph.D.**
**Minister**
**Ministry of Health and Welfare**
**Taiwan**

The "Dual Acts" refer to the Regenerative Medicine Act and the Regenerative Medicinal Products Act. For Taiwan, this is not just an update of legal text. It marks a major step forward from a technical, trial-based approach under the "Regulations of Special Medical Techniques" framework to a product-based, full life-cycle regulatory system. Looking back to 2018, when the Ministry of Health and Welfare (MOHW) announced and amended the Regulation Governing the Application of Specific Medical Examination Technique and Medical Devices (commonly known in Taiwan as the "Regulations of Special Medical Techniques"), our guiding principle has remained consistent: while responding to urgent clinical needs, we must manage risks, ensure quality, and support responsible industry development within one coherent framework. Our goal is to help innovative therapies reach patients earlier and more safely, in a way that earns public trust and, in doing so, strengthens Taiwan's biomedical and healthcare industry.

In September 2018, by amending the Regulations of Special Medical Techniques, we opened six cell therapy items for clinical use for the first time. We started with autologous (self-derived) cells for a clear reason: they are generally safer and have more predictable outcomes, based on existing evidence. At the same time, we expanded cancer-related indications from end-stage solid tumors to include patients with stage I to stage III cancers that did not respond to standard treatments, as well as certain hematologic malignancies. This enabled cell therapies to enter clinical practice within a controlled regulatory framework and to respond to patients' urgent needs.

By the end of August 2019, when applications had reached 84 cases, we further required hospitals to adopt outcome-based, staged payment and refund mechanisms, and we announced plans to revise the regulations and build a public information portal.

**Taiwan Regenerative Medicine Regulatory Governance: Key Milestones**




*MOHW: Ministry of Health and Welfare; TFDA: Taiwan Food and Drug Administration; GTP: Good Tissue Practice; IND: Investigational New Drug*

*Provided by The Editorial Office, The ACTO Times*

In my view, progress in regenerative medicine is not only about whether we can do it, but whether we can do it responsibly. Patient protection and transparency must be built in from the start.

Two years later, in August 2020, I was invited to give a keynote address at the Taiwan Association of Cellular Therapy (TACT) Annual Meeting. Reviewing the outcomes since the Regulations of Special Medical Techniques took effect, I stated seriously that "the Regulations of Special Medical Techniques framework is reaching its limits."

This was not a denial of its value, but a reminder: as case numbers grow and clinical use expands, a purely technical, case-by-case management approach cannot carry the system forever; we need a stronger legal structure. At that time, applications had reached 178 cases, with 46 approvals. I also made it clear that pricing should follow staged payments based on treatment course and outcomes, because risk control and patient rights must not be weakened by market enthusiasm.

In December 2020, at a press conference on cell therapy outcomes for chronic wounds at Tri-Service General Hospital, I further explained that we would announce an updated version of the Regulations of Special Medical Techniques, bring cell storage banks under management, strengthen patient registration and follow-up, and begin considering an expansion from autologous to allogeneic (donor-derived) cells. This reflected a shift in policy thinking—from "safety first" toward building a scalable supply and quality system for broader clinical use in the future.

From 2021 to 2023, we entered a critical phase: moving toward dedicated legislation and building the backbone of a long-term system.

In March 2021, at the annual forum of the Formosan Association of Regenerative Medicine (FARM), I presented the key elements of the draft regenerative medicine legislation: defining regenerative medicine, regenerative products, and regenerative medical technologies; establishing an advisory committee; introducing a conditional approval mechanism; building a national-level cell bank; and allowing the Regulations of Special Medical Techniques framework to "complete its mission" and be replaced by a more comprehensive legal system.

In December 2021, we also proposed an initial concept of "three regenerative medicine laws," emphasizing the importance of product-side regulation. If regenerative medicine is to scale up and move toward automation, the field will inevitably shift from autologous to allogeneic approaches—only then can costs come down and access expand beyond a small group of patients. Meanwhile, TFDA's approvals of advanced therapy medical products such as Zolgensma and Kymriah also showed that Taiwan had begun building experience in reviewing advanced therapy products, laying the groundwork for a more mature regulatory system.

In May 2022, the legislative structure was refined into the "Regenerative Medicine Dual Acts" and submitted to the Executive Yuan for review. I summarized three major benefits of the proposed system: establishing a regenerative medicine fund, building a national cell bank, and using conditional approval with supporting measures to shorten development timelines and accelerate market entry.

In November 2022, at a biotech forum, I again emphasized that the key regulatory focus should include manufacturing controls, sales and distribution management, and traceability of tissue and cell sources. In March 2023, responding to concerns that the Regulations of Special Medical Techniques framework might discourage formal clinical trials, I clarified that, while applications had reached 400 and about 190 had been approved, the number of INDs for regenerative medicinal products continued to rise. In other words, the system did not stop R&D; instead, it helped us find a more practical balance between clinical needs and development pathways.

In an April 2023 interview with GeneOnline, I further explained that regenerative medicine must address future trends, including allogeneic cells, gene modification, and derivatives (including exosomes). High-risk therapies require longer follow-up and stronger safety surveillance. The policy principle behind conditional approval is to meet patient needs while appropriately controlling risks and respecting patient autonomy.

From 2024 to 2026, the focus shifted to implementation and responsible commercialization. After years of effort, the Dual Acts were passed on June 4, 2024, and were set to take effect on January 1, 2026. In August 2024, at the BTC conference, I explained that the passage of the Dual Acts was a major achievement in Taiwan's regulatory development. Their implementation will support clinical use and commercialization, and will also connect with broader infrastructure such as biomedical data governance and precision medicine.

In August 2025, at the opening of a regenerative medicine clinical trial training program, I emphasized that the Regenerative Medicine Act is not only a regulatory milestone but also signals that Taiwan's National Health Insurance (NHI) system is beginning to seriously address reimbursement strategies and cost-effectiveness for new therapies.

At that time, six regenerative medicinal products had already been approved by TFDA, and the NHI was working through parallel review, expanded budgets, and stronger health technology assessment to help patients benefit earlier while maintaining safety and effectiveness. In late 2025, just before the Dual Acts took effect, I also highlighted another key priority: advertising control and preventing "Bad money drives out good (Gresham's Law).

I specifically pointed to the disorder in the exosome market and warned that illegal efficacy claims would face heavy penalties—up to NT$20 million. At the same time, we ensured a seamless transition for existing cases under the Regulations on Special Medical Techniques.

After the Dual Acts took effect, on January 6, 2026, I again explained in a policy forum that the core spirit of the Dual Acts is full life-cycle management: enabling earlier clinical access through conditional approval for therapies addressing high unmet medical needs, while controlling risks through institutionalized quality and safety monitoring.

In subsequent public talks and media interviews, I also emphasized a key goal for 2026: to see regenerative medicine products truly move into the stage of formal approval and market entry. TFDA will form dedicated support teams to help promising products navigate regulatory and review processes and accelerate approval.

**To summarize** in one sentence: the meaning of the Dual Acts is not simply "upgrading" the Regulations of Special Medical Techniques framework into higher-level laws. It is about building a complete ecosystem—from clinical pilot use, data accumulation, and risk governance, to product development, scalable manufacturing, and market oversight.

Our policy pathway can be described as follows: start with autologous cells within hospitals to establish safety and follow-up; gradually expand to allogeneic and more complex technologies; use conditional approval to shorten the waiting time for patients; ensure traceability and risk control through national cell banking and quality monitoring; and maintain market order through advertising and compliance enforcement.

The real challenges ahead are clear: whether real-world data collected after conditional approval can be analyzed with high quality; whether long-term follow-up and adverse event reporting can be fully implemented; whether regulatory capacity and industry support can grow together; and whether reimbursement decisions can remain transparent, consistent, and fair.

If these elements are institutionalized and executed well, 2026 will not only be the year the Dual Acts took effect, it will also be a true turning point for Taiwan, moving regenerative medicine from research to broader clinical access and from isolated cases to an affordable, well-regulated market.

Finally, Taiwan's experience reflects our long-standing core values: We are family / Team Taiwan, and Taiwan can help. We are willing to share our experience in system-building, risk governance, and responsible industry development with all ACTO members, so that regenerative medicine can benefit more patients on a safer, more transparent, and more sustainable foundation.

Dr. Yueh-Ping Liu, MD.
Director-General of Department of Medical Affairs
Ministry of Health and Welfare, Taiwan

IMAGE FROM CANVA.COM

# From policy blueprint to implementation: the current status and future outlook of regenerative medicine in Taiwan

**Dr. Yueh-Ping Liu, MD.**
**Director-General**
**Department of Medical Affairs**
**Ministry of Health and Welfare**
**Taiwan**

To respond to the rapid advancement of frontier medical technologies and the public's growing expectations for more comprehensive healthcare options, the Ministry of Health and Welfare (MOHW) has long been committed to establishing a transparent and data-driven governance framework for emerging medical technologies. The public proposals submitted through the national online policy participation platform in 2015 highlighted the actual needs of patients and families seeking access to cancer immunotherapy and cell-based treatments. These inputs enabled the MOHW to incorporate public sentiment directly into policy planning in a timely manner. This milestone prompted the government to initiate cross-ministerial collaboration, gradually shaping a national-level blueprint for regenerative medicine policy.

In 2018, the MOHW completed a major revision of the Regulations Governing the Application or Use of Specific Medical Techniques, Examinations, and Medical Devices, formally integrating cell therapy into a structured regulatory system and ensuring the safe, professional oversight of these technologies.

In 2026, the implementation of the Regenerative Medicine Act and the Regenerative Medicinal Products Act marked Taiwan's entry into a new stage of comprehensive legal governance, establishing clear responsibilities and aligning regulatory structures with international trends.

Amid the global expansion of regenerative medicine, the MOHW bears the dual responsibility of safeguarding patient safety while supporting medical innovation. To achieve this balance, the government has adopted a risk-stratified and dual-track regulatory model—comprising a technique track and a product track—to ensure that every stage, from preparation and validation to clinical application, adheres to clear quality standards and safety requirements, while continuous monitoring and scientific assessment support ongoing policy refinement. Under the technique track, autologous cell therapies are performed by medical institutions within Good Tissue Practice (GTP)–compliant manufacturing environments.

Under the product track, regenerative medicinal products are governed by the Pharmaceutical Affairs Act, requiring compliance with Good Manufacturing Practice (GMP)standards and market authorization to ensure product quality meets international standards.
As of the end of 2025, a total of 468 cell therapy implementation plans had been approved nationwide, with 2,365 patients receiving treatment. The MOHW compiles these implementation outcomes into annual reports, which serve as an important basis for policy adjustment, risk management, and enhanced international transparency. To address illegal medical practices and misleading advertisements, the dual-law framework strengthens inspection and enforcement mechanisms, including substantial fines, public disclosure of violations, and, when necessary, confiscation of equipment, in order to protect public rights and promote a responsible healthcare environment.

With respect to exosome-based therapies, a topic of significant public attention, the MOHW adheres to a principle of “evidence first, patient safety foremost.” Due to the current immaturity of clinical evidence, exosome therapies are not permitted for routine clinical use. The MOHW will continue monitoring global research developments, convening expert consultations, and reviewing regulatory approaches as appropriate. The MOHW urges the public to avoid unapproved treatments and requires medical institutions to uphold professional ethics and comply with legal standards.

Regenerative medicine is not only a scientific endeavor but also an embodiment of public values and patient rights. The MOHW places great emphasis on informed consent, patient participation in decision-making, and the quality of communication between healthcare providers and patients.

Moving forward, the MOHW will continue advancing digital governance by establishing interoperable data systems across institutions, strengthening cybersecurity and personal data protection, leveraging artificial intelligence and big-data analytics for risk surveillance, and integrating genomic, imaging, and medical record data to support a comprehensive ecosystem for data-driven decision-making.

The year 2026 marks the inaugural year of implementation of Taiwan’s dual regenerative medicine laws and an important governance milestone in the field of emerging medical technologies. The MOHW will remain committed to advancing regenerative medicine guided by scientific evidence, transparency, and a patient-centric approach. Together with the medical community, industry, and the public, the MOHW aims to build a safe, ethical, and sustainable regenerative medicine environment and strengthen Taiwan’s competitiveness in the global regenerative medicine landscape.

Dr. Chih-Kang Chiang, MD., Ph.D.
Director-General of Taiwan Food and Drug Administration
Ministry of Health and Welfare, Taiwan

IMAGE FROM CANVA.COM

# Ushering in a new regulatory era for regenerative medicine in Taiwan

Due to rapid development of biotechnology in recent years, the field of regenerative medicine has attracted considerable attention. Regenerative medicine related regulations have been established in several countries to ensure the quality, safety and efficacy of innovative treatments. Considering the diversity of regenerative medicine, the regulatory framework in Taiwan have been adjusted in response to global trend and local demand. Before 2010, cell and gene therapies were regarded as “new medical practice” under the “Medical Care Act”. Along with the establishment of Taiwan Food and Drug Administration (TFDA) in 2010, regenerative medicine was regulated as “medicinal products” under the “Pharmaceutical Affairs Act”. Then, the Ministry of Health and Welfare (MOHW) established a new dual-track regulatory pathway for regenerative medicine in 2016.

The dual-track pathway divided regenerative medicine into medical practices and medicinal products, aiming to improve the accessibility of new treatments to patients and maintain the flexibility for clinical operations. In order to refine the regulation, the MOHW proposed two draft Acts for regenerative medicine in 2022. On June 4th 2024, the Taiwan Legislative Yuan passed the “Regenerative Medicine Act” and the “Regenerative Medicinal Products Act”, and the Taiwan Executive Yuan announce both of the Act enforce On January 1 2026. It is expected that the research and development of regenerative medicine can be further accelerated, thus providing early access to innovative therapies for patients in the future.

**Dr. Chih-Kang Chiang, MD., Ph.D.**
**Director-General**
**Taiwan Food and Drug Administration**
**Ministry of Health and Welfare**
**Taiwan**

**Dr. Chih-Kang Chiang** is the Director-General of the Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare, Taiwan. Dr. Chiang has a multidisciplinary background bridging clinical medicine, toxicology, and law to advance public health and safety. In addition to his leadership at the TFDA, Dr. Chiang serves as the Attending Director of the Hemodialysis Division at National Taiwan University (NTU) Hospital and as a Professor and Director of NTU’s Graduate Institute of Toxicology. and Deputy Vice President of Academic Affairs. Dr. Chiang holds an M.D. from Chung Shang Medical University, a Ph.D. in Toxicology and an M.S. in Clinical Medicine from NTU, and an M.S. in Law from National Chengchi University

Yueh-Tung Tsai, Wen-Hsiu Chiu, Chia-Ping Liu, & Chih-Kang Chiang

Taiwan Food and Drug Administration
Ministry of Health and Welfare, Taiwan

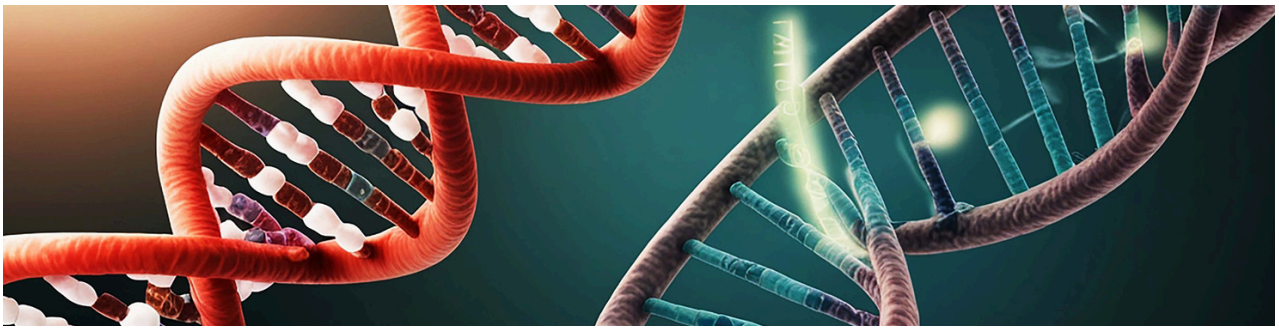


IMAGE FROM CANVA.COM

# Update on regulation of regenerative medicine in Taiwan – The management of the regenerative medicinal products act

**Abstract**

Due to rapid development of biotechnology in recent years, the field of regenerative medicine has attracted considerable attention. On June 4th 2024, the Taiwan Legislative Yuan passed the“Regenerative Medicine Act” and the “Regenerative Medicinal Products Act”, and the Taiwan Executive Yuan announce both of the Act enforce On January 1 2026. These changes aim to ensure the safety, quality, and effectiveness of regenerative medicine, and to protect patients’ rights to receive treatment and give the development of Taiwan's biomedical industry a shot in the arm.

## Introduction

The field of regenerative medicine is a new area for pharmaceutical management. There are different regulatory framework for regenerative medicine in advanced countries worldwide as well as Taiwan.

Regenerative medicine related regulations have been established in several countries to ensure the quality, safety and efficacy of innovative treatments. Considering the diversity of regenerative medicine, the regulatory framework in Taiwan have been adjusted in response to global trend and local demand. Before 2010, cell and gene therapies were regarded as “new medical practice” under the “Medical Care Act”. Along with the establishment of Taiwan Food and Drug Administration (TFDA) in 2010, regenerative medicine was regulated as “medicinal products” under the “Pharmaceutical Affairs Act”. Then, the Ministry of Health and Welfare (MOHW) established a new dual-track regulatory pathway for regenerative medicine in 2016. The dual-track pathway divided regenerative medicine into medical practices and medicinal products

This paper aims to describe the new regulatory framework of the “Regenerative Medicine Act” and the “Regenerative Medicinal Products Act” to promote the quality of regenerative medicine and ensure patients' safety in Taiwan.

## New Regulatory Framework for Regenerative Medicine

*The New regulatory framework: two Acts of Regenerative Medicine*

Those two special events were deemed as a turning point for the regulatory framework transformation to accelerate regenerative medicine innovation and enhance patient access. New acts for regenerative medicine were enforced on January 1st 2026. The two new acts, the “Regenerative Medicine Act” and the “Regenerative Medicinal Products Act,” are legislated based on scientific evidence. The comparison of two acts is summarized in Fig. 1.

The establishment of the new regenerative medicine acts not only aims to refine the regulation and reinforce the management system, but also assist to expedite the approval and accelerating patient access to innovative regenerative medicine in Taiwan.

*The Regenerative Medicine Act*

The establishment of the Regenerative Medicine Act is to strengthen the supervision of regenerative medicine therapies in medical institutions, as well as the cell processing procedures in the cell processing unit(CPU). Regenerative Medicine Act regulates multiple aspects of regenerative medicine therapies, including, e.g., the scope of regenerative medicine therapies, qualification-

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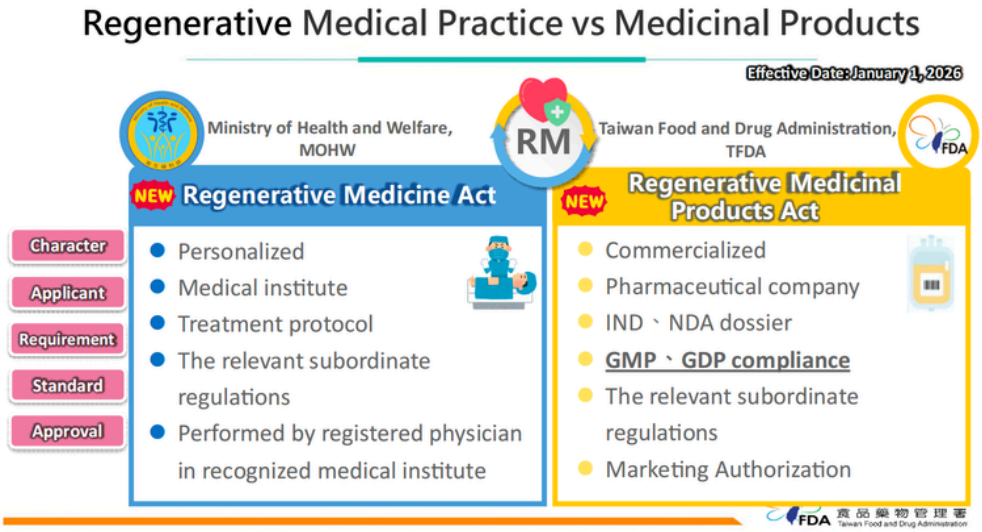


Figure 1. Comparison of two acts

of physicians and cell processing technicians, CPU quality management, cell and tissue donor related regulations and relief measures, which intensifies the quality management of regenerative medicine therapies and provides safe medical care to the patients.

*The Regenerative Medicinal Products Act*

The regenerative medicine provides unprecedent potential to cure previously intractable diseases such as cancers and genetic disorders. Living somatic cells as active ingredients had been reported to treat diseases, such as modified immune T cells treating acute lymphocytic leukemia. Prevention of contamination, transmission of infectious diseases during manufacture process needs to be taken into considerations due to the characteristics of living cells. To ensure patients' safety, it is necessary to construct specific regulatory framework for regenerative medicinal products. Specifically, the determination of donor eligibility, donor informed consents, donor recruitment advertisement, as well as the management of traceability are not addressed in the "Pharmaceutical Affairs Act". Thus, the Regenerative Medicinal Products Act serves as the specific law for the Pharmaceutical Affairs Act to strengthen the management. The Act covers whole lifecycle management of regenerative medicinal products and consists of six sections such as general provision, product registration, conditional approval, manufacture and distribution, post-approval management and penalties, the framework of "Regenerative Medicinal Products Act" is summarized in Fig. 2.

*General Provision*

The purpose and scope of the Act, the competent authority, definition of regenerative medicinal products, and qualification of pharmaceutical firms are regulated in this section. According to the definition, the regenerative medicinal products are classified into four types based on their unique characteristics, which are gene therapy products, cell therapy products, tissueengineered products and combination products.

*Product Registration*

The registration requirements for regenerative medicinal products are the same as those of biological products. A regenerative medicinal product shall be granted marketing authorization and get a drug product license before it can be used in patients. Post-market variations and extension of drug product license shall be implemented with prior approval, and use the "Regulations for Registration and Permission of Regenerative Medicinal Products" as supporting measures.

*Conditional Approval*

Conditional approval for regenerative medicinal products is new in the Act. It offers opportunities for patients with life-threatening and severe disability diseases to have earlier access to innovative regenerative medicinal products. A regenerative medicinal product that is used to treat life-threatening diseases might be granted conditional approval with confirmed safety and preliminary efficacy. Besides, additional requirements will be imposed and shall be completed within a limited time frame to ensure patients' rights.

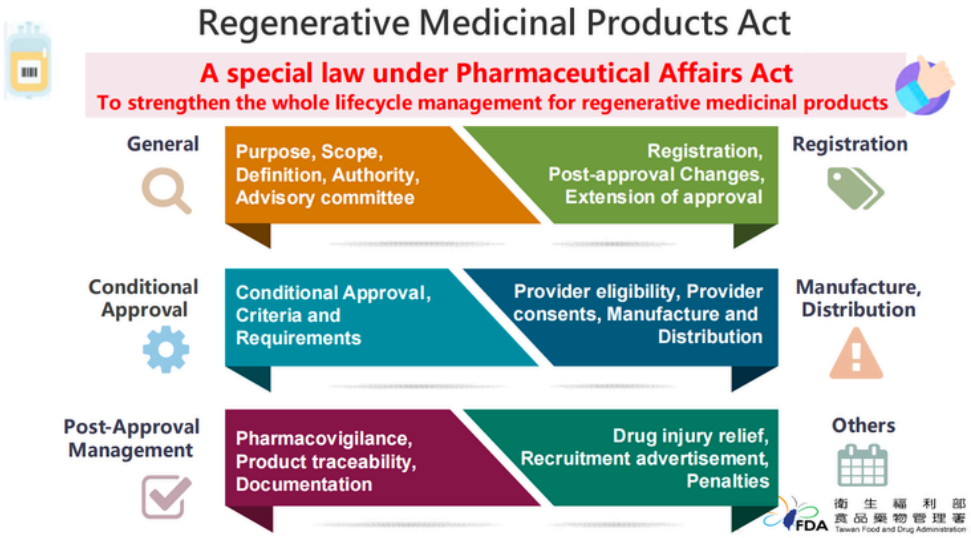


Figure 2. The framework of "Regenerative Medicinal Products Act"

*Manufacture and Distribution*

The manufacturer shall ensure the donor eligibility and obtain consents from cell donors before collecting the sample of the regenerative medicinal products, and use the"Regulations on the Eligibility Determination of Human Cell and Tissue Donors for Regenerative Medicinal Products" as supporting measures. The items of donor consent information and the way of informed consent are regulated in the act, and use the"Regulations on Informed Consent of Those Who Provide Their Tissues or Cells for Regenerative Medicinal Products" as supporting measures, the cell donors should be recruited by pharmaceutical companies only. Moreover, the donor recruitment advertisements shall be reviewed and approved, and use the "Regulations Governing Publication of Regenerative Medicinal Tissue and Cell Provider Recruitment Advertisement" as supporting measures. As for the manufacture and distribution of regenerative medicinal products, it should meet the standards of PIC/S GMP and Good Distribution Practice (GDP), and shall obtain a manufacturing and distribution license.

*Post-Approval Management*

To ensure consistency and quality of regenerative medicine after marketing approval, the requirement of pharmacovigilance use the " Regulations on the Safety Surveillance of
Regenerative Medicinal Products" as supporting measures. Besides, product traceability and drug injury relief are regulated in the act, and use the"Regulations on Traceability and
Tracking for Regenerative Medicinal Products" as supporting measures. Moreover, the case of money be paid use the"Fee-charging Standards for Regenerative Medicinal Products" as supporting measures.

*Penalties*

The penalties about non-compliance with the draft act are stated.

**The future of Regenerative Medicine**

Looking ahead, with the enforcement of the " Regenerative Medicine Act" and the "Regenerative Medicinal Products Act", regenerative medicine is set to continue becoming a key focus in healthcare and biotechnology policy. The Taiwan Food and Drug Administration is developing a dedicated support program for regenerative medicinal products, will guide industry-academia-research collaborations, aiming to provide case-specific regulatory consultation and support and accelerate the development of domestically products, we will continuously monitor the implementation and enforcement of regulations, and, by referencing international trends, make iterative adjustments to the regulations. Through proactive promotion of related policies, it is hoped that regenerative medicine will achieve new milestones.

**Conclusion**

Regenerative medicine represents an important innovation in the treatment of unmet medical needs. In order to further refine the regulatory framework for regenerative medicine, the "Regenerative Medicine Act" and the "Regenerative Medicinal Products Act" were enforced on January 1 2026. We believe that the promulgation of the two new Acts will enhance the regulatory infrastructure of regenerative medicine, foster the research and development of regenerative medicine, reinforce the management system and increase patient accessibility in Taiwan.

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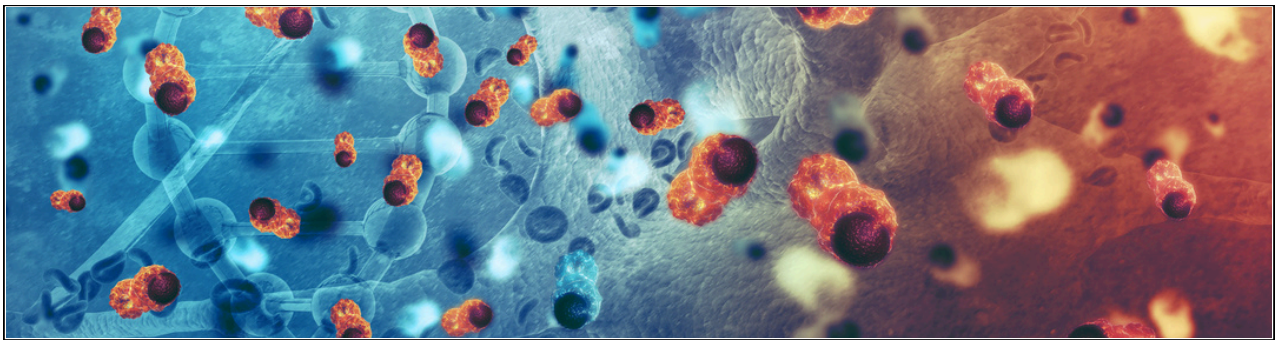

IMAGE FROM CANVA.COM

# The new era of regenerative medicine: synergistic development of innovative therapies and the national health insurance system

With the rapid development of regenerative medicine, innovative therapies are gradually transforming disease treatment paradigms. To address high-cost therapies associated with significant uncertainty, Taiwan's National Health Insurance (NHI) has established corresponding reimbursement and management mechanisms.

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**Cell and Gene Therapy: Opening a New Era of Medicine**

In recent years, cell and gene therapies have made breakthroughs in disease treatment. Compared to traditional treatments by medicinal products, these therapies offer one-time treatment or limited treatment regimens with long-term efficacy, bringing new hope for patients. *The Regenerative Medicine Act* and *the Regenerative Medicine Products Act* were enacted in January 2026, comprising the legal basis for establishing a comprehensive system for clinical applications and product life cycle management. These acts ensure medical safety and quality while laying the foundation for the subsequent inclusion of innovative therapies into the NHI evaluations.

However, these products are typically personalized, involving complex manufacturing processes and high costs. Therefore, balancing patient accessibility with the sustainability of Taiwan's NHI system has become a critical issue.

**From CAR-T to Gene Therapy: Expanding NHI Coverage for Breakthrough Therapies**

As of 2023, the CAR-T therapy *tisagenlecleucel,* indicated for certain relapsed or refractory hematologic cancers, has been reimbursed under the “Provisional Payment”. This represents the first cell therapy reimbursed under Taiwan’s NHI and marks a milestone in personalized precision medicine. Meanwhile, a case registration system has been established for data collection.

Assessments of efficacy and other outcomes will be conducted after a period of reimbursement. Taiwan's NHI will evaluate three years of real-world data and clinical evidence to determine whether the therapy should be incorporated into regular reimbursement scheme.

Additionally, only certified healthcare institutions meeting quality management requirements are authorized to provide the therapy, ensuring treatment effectiveness and patient safety.

In the same year, onasemnogene abeparvovec became the first gene therapy product covered by NHI for the treatment of spinal muscular atrophy (SMA), a rare disease. A single intravenous infusion can provide long-term therapeutic benefits; however, the cost of a single treatment course is extremely high. To alleviate the financial burden, the Taiwan's NHIA has signed an "Outcome-based Installment Payment Agreement" with the manufacturer. Real-world data will be collected through the case registration system, and if the therapeutic effect does not meet expectations, payments will be halted.

The gene therapy eladocagene exuparvovec, indicated for the rare disease aromatic L-amino acid decarboxylase (AADC) deficiency, was also included under Taiwan's NHI Provisional Payment in 2025, with efficacy to be evaluated after three years. This one-time gene therapy is designed to improve neural transmission, offering new therapeutic opportunities for affected children.

**The Era of High-Cost Innovative Therapies: Balancing Innovation and Sustainability of NHI**

In recent years, an increasing number of cell and gene therapies have been evaluated for NHI reimbursement, including treatments for hematologic cancers, hemophilia, and rare diseases. Given their high-cost nature—often ranging from tens of millions to over a hundred million New Taiwan Dollars per treatment—reimbursement decisions must carefully weigh clinical efficacy, safety, ethics, cost-effectiveness, patient populations, and financial impact. Strategies such as the Provisional Payment, Managed Entry Agreements (MEA), and real-world data collection have been implemented. Taiwan's NHI will continue to establish sustainable reimbursement models aligned with precision medicine to ensure patient well-being.

# Regional Report
# Indonesia CGT Update

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IMAGE FROM CANVA.COM

## Indonesia cell & gene therapy (CGT) 2026 update

Cell and gene therapy (CGT) has emerged as one of the most transformative innovations in modern medicine, offering new hope for patients with previously untreatable conditions. In Indonesia, the journey of CGT is still in its early stages, but recent developments highlight a growing commitment to advancing this field. From initial research initiatives and academic workshops to government-led discussions on regulation and infrastructure, Indonesia is beginning to lay the foundation for integrating CGT into its healthcare system. This article explores the recent updates of cell and gene therapy in industry, clinical trials, research, and society (including FARM-related aspects).

Indonesia's CGT market is expanding rapidly, driven by rising demand for treatments targeting malignancies, genetic disorders, and rare diseases. With strong support from both government initiatives and private investment, the sector is projected to grow steadily through 2031. The Stem Cell & Cancer Institute (SCI) plays a central role in advancing stem cell therapy, cancer research, and diagnostic innovation. Increasing collaboration between pharmaceutical and biotech firms, hospitals, and cancer care centers signals promising progress in CGT development. This momentum is further reinforced by the Ministry of Health and the National Research and Innovation Agency (BRIN), underscoring Indonesia's commitment to building a robust future for advanced therapies. As these foundations strengthen, the next critical step lies in the initiation and expansion of clinical trials, which will determine how CGT can be safely and effectively integrated into Indonesia's healthcare system.

At present, only a small number of active CGT clinical trials are registered in Indonesia for 2024–2025. Most remain in early-phase (Phase I/II) studies, focusing on stem cell-based therapies and regenerative medicine.

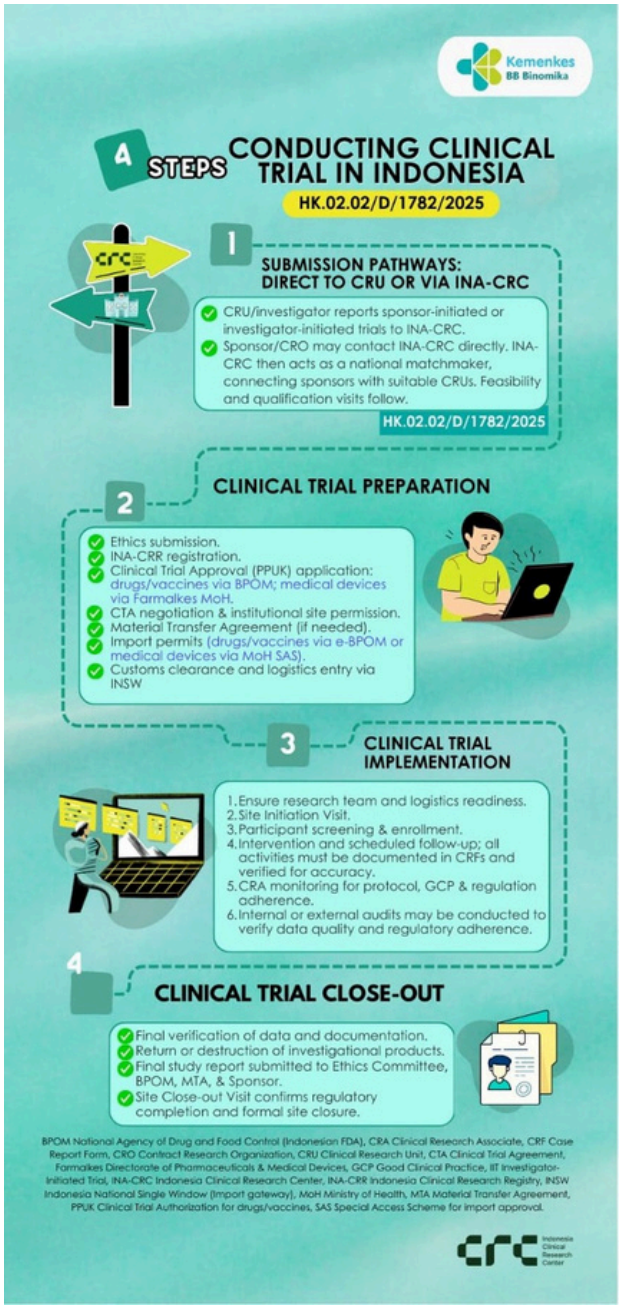

These trials are typically conducted in collaboration between hospitals, universities, and biotech firms, under the oversight of the Ministry of Health and BRIN. To create an environment suitable for further clinical trial development, the Indonesian government established the Indonesia Clinical Research Centre (INA-CRC) in mid-2024 to streamline trial processes and attract international sponsors.
Since its inception, INA-CRC has strengthened the regulatory framework for CGT, advanced capacity building, and initiated global partnerships. In late 2025, INA-CRC, together with the WHO Indonesia Country Office and the WHO Western Pacific Regional Office (WPRO), hosted a national workshop in Jakarta.

The workshop focused on strengthening Indonesia's clinical trial ecosystem and piloting the WHO Clinical Trial Unit-Maturity Framework (CTU-MF), aligning with the Global Action Plan for Clinical Trial Ecosystem Strengthening. The establishment of INA-CRC and Indonesia's move to WPRO in 2025 mark a major step forward in clinical trial readiness, creating stronger opportunities for cell and gene therapy trials as Indonesia aligns with international standards and expands regional collaboration. Building on this foundation, Indonesia is now entering the next phase: advancing CGT research to translate these early efforts into scientific breakthroughs and clinical applications.

Research in Indonesian cell and gene therapy (CGT) has largely concentrated on the application of stem cells in oncology, cardiovascular conditions, degenerative disorders, and infectious disease studies. To foster innovation, the National Research and Innovation Agency (BRIN) partnered with the Indonesian Stem Cell Association (ASPI) to organize international seminars promoting advances in stem cell research and regenerative medicine. One such event, titled Future Directions and Opportunities in Stem Cell Innovation for Clinical Application and the Health Industry, took place at Gedung B.J. Habibie BRIN in Jakarta on August 5–6, 2025. This collaboration was intended to accelerate the transition of research from the laboratory to industrial application. The seminars were followed by a continuous technical workshop designed to enhance researchers' capacity in bridging scientific findings with healthcare practice.

In general, while sentiments toward new CGT innovation are largely positive, some concerns remain regarding their long-term safety. This underscores the need for continued research and clinical trials to validate both their benefit and lasting impact. Innovation in CGT is not limited to healthcare; gene-editing technologies are also being explored in food and agriculture to enhance food security and crop resilience. Yet, public debate persists: scientists emphasize opportunities for sustainable farming and improved nutrition, whereas skeptics raise concerns about biodiversity and the potential health implications of GMO crops or lab-produced food.

Although CGT still has a long journey before becoming widely established and accessible, it remains a promising pursuit. With the support of the Indonesian government, various research institutes, universities, and industries are working collaboratively to advance CGT to the future where CGT can be utilized fully to enhance quality of life of Indonesian citizens.



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# Regulation of cell and gene therapy (CGT) product in Indonesia: perspective of BPOM

**Introduction**

Cell and Gene Therapy (CGT) represents a rapidly advancing field in biomedical science, offering innovative treatment strategies for diseases that were previously difficult or impossible to treat. These therapies involve the modification or administration of living cells or genetic material to restore normal biological functions, regenerate damaged tissues, or enhance immune responses against diseases such as cancer. Due to their complex biological nature and potential risks, CGT products require rigorous regulatory oversight to ensure their safety, quality, and efficacy.

In Indonesia, the regulation of CGT products is primarily overseen by the national drug regulatory authority, the Badan Pengawas Obat dan Makanan (BPOM). BPOM is responsible for the evaluation, approval, and monitoring of pharmaceutical and biological products before and after they are introduced into the market. Recognizing the rapid development of advanced therapies, BPOM issued the BPOM Regulation No. 8 of 2025 on Guidelines for the Evaluation of Advanced Therapy Products to establish a regulatory framework specifically addressing advanced therapeutic products, including cell and gene therapies. This regulation aims to ensure that innovative therapies are developed and implemented responsibly while maintaining patient safety.

**Scope and Definition of Cell and Gene Therapy Products**

Within the Indonesian regulatory system, CGT products fall under the broader category of **Advanced Therapy Products.** According to BPOM Regulation No. 8 of 2025, advanced therapy products include three main types: somatic cell therapy products, gene therapy products, and tissue-engineered products.

- Somatic cell therapy products consist of cells or tissues that have undergone significant manipulation or are used for purposes different from their original biological functions. These products exert therapeutic effects through pharmacological, immunological, or metabolic mechanisms. Examples include modified immune cells used in immunotherapy or expanded stem cells used for regenerative medicine.
- Gene therapy products involve the introduction, removal, or modification of genetic material within a patient's cells. These products typically contain recombinant nucleic acids that regulate or modify gene expression to treat or prevent diseases. Gene therapy has shown promise in treating genetic disorders, cancers, and rare diseases.
- Tissue-engineered products, on the other hand, are designed to repair, regenerate, or replace damaged human tissues. These products may involve cells combined with scaffolds or biomaterials to support tissue growth and structural integrity.

However, the regulation does not include certain biological products such as vaccines for infectious diseases, conventional blood products, or products derived from embryonic stem cells. By defining these categories, BPOM establishes a clear regulatory scope for advanced therapies within Indonesia.

**Regulatory Authority and Institutional Framework**

The primary regulatory authority responsible for the oversight of CGT in Indonesia is BPOM. As the national agency responsible for drug and food control, BPOM has the mandate to regulate pharmaceutical products throughout their lifecycle. Its responsibilities include pre-market evaluation, authorization of clinical trials, approval of marketing applications, and post-market surveillance.

The authority of BPOM in regulating pharmaceutical and biological products is supported by national legal frameworks such as the Presidential Regulation No. 80 of 2017 on the National Agency of Drug and Food Control. Under this framework, BPOM ensures that all therapeutic products entering the Indonesian market meet established standards of safety, quality, and efficacy.

In addition to BPOM oversight, CGT development in Indonesia also involves collaboration with other institutions, including medical research institutions, hospitals, and ethics committees that evaluate the ethical aspects of clinical trials involving human subjects.

**Regulatory Pathway for CGT Products**

The development and approval of CGT products in Indonesia involve several stages of regulatory evaluation. These stages generally include preclinical research, manufacturing control, clinical trials, and marketing authorization.

*Preclinical Development*

Before a CGT product can enter clinical trials, developers must conduct extensive preclinical studies to evaluate its biological characteristics, safety, and therapeutic potential. These studies typically involve laboratory experiments and animal models. Developers must demonstrate that the product has an acceptable safety profile and a clear scientific rationale for its therapeutic use.

BPOM adopts a risk-based approach when evaluating advanced therapy products. Several risk factors are considered, including the origin of the cells, the degree of manipulation involved, the possibility of immune reactions, and the potential for uncontrolled cell growth or tumor formation.

*Manufacturing and Quality Control*

Manufacturing of CGT products must comply with Good Manufacturing Practices (GMP), which in Indonesia are referred to as Cara Pembuatan Obat yang Baik (CPOB). These standards ensure that biological products are consistently produced and controlled according to strict quality requirements.

For CGT products, manufacturing oversight is particularly important due to the variability of living cells and biological materials. Regulatory authorities require detailed documentation regarding the source of cells, methods of cell processing, storage conditions, sterility testing, and product characterization. Facilities involved in cell processing and manufacturing must meet specific regulatory standards and obtain appropriate certification.

*Clinical Trial Authorization*

Clinical trials are required to evaluate the safety and effectiveness of CGT products in human subjects. In Indonesia, all clinical trials involving investigational therapies must receive approval from BPOM before they can begin.

In addition, the research protocol must be reviewed by an institutional ethics committee to ensure compliance with ethical standards.

Clinical trials are typically conducted in multiple phases to evaluate different aspects of the therapy, including safety, optimal dosage, and therapeutic efficacy. Due to the complex nature of CGT products, long-term follow-up studies are often necessary to monitor potential delayed adverse effects.

*Marketing Authorization*

After successful clinical trials, developers may apply for marketing authorization from BPOM. The regulatory submission must include comprehensive data on product quality, preclinical research, and clinical trial results. BPOM evaluates the benefit-risk profile of the product before approving commercial use.

Because CGT products are highly innovative and may involve unique manufacturing processes, BPOM may conduct case-by-case evaluations based on the specific characteristics of the therapy.

**Alignment with International Regulatory Standards**

Indonesia's regulatory framework for CGT is increasingly aligned with international guidelines. BPOM frequently refers to regulatory approaches used by global agencies such as the World Health Organization, the European Medicines Agency, and the U.S. Food and Drug Administration when evaluating advanced therapy products.

Adopting international standards helps ensure that CGT products developed or marketed in Indonesia meet globally recognized safety and quality requirements. This alignment also facilitates international collaboration in clinical research and biotechnology development.

**Conclusion**

Cell and Gene Therapy represents a transformative approach in modern medicine, but its complexity requires comprehensive regulatory oversight. In Indonesia, BPOM plays a central role in ensuring that CGT products are developed, evaluated, and monitored according to strict safety and quality standards. Through BPOM Regulation No. 8 of 2025, Indonesia has established a structured regulatory framework that addresses the unique challenges associated with advanced therapeutic products.

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# Academic Highlight

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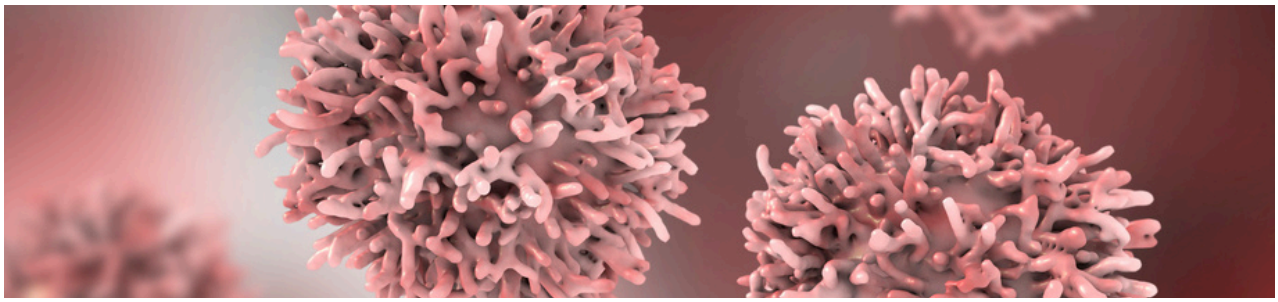

IMAGE FROM CANVA.COM

# Beyond carcinogenesis: connecting nicotine signaling with cancer stemness and metastatic progression in triple-negative breast cancer

**Abstract**

Nicotine, a genotoxic agent and tumor-promoting factor, has been linked to various types of cancer. This commentary highlights recent findings demonstrating that nicotine exposure promotes tumor malignancy in triple-negative breast cancer (TNBC) through coordinated activation of the nicotinic acetylcholine receptors α9 (CHRNA9) and insulin-like growth factor-1 receptor (IGF1R) signaling axis. Evidence from multiple experimental approaches and models, including cellular systems, animal studies, patient cohorts, and public datasets, indicates that elevated expression of CHRNA9, IGF1R, and stemness-related genes correlates with poor survival in patients with TNBC. Furthermore, nicotine enhances cancer stemness properties, invasion, metastasis, and tumor progression, whereas genetic silencing of IGF1R effectively suppresses these malignant phenotypes and prolongs survival in vivo. Mechanistically, IGF1R functions as a critical downstream mediator sustaining nicotine-induced stemness programs. Collectively, these findings have important translational implications, identifying the CHRNA9-IGF1R regulatory axis as a potential target for biomarker-guided therapeutic intervention. Beyond oncology, this study also emphasizes the broader public health significance of environmental nicotine exposure, suggesting its potential impact on tumor aggressiveness and cancer survivorship.

**Keywords:**

Nicotine; Environmental exposure; TNBCs; IGF1R; CHRNA9; Stemness; Metastasis; Recurrence; Survival

## Background

Accounting for roughly 10-20% of breast cancers, triple-negative breast cancer (TNBC) is an aggressive subtype marked by a high risk of early relapse and a lack of effective targeted therapeutic strategies. Cigarette smoking has been epidemiologically linked to poorer clinical outcomes in breast cancer patients [1]. Despite nicotine being a principal constituent of tobacco smoke and e-cigarette vapor, its mechanistic contribution to TNBC progression remains largely unresolved. Our recent study in the Journal of Pathology elucidates how nicotine promotes malignancy in TNBC [2]. In this study, we define the mechanistic link between nicotine exposure and stemness-related TNBC tumor progression and demonstrate IGF1R as a promising therapeutic target to reduce tumor aggressiveness in TNBC patients (Figure 1).

## Establish a clinically relevant role of IGF1R and CHRNA9 in TNBC

We demonstrate the clinical relevance of nicotinic acetylcholine receptors α9 (CHRNA9) and IGF1R signaling in TNBC by integrating a large public dataset (n = 299 TNBC cases) and two patient cohorts (n = 67 and n = 42). Kaplan-Meier survival analyses of TNBC cases reveal that elevated expressions of CHRNA9, IGF1R, IGF2, and stemness-related genes, including SOX2 and POU5F1, are significantly associated with poorer relapse-free survival (RFS) and distant metastasis-free survival (DMFS). Gene expression analyses of TNBC tumor tissues further show strong positive correlations between CHRNA9, IGF1R signaling components, and stemness markers, indicating coordinated activation of a stemness-related oncogenic network.

**Dr. Kuo** is an assistant research fellow of TMU Research Center for Cell Therapy and Regeneration Medicine; a member of TMU Research Center of Thoracic Medicine, Taipei Medical University, Taipei, Taiwan. His research focuses on how microenvironmental signals regulate stemness programs to determine cellular fate in both cancer progression and tissue regeneration

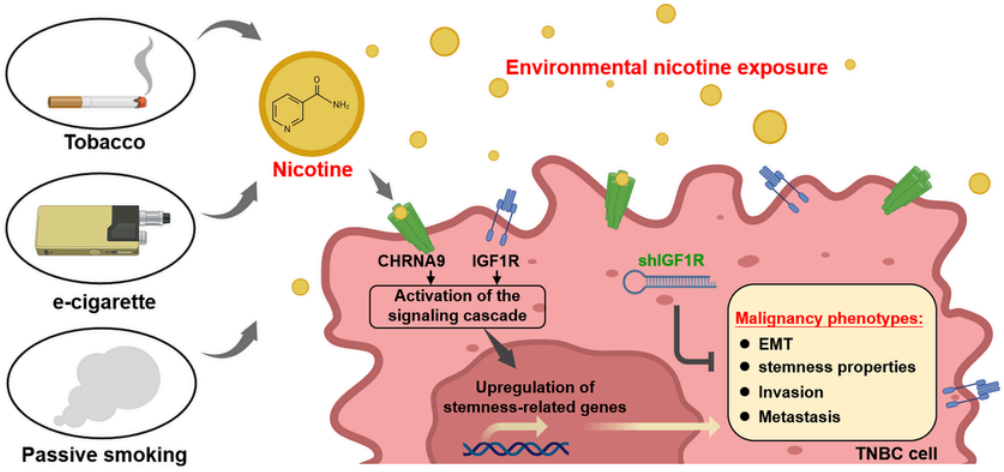


Figure 1. Brief diagram of connecting nicotine signaling with cancer stemness and metastatic progression in Triple-Negative Breast Cancer. Nicotine is a principal constituent of tobacco smoke and e-cigarette vapor; in addition, nicotine exposure also comes from passive (secondhand) smoking. Our findings reveal that nicotine significantly upregulates CHRNA9 and IGF1R, and activates signaling cascades to promote stemness-related gene expression, thereby enhancing malignancy phenotypes in TNBC cells. Moreover, knockdown of IGF1R expression diminishes nicotine/CHRNA9-induced malignancy phenotypes in vitro and in vivo. This diagram was created in BioRender. https://BioRender.com

Protein-level validation using tissue microarrays confirms increased expression and co-localization of CHRNA9, IGF1R/p-IGF1R, and POU5F1 in tumor tissues compared with normal breast tissues. Moreover, multivariate clinical analyses further demonstrate that high expression or co-expression of these molecules significantly correlated with tumor recurrence, supporting their role as prognostic indicators of aggressive disease behavior in TNBC [2].

**Nicotine exposure enhances tumor malignancy**

Using TNBC cellular and animal models, we demonstrate how nicotine exposure promotes stemness-associated malignant phenotypes in TNBC through coordinated regulation of IGF1R and CHRNA9 signaling. Nicotine exposure significantly upregulates CHRNA9 expression in TNBC cells, thereby increasing stemness-related proteins, such as POU5F1. Functional assays also demonstrate that nicotine enhances cancer stemness properties, as reflected by increased ALDH-positive cell populations, migration, and invasion abilities. Importantly, mechanistic investigations further reveal that IGF1R functions as a critical downstream regulator of nicotine-induced stemness. RNA interference targeting IGF1R markedly reduces the expression of CHRNA9, stemness markers, and epithelial-mesenchymal transition (EMT)-related genes. Knockdown of IGF1R significantly attenuates these nicotine-induced multiple malignant effects, indicating that IGF1R signaling is essential for maintaining nicotine-mediated cancer stemness programs in TNBC [2].

To further evaluate the biological relevance of highly metastatic disease, we have also established metastatic TNBC animal models.

Highly metastatic cells exhibit high levels of IGF1R, CHRNA9, and stemness-associated proteins, along with enhanced invasive capacity. Notably, silencing IGF1R substantially reduces stemness properties, suppresses nicotine-induced lung metastasis, and inhibits tumor progression in vivo, ultimately prolonging survival in xenograft mouse models.

**Perspectives and implications for clinical research and public health**

Our findings provide important translational evidence demonstrating that nicotine exposure directly influences TNBC tumor biology rather than acting solely as a cancer-initiating factor. Nicotine exposure from tobacco smoking, e-cigarette vapor, and passive (secondhand) smoking may promote TNBC tumors with enhanced stemness characteristics, metastatic potential, and chemotherapy-drug resistance [2, 3], thereby contributing to poorer clinical outcomes observed in TNBC patients.

Clinically, our study identifies a potential biomarker-defined TNBC subgroup characterized by elevated CHRNA9 and IGF1R signaling. Previous failures of IGF1R-targeted therapies may have resulted from non-stratified clinical trials, whereas patient selection based on nicotine-associated signaling activation may improve therapeutic responses [4]. On the other hand, it also highlights opportunities to investigate nicotinic receptor antagonists or repurposed agents targeting cholinergic signaling pathways [5].

Finally, from a public health perspective, our study expands the traditional cancer prevention paradigm by suggesting that environmental nicotine exposure may influence not only cancer incidence but also tumor aggressiveness, recurrence, and patient survival. Continued nicotine exposure following cancer diagnosis may contribute to disease progression, raising concerns regarding persistent smoking and increasing e-cigarette use. These findings highlight the importance of incorporating environmental exposure history, including smoking and vaping behaviors, into oncologic risk assessment and precision prevention strategies. Moreover, populations with higher tobacco exposure may be disproportionately affected by biologically more aggressive cancers, implying a potential health risk. Collectively, the results support future cancer control approaches that integrate molecular oncology with behavioral interventions and environmental health policies, thereby bridging individual cancer care with population-level health management.

**Acknowledgements**

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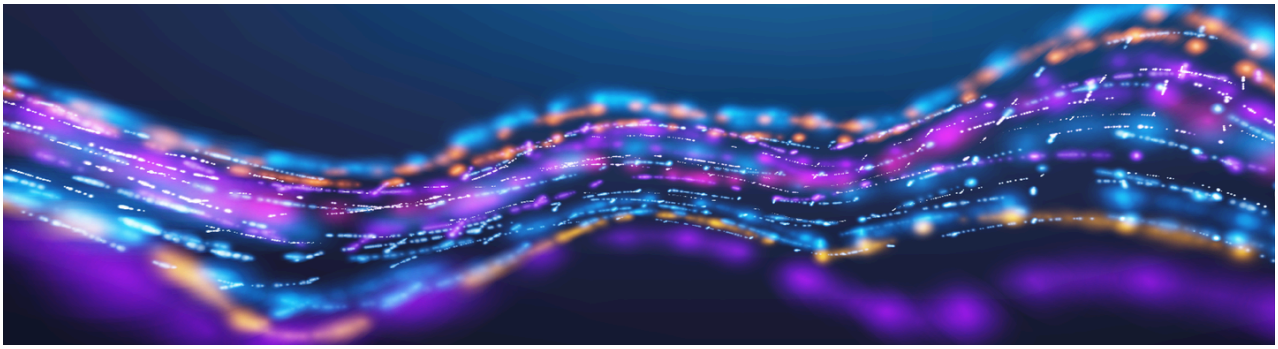

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# Artificial intelligence in cell therapy: advancing development, manufacturing, and clinical translation

Artificial intelligence (AI) is reshaping the life sciences industry at an unprecedented pace. Among the most transformative areas is cell and gene therapy (CGT), a field that promises curative approaches for cancer, genetic disorders, autoimmune diseases, and degenerative conditions. As CGT advances from experimental innovation to commercial reality, AI is emerging not merely as a supporting technology but as a central driver of scalability, efficiency, and precision. Recent market analyses suggest that AI-powered digital innovation is poised to redefine the manufacturing and development landscape of advanced therapies over the coming decade. The global cell and gene therapy manufacturing market, valued at approximately USD 14.69 billion in 2025, is projected to surpass USD 122.86 billion by 2034, reflecting a compound annual growth rate of 26.6% (BioSpace, 2024). Such rapid expansion is unlikely to be sustainable without digital optimization, making AI-driven systems increasingly indispensable in addressing biological variability, manufacturing bottlenecks, and regulatory complexity inherent to advanced therapies.

One of the most significant applications of AI lies in intelligent manufacturing. Cell therapy production involves dynamic biological processes that are highly sensitive to environmental fluctuations, culture conditions, and operator variability. Machine learning algorithms now enable continuous monitoring of cell growth kinetics, metabolic indicators, and environmental parameters in real time. By identifying deviations at early stages, AI reduces batch failures and improves consistency across production runs. This transition from reactive quality control to predictive process management represents a fundamental shift in biomanufacturing philosophy (BioSpace, 2024).

In addition, AI supports predictive quality modeling. Whereas traditional quality assurance often relies on endpoint testing that detects failure only after significant resources have been expended, AI systems trained on historical production datasets can recognize patterns associated with suboptimal outcomes and intervene proactively.

This approach enhances reproducibility and lowers overall production costs, an essential advancement for therapies that are frequently patient-specific and manufactured in small batches. Digital twin technology further extends this paradigm. By constructing virtual replicas of manufacturing environments, AI-driven simulations allow researchers to test parameter adjustments, forecast yields, and assess risk scenarios before implementing changes in physical systems, thereby accelerating process optimization and shortening the path from laboratory development to commercial-scale production (BioSpace, 2024).

Beyond manufacturing, AI is equally transformative in early-stage research and therapeutic design. In CAR-T and other engineered cell therapies, machine learning models analyze genomic, transcriptomic, and proteomic datasets to identify optimal targets and refine receptor specificity. Predictive modeling assists in minimizing off-target toxicity and improving therapeutic durability (McKinsey & Company, 2023). Deep learning approaches are also being explored to anticipate cytokine release syndrome risk and other adverse immune reactions, potentially increasing clinical trial success rates (Ni, 2025). The integration of AI with computational immunology and protein engineering represents another frontier. Generative models trained on protein sequence data are now capable of assisting in the design of T-cell receptors and antibody constructs with enhanced binding properties (Xie, 2026). These technologies expand the conceptual boundaries of cell therapy development, shifting the field from empirical experimentation toward data-guided design.

AI is also enabling more personalized therapeutic strategies. By integrating multi-omic patient data with clinical histories and treatment outcomes, predictive models can support individualized therapy selection and optimization (Choudhery, 2024).

Such tools are particularly relevant in autologous cell therapies, where patient heterogeneity directly influences product characteristics and therapeutic response. Increasing emphasis is also being placed on the integration of real-world data (RWD) into AI-driven cell therapy platforms. Post-approval treatment outcomes, long-term safety monitoring, and real-world effectiveness metrics provide insights that extend beyond traditional clinical trial endpoints. When systematically analyzed, these datasets can inform continuous refinement of manufacturing parameters, product characterization strategies, and therapeutic design. AI systems capable of processing large-scale real-world evidence (RWE) offer the potential for adaptive optimization across the entire therapy lifecycle. By linking longitudinal clinical performance back to specific production variables, AI enables a feedback loop between bedside outcomes and biomanufacturing processes. This bidirectional data flow may ultimately shift cell therapy from a static, one-time product paradigm toward a continuously learning and evolving therapeutic ecosystem.

The geographic and industrial landscape reflects these technological shifts. North America currently dominates the CGT manufacturing market, supported by strong infrastructure and regulatory frameworks, while the Asia-Pacific region is projected to experience the fastest growth, driven by expanding investments in digital biomanufacturing platforms and advanced therapy facilities (BioSpace, 2024). Contract manufacturing organizations are increasingly incorporating AI into their production systems to enhance competitiveness and scalability. Despite its transformative potential, AI integration faces important challenges. Data standardization remains a critical barrier, as manufacturing datasets are often fragmented or inconsistently formatted, restricting model generalizability (Di Cerbo, 2025). Regulatory oversight also presents complexity, requiring AI-driven decision systems to demonstrate transparency, reproducibility, and explainability. Furthermore, the capital investment required for automation infrastructure and computational platforms may limit adoption among smaller biotechnology firms.

Nevertheless, the trajectory is clear. As computational models become more sophisticated and data ecosystems more integrated, AI will continue to reshape how advanced therapies are designed, manufactured, and delivered. Multi-modal AI systems that combine imaging analytics, omics integration, real-world evidence, and process engineering data are likely to define the next phase of digital biomanufacturing. Artificial intelligence is no longer an auxiliary innovation in cell therapy; it is becoming the digital backbone of next-generation advanced therapeutics. By enabling predictive manufacturing, intelligent therapy design, lifecycle learning, and personalized treatment strategies, AI is accelerating the transition of cell therapy from specialized innovation to scalable and adaptive clinical reality.

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# Developing gene therapy capacity in Thailand: clinical, economic, and regulatory perspectives

**Abstract**
Gene therapy has emerged as a transformative therapeutic modality for genetic and hematologic diseases. In Thailand, where hemoglobinopathies and pediatric acute lymphoblastic leukemia (ALL) represent significant public health burdens, the development of domestic gene therapy capacity presents both clinical opportunity and economic challenge. This manuscript examines Thailand's healthcare financing structure, disease burden, research ecosystem, regulatory preparedness, and emerging industrial capacity in gene and cell therapies. While hematopoietic stem cell transplantation (HSCT) remains the only curative option for severe beta-thalassemia and relapsed ALL, gene therapy offers the potential for durable remission and long-term cost offsets. However, uncertainties regarding long-term efficacy, affordability, regulatory readiness, and workforce preparedness remain substantial. We discuss Thailand's strategic investments under the Thailand 4.0 framework, the establishment of local GMP-certified manufacturing infrastructure, and the regulatory evolution surrounding Advanced Therapy Medicinal Products (ATMPs). The analysis highlights both the promise and systemic challenges of positioning Thailand as a regional gene therapy hub within ASEAN.

**Keywords:**
Advanced Therapy Medicinal Products, CAR-T cell Therapy, Refractory/relapsed ALL, Adoptive Cell Immunotherapy

## Introduction

Gene therapy has experienced renewed global momentum, driven by advances in vector design, genome editing technologies, and chimeric antigen receptor T-cell (CAR-T) therapies. Genetic diseases arise from defective genes that result in dysfunctional or absent protein production. Therapeutic correction at the genetic level represents a potentially curative approach rather than symptomatic management. To date, there have been 32 gene therapies approved worldwide by the US FDA (US FDA website), with more than 2,000 therapies in development, ranging from preclinical stages to pre-registration (American Society of Gene and Cell Therapy, 2023). Based on the current landscape, gene therapies are anticipated to become a key component of mainstream medical care in the near future, though restricting in the high-income countries due to the high initial treatment price.

For middle-income countries such as Thailand, the burden of genetic disorders extends beyond clinical morbidity. High-prevalence hereditary diseases impose sustained financial pressures on public health systems and reduce long-term economic productivity. Consequently, effective gene therapy—if made accessible and cost-effective—could significantly alleviate both healthcare expenditure and societal burden.

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**Dr. Kitipong Uaesoontrachoon** is a leading scientist in genetic medicine and currently serves as the Chief Scientific Officer of Genepeutic Bio, Thailand's first GMP-certified cell and gene therapy manufacturing facility. He earned his PhD in Molecular and Cellular Biology from the University of Melbourne and completed postdoctoral training at the Children's National Medical Center. Specializing in neuromuscular diseases, particularly Duchenne Muscular Dystrophy, he has authored more than 50 peer-reviewed publications and contributed significantly to therapeutic development in this field.
Prior to his current role, Dr. Uaesoontrachoon served as Principal Director of Research at AGADA Biosciences in Canada and held an adjunct professorship at Dalhousie University. He is also a key figure in Thailand's national "Medical Hub" initiative, leading Genepeutic Bio to obtain the first certification from the Thai Food and Drug Administration for a CAR-T cell manufacturing facility and to initiate first-in-human clinical trials for pediatric acute lymphoblastic leukemia (ALL). Through this work, he has played an important role in advancing Thailand's capabilities in advanced therapy medicinal products (ATMPs) and strengthening the bridge between global research standards and local clinical accessibility.

**Disease Burden in Thailand**

*Beta-Thalassemia and Hemoglobinopathies*

Hemoglobinopathies are the most prevalent inherited disorders in Southeast Asia. In Thailand, approximately 3,000 infants are born annually with severe beta-thalassemia (Fucharoen et al, 2012). Patients require lifelong monthly blood transfusions to survive. Without transfusion support, survival is limited to only a few years.

Chronic transfusion therapy is associated with several challenges:

- Blood shortages and screening costs
- Iron overload leading to organ failure
- Requirement for intensive iron chelation therapy (8–12 hours daily, 5–7 days per week)

These treatment burdens significantly reduce quality of life and generate sustained healthcare costs (Riewpaiboon et al, 2010).

*Acute Lymphoblastic Leukemia (ALL)*

Acute lymphoblastic leukemia (ALL) is the most common pediatric malignancy worldwide and in Thailand. Between 2006 and 2011, Thailand reported an age-standardized incidence rate of 38 per million children, of which 28 per million were ALL cases (Tharnprisan et al, 2013). B-cell ALL accounted for 83.5% of cases. Peak incidence occurs between ages 2–5 years, representing over 75% of cases (Wiangnon et al, 2014).

Currently, hematopoietic stem cell transplantation (HSCT) is the only established curative therapy for both severe beta-thalassemia and relapsed ALL.

**Health Economics and Public Financing**

Thailand's Universal Coverage Scheme (UCS) provides comprehensive health coverage for its citizens which has become a key element in the national health infrastructure. The UCS provides medical access to approximately 76% of Thailand's population. The scheme offers free healthcare services, encompassing outpatient, inpatient, and emergency care, to uninsured individuals not covered by the two other main health insurance programs: the Civil Servant Medical Benefit for government employees and retirees and the Social Health Insurance for private sector employees (Tangcharoensathien et al, 2018). These established prevention and treatment strategies are efficiently administered and remain affordable within the country's fiscal spaces. More than 600,000 thalassemia patients receive government-funded care at an estimated cost of approximately US$3,000 per patient per year (NHSO, 2021).

For patients undergoing HSCT, the government provides approximately US$21,000 to cover treatment and monitoring during the first year surrounding transplantation (Leelahavarong et al, 2010). Cost-effectiveness analyses suggest that HSCT is economically justified for patients younger than 10 years of age.

However, gene therapies are typically associated with high upfront costs. The excessively high cost of gene therapies could undermine the willingness of government funders to cover the expenses, potentially reducing the availability of services for other patients within the healthcare programs. The individual price tag of $2.8 million for betibeglogene autotemcel is nearly identical to the entire $2.91 million fiscal year budget utilized by the UCS in 2021 to provide hematopoietic stem cell transplantation (HSCTs) to 107 individuals with leukemia, lymphoma, and thalassemia (NHSO, 2023). Although they may provide long-term savings by reducing lifetime treatment expenses, uncertainty regarding durability of response complicates reimbursement decisions. Therefore, experts advocate for coverage with evidence development (CED), whereby reimbursement is conditional upon long-term outcome data collection (Mohara et al, 2012).

Such models require:

- Coordination among multiple health insurers
- National registries and data-sharing mechanisms
- Transparent governance of long-term clinical data

Potential conflicts may arise if proprietary registries are controlled by private gene therapy companies.

**National Research and Innovation Strategy**

Thailand launched its "Thailand 4.0" strategy in 2017, aiming to increase R&D expenditure to 4% of GDP by 2036. As of 2018, R&D spending stood at 1.11% of GDP—below the averages for upper-middle-income (1.41%) and high-income countries (2.43%; NXPO, 2019).

To strengthen competitiveness, Thailand established (Yuthavong et al, 2019):

- Thailand Towards Excellence in Clinical Trials (ThaiTECT)
- Incentives for private-sector R&D investment (up to 15-year tax exemptions; BOI, 2023)
- Technology and Innovation Implementation Programs supporting SMEs
- Talent Mobility programs linking academia and industry

Despite these advances, continuing professional education in advanced health biotechnology remains limited. Strengthening domestic expertise and incentivizing overseas-trained Thai professionals to return may be critical to sustaining gene therapy innovation.

**Clinical Development and Industrial Capacity**

Thailand has begun participating in international gene therapy clinical trials for beta-thalassemia in collaboration with a US company called Bluebird Bio. In parallel, domestic infrastructure development has accelerated.


**Figure 1.** Thailand's First GMP-Certified ATMP Manufacturing Suite. Located at Genepeutic Bio, this facility achieved the historic first Thai FDA certification for CAR T-cell manufacturing in 2023. The infrastructure is designed specifically to support the production of Advanced Therapy Medicinal Products (ATMPs) under international PIC/S GMP standards, providing the industrial backbone for the country's "Medical Hub" initiative.

Genepeutic Bio Co., Ltd, established in 2020, represents Thailand's first GMP-certified gene therapy manufacturing facility (Figure 1). The organization focuses on bridging the gap between advanced biomedical research and clinical accessibility for patients with hard-to-treat cancers.With partial governmental support, GNPT aims to locally produce CAR-T cell therapies and gene therapies.

*Clinical Focus:* The lead pipeline programs target CD19-positive B-cell malignancies, including Acute Lymphoblastic Leukemia (ALL) and Diffuse Large B-cell Lymphoma (DLBCL). Its CAR-T construct has secured both proprietary interllecture property (IP) and the necessary freedom to operate (FTO). This ensures that clinical translation and commercial scaling are not hindered by international patent litigation—a common barrier for biotech firms in middle-income countries.

*Manufacturing Excellence:* By utilizing automated closed-system processing, Genepeutic Bio minimizes contamination risks and ensures the scalability of highly complex cell products.

- While currently approved CD19 CAR-T cell products globally are primarily restricted to the autologous setting—relying on the genetic modification of a patient's own T-cells—this approach presents substantial logistical and clinical challenges. Autologous manufacturing is often hindered by the poor fitness of T-cells from heavily pre-treated patients, as well as the high cost of individualized, small-batch production.
- To address these limitations, Genepeutic Bio is developing a pioneering allogeneic platform. This strategy utilizes T-cells from healthy donors rather than the patients themselves, offering several systemic advantages:

1. Donor Selection and HLA-Matching: The methodology utilizes either HLA-matched or haploidentical (half-matched) donors as the source of the starting cellular material. This allows for rigorous pre-screening and selection of high-potency immune cells.
2. Scalability and Accessibility: Allogeneic products can be manufactured in large batches, cryopreserved, and shipped on demand. This eliminates the 3–4 week manufacturing wait time inherent in autologous processes, which is critical for patients with rapidly progressing malignancies.
3. Historic Milestone: If approved by the Thai FDA, this would represent the first clinical product to successfully utilize an allogeneic method for CAR-T cell treatment in the region, positioning Thailand at the global forefront of cellular immunotherapy innovation.

The establishment of Genepeutic Bio represents a shift in the regional healthcare landscape:

- Local Self-Reliance: Reducing dependence on expensive, logistically complex imports of cell and gene therapies from the West.
- Cost Accessibility: Drastically lowering the "price-per-dose" to make life-saving treatments viable for the ASEAN patient population.
- Regulatory Leadership: Collaborating closely with the Thai FDA to establish the gold standard for Advanced Therapy Medicinal Products (ATMPs) in the region by adopting the international standards.

**Key Milestone:** In 2023, Genepeutic Bio successfully received the first-ever Thai FDA certification for a CAR T-cell manufacturing site, marking a historic leap for Thailand's "Medical Hub" initiatives, and initiated its first-in-human clinical trial.
In a landmark proof-of-concept evaluation, domestic CAR-T therapy was successfully administered to an 11-year-old patient facing an exceptionally high-risk clinical scenario. The patient presented with B-cell ALL in its fourth relapse, complicated by extramedullary central nervous system (CNS) involvement—a condition traditionally associated with poor prognosis and limited therapeutic options.

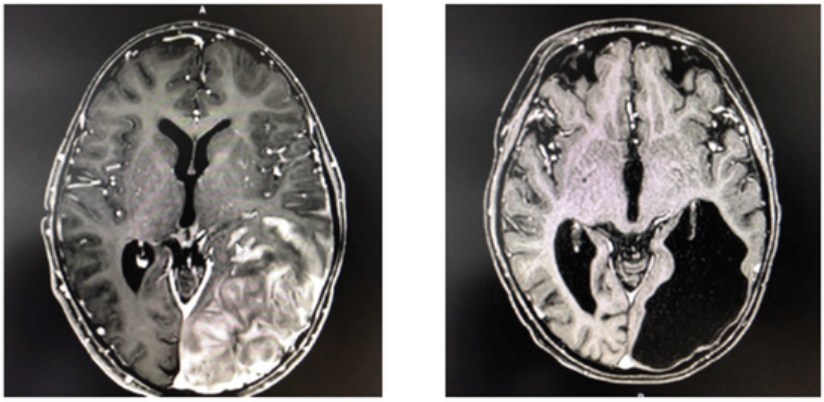

**Figure 2.** Magnetic Resonance Imaging (MRI) demonstrating regression of leukemic brain infiltration after haploidentical CD19 CAR-T cells infusion resulting in remission of 18 months.

This complexity was further compounded by a persistent minimal residual disease-positive (MRD+) status and a history of prior Haploidentical Stem Cell Transplantation.

Notably, the haploidentical allogeneic CAR-T cell infusion demonstrated potent therapeutic efficacy by successfully clearing the leukemic cells within the CNS (Figure 2). The treatment was well tolerated, achieving MRD-negative complete remission within 30 days of administration. Longitudinal data from this initial cohort using allogenenic setting reflects the robust durability of the response, with overall survival (OS) and leukemia-free survival (LFS) rates of 70% and 80%, respectively (Figure 3).

Clinical trial evaluating mainly the safety profile (Phase I) of the company's first product and the very first in human study for gene therapy in Thailand was completed in 2025. The safety profile and dose escalation were demonstrated a manageable safety profile across dose levels evaluated in the dose-escalation phase (Thai Clinical Trials Registry: TCTR20220624004; unpublished data).

- Dose-Limiting Toxicities (DLTs): No DLTs were observed within the predefined 28-day evaluation window following infusion at either dose level.
- Adverse Events of Special Interest: While incidents of Cytokine Release Syndrome (CRS) and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) were monitored according to ASTCT (American Society for Transplantation and Cellular Therapy) consensus grading, all events were clinically manageable with standard institutional protocols (e.g., tocilizumab and/or corticosteroids).
- Tolerability: The current safety data supports the continued clinical development and potential dose expansion of GNPTCD19SPA-0001 in this highly pre-treated patient population.
- Secondary outcome analysis was conducted on an initial cohort of evaluable patients with relapsed/refractory B-cell malignancies. Preliminary data indicate a potent therapeutic signal with :
  - **Objective Response Rate (ORR): 100%.**
  - **Complete Remission with Incomplete Hematologic Recovery (CRi): 100%.**

These high rates of molecular and hematologic response, even at the lower dose cohorts, suggest that the locally manufactured GNPTCD19SPA-0001 construct possesses robust in vivo expansion and anti-tumor effector function. The clinical development of Thailand's first domestic CAR-T therapy has reached a critical juncture. In March 2026, the company officially initiated its Phase II clinical trial, building on the high efficacy and safety profile established in earlier proof-of-concept evaluations.

Under the current regulatory framework, which emphasizes "Fast-Track" access for rare life-saving therapeutics, the trial is strategically positioned for a rapid conclusion. The company expects to complete this phase and secure conditional approval from the Thai FDA by the end of 2026. This milestone would mark a historic shift in the Thai healthcare landscape, transitioning from experimental research to the official provision of locally manufactured, high-value cellular immunotherapy.

**Regulatory Framework and Policy Evolution**

In 2018, Thailand introduced regulations governing Advanced Therapy Medicinal Products (ATMPs), including gene and cell therapies. However, regulatory capacity remains under development, particularly regarding:

- Manufacturing oversight
- Product traceability
- Quality assurance standards
- Long-term pharmacovigilance

Thailand aims to harmonize its regulatory framework with established systems in the United States, European Union, Japan, and Australia.

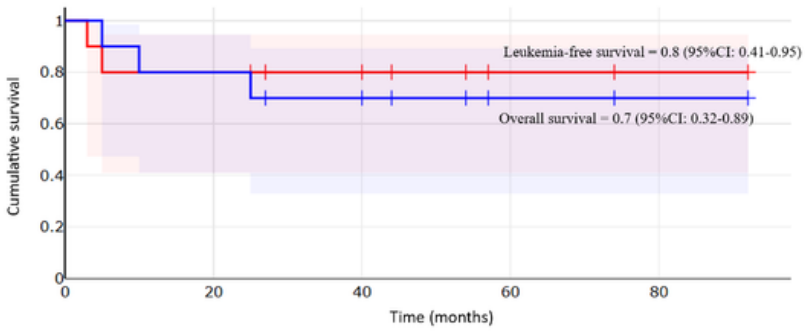


**Figure 3.** Kaplan-Meier analysis of Overall Survival (OS; 70%) and Leukemia-Free Survival (LFS; 80%) in patients with relapsed/refractory B-ALL treated allogeneic CD19 CAR-T cells.

Risk-based and accelerated approval pathways may be appropriate for life-threatening diseases lacking alternative treatments (Yuthavong et al, 2021).

Close collaboration between regulators and pioneering domestic companies will be essential to building regulatory expertise in personalized medicine.

**Regional Positioning and Medical Tourism**

Thailand has historically positioned itself as a regional leader in medical tourism. With regulatory maturation and manufacturing capability, gene therapy could become a high-value extension of this sector.

**Strategic Shift to High-Value Healthcare**

Under the Thailand 4.0 framework and the Strategic Plan for Thailand: A Hub of Wellness and Medical Services (2016–2025/2026), the Thai government is shifting its medical tourism focus from elective cosmetic and dental procedures to "High-Value Healthcare" such as Advanced Therapy Medicinal Products (ATMPs). The inclusion of gene and cell therapies is projected to generate an additional 1.5 billion THB (approx. US$42 million) in annual revenue by 2026 (MOPH, 2025).

- Regional Dominance: Thailand currently leads ASEAN in medical tourism, but the domestic production of CAR T-cells by Genepeutic Bio provides a unique competitive edge against regional peers (e.g., Singapore, Malaysia) by offering world-class therapy at a significantly lower "price-per-dose."
- The "Medical Valley" Initiative: The development of specialized zones, such as the EECmd (Eastern Economic Corridor of Medicine) and the Phuket International Medical Tourism Complex (Medical Plaza), aims to integrate advanced cell therapy clinics with luxury recovery services for international patients.

**Genepeutic Bio as a Gateway for International Patients**

As the first GMP-certified for cell and gene therapy company in Thailand, Genepeutic Bio serves as the industrial backbone for this "Medical Hub" policy:

- Cost Competitiveness: While CAR T-cell therapies in the United States or Europe can cost upwards of US$375,000–$475,000, domestic manufacturing in Thailand aims to provide these treatments at a fraction of the cost, attracting "self-pay" patients from across the Asia-Pacific and the Middle East.
- Inbound Partnerships: The company is actively fostering international corridors to streamline patient referrals and technology transfers between Thailand and overseas.
- Visa Facilitation: To support these high-complexity cases, the Thai government has introduced specialized Medical Visas that allow for extended stays (up to 90 days, extendable) for patients undergoing long-term monitoring post-infusion.

The integration of domestic ATMP manufacturing into Thailand's 'Medical Hub' policy marks a strategic evolution toward high-value medical tourism. By leveraging the lower cost-base of Genepeutic Bio's CAR T-cell production, Thailand is positioned to capture a significant share of the regional oncology market, specifically targeting patients from the GCC and Asia-Pacific who seek affordable, international-standard gene therapies (Bangkok Post, 2025; ArokaGO, 2025).

Policy Implications and the Path Forward

Thailand's experience highlights broader lessons for LMICs:

- High upfront cost is the central barrier to gene therapy access.
- Local manufacturing and technology transfer may significantly reduce prices.
- Regulatory readiness must evolve alongside industrial capacity.
- Strategic purchasing alone cannot absorb multimillion-dollar therapies without structural innovation.
- Regional ASEAN collaboration could distribute infrastructure costs and expand patient pools.

By leveraging universal health coverage, prior success in integrating expensive treatments, and growing biotechnology capacity, Thailand could emerge as a regional gene therapy hub.

**Conclusions**

Gene therapy presents a transformative opportunity for Thailand to reduce the long-term burden of hemoglobinopathies and pediatric leukemia while strengthening its biomedical innovation ecosystem. Strategic investments in regulation, reimbursement models, workforce development, and local manufacturing will determine whether Thailand can successfully transition from participant to regional leader in advanced therapeutics.

Thailand stands at a pivotal moment in the development of domestic gene therapy capacity. The country benefits from:

- Universal health coverage
- Strong government commitment to innovation
- Emerging GMP-certified manufacturing infrastructure
- Growing clinical research capacity

However, major challenges persist:

- High upfront costs and uncertain long-term efficacy
- Regulatory readiness and pharmacovigilance capacity
- Workforce training gaps
- Sustainable reimbursement mechanisms

If addressed systematically, Thailand could emerge as a regional leader in gene therapy development and delivery within ASEAN.

**Disclosure:** The author declares that there is no relevant or material financial interests that relate to the informationdescribed in this paper. Genepeutic Bio is a private clinical-stage biotech company for the manufacturing of cell and gene therapy products (CAR-T cells) for oncologic diseases. The company also receives funding from the Program Management Unit for Competitiveness (PMUC) for its clinical stage development of CAR-CD19 T-cells for Acute Lymphocytic Leukemia (ALL).

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More information:
https://www.ace-enterprise.jp/apsev-jsev2026/en_index.html



# ISSCR - iPSC 20th Anniversary Symposium

The discovery of induced pluripotent stem cell (iPSC) technology has revolutionized biomedical research and regenerative medicine.
To celebrate the 20th anniversary of this transformative breakthrough, the ISSCR is bringing together the global stem cell community in Kyoto, the birthplace of iPS cells, for a three-day symposium. This program will reflect on two decades of remarkable progress and explore the future of the field.

More information:
https://www.isscr.org/upcoming-programs/2026-kyoto-international-symposium

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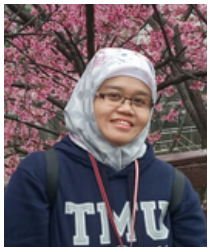

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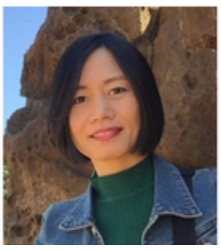

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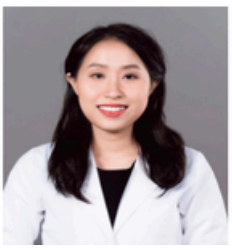

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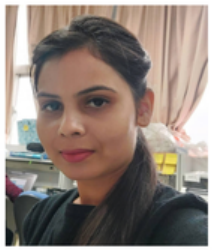

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