BIO KOREA
INTERNATIONAL CONVENTION

20TH BIOKOREA

2025
BIO KOREA

International Convention

May 7(Wed) ~ 9(Fri), 2025
COEX, SEOUL

Conference Preview

English Version

Johnson&Johnson

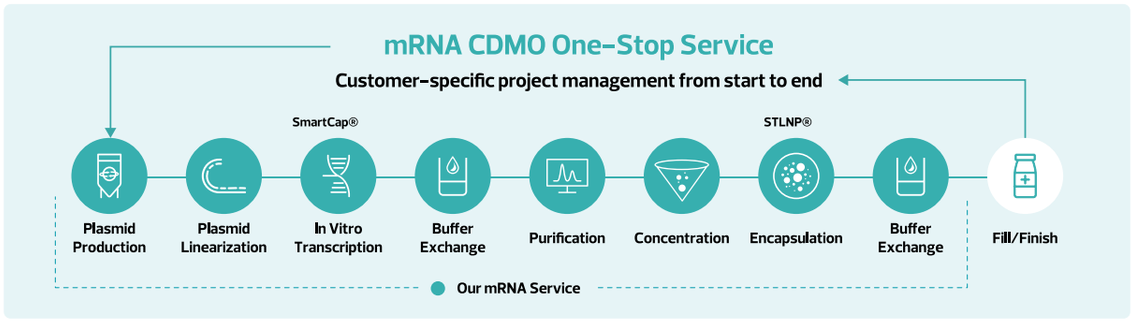
ST PHARM

SCIENCE
TECHNOLOGY
PROGRESS

OUR mRNA CDMO BUSINESS

The most recent step in the ST Pharm journey is the formation of our newest strategic business unit: the mRNA CDMO SBU. Offering a technology platform of proprietary 5' capping reagents and lipid nanoparticle (LNP) formulation, as well as R&D and cGMP in vitro transcription (IVT) capabilities, ST Pharm is ready to help you rapidly usher in the next generation of mRNA vaccines and therapeutics.

- One stop service : Offering in-house plasmid DNA production, IVT synthesis (including mRNA, circRNA and saRNA) to LNP formulation in both non-GMP and GMP grades



Science

- Deep know-how in IVT-based mRNA synthesis & codon optimization
- Analytical and biophysical characterization & analytical method development services

Technology

- SmartCap® proprietary novel 5'-capping analog
- Capping Library Screening Service using ORF-specific screening to identify most suitable cap analog
- STLNP® for xRNA delivery system with novel ionizable lipid to improve immune response and potency

>30 In-House Cap Analogs

Powder or Solution Form

Strong IP Position

Progress

- Applying our synthetic and enzymatic chemistry knowledge to a new paradigm
- Enabling the next generation of mRNA-based vaccines and therapeutics through an established manufacturing platform

BIO KOREA
KOREA 2025

Platform for sharing the cutting-edge technological trends
and information among biohealth industry stakeholders

BIO KOREA
CONFERENCE

BIO KOREA
KOREA 2025

2025 BIO KOREA International Convention

CONTENTS

01

BIO KOREA 2025









20 Years of Bio Korea: A Milestone Journey in Biotechnology

2025 BIO KOREA International Convention

Over the past 20 years of BIO KOREA International Convention,
417,049 participants
from **10,921** companies worldwide have joined
and created **15,196** business opportunities

2006
Visitors 15,117
Participating Companies 344
1:1 Meetings 250
START: Aspiring to Become One of the World's Top Seven Bio Nations

2007
Dynamic Korea: A Strong Leap Toward Becoming a Global Bio Power
Visitors 17,102
Participating Companies 380
1:1 Meetings 381

2008
Visitors 18,090
Participating Companies 336
Networking: Establishing a Marketplace for Innovative Bio Products and Technologies

2009
Potential: Exploring New Opportunities in Korea's Healthcare Industry
Visitors 17,073
Participating Companies 383

2010
Visitors 17,073
Participating Companies 414
1:1 Meetings 313
Grow-up: Establishing Itself as Korea's Premier International Bio Event

2011
Emerging Market: Becoming a Growth Engine for the Global Bio Industry
Visitors 16,849
Participating Companies 539
1:1 Meetings 466

2012
Visitors 17,877
Participating Companies 531
1:1 Meetings 479
Development: Pioneering a New Horizon for Korea and the Global Economy

2013
Convergence: Presenting Development Strategies Through Creative Convergence
Visitors 19,430
Participating Companies 548
1:1 Meetings 590

2014
Visitors 20,712
Participating Companies 546
1:1 Meetings 570
Open Innovation: A Platform for Technological Exchange Driving Open Innovation

2015
From Local Innovation to Global Collaborations
Visitors 20,907
Participating Companies 606
1:1 Meetings 1,129

2016
Visitors 23,942
Participating Companies 664
1:1 Meetings 1,130
Hub of Bio-industry: Strengthening Corporate Networks for the Advancement of the Bio-Health Industry

2017
The 4th Wave: Transforming the Industry Through Innovation in the Bio-Health Ecosystem
Visitors 24,308
Participating Companies 675
1:1 Meetings 1,392

2018
Visitors 24,032
Participating Companies 709
1:1 Meetings 1,452
Global: Envisioning the Future of the Global Healthcare Industry

2019
Springboard: Rising to the Challenge of Biotechnology Advancement
Visitors 26,181
Participating Companies 673
1:1 Meetings 1,728

2020
Visitors 40,051
Participating Companies 679
1:1 Meetings 757
2020 What Comes Next: Showcasing Future Bio-Health Technologies Integrated with IT

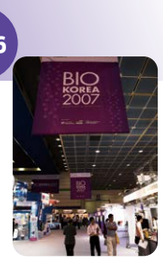
2021
New Normal: Overcoming Limitations Through Bio-Technological Innovation
Visitors 13,283
Participating Companies 781
1:1 Meetings 609

2022
Visitors 22,401
Participating Companies 624
1:1 Meetings 730
Technology: Showcasing Cutting-Edge Innovations Through New Platforms

2023
Transformation: Leading the Era of Digital Transformation
Visitors 29,405
Participating Companies 782
1:1 Meetings 1,320

2024
Visitors 33,216
Participating Companies 707
1:1 Meetings 1,900
Collaboration: Establishing Itself as a Center for Global Cooperation

2025
Future: BIO KOREA 2025 - Dreaming of Another Future Alongside 20 Years of Achievements











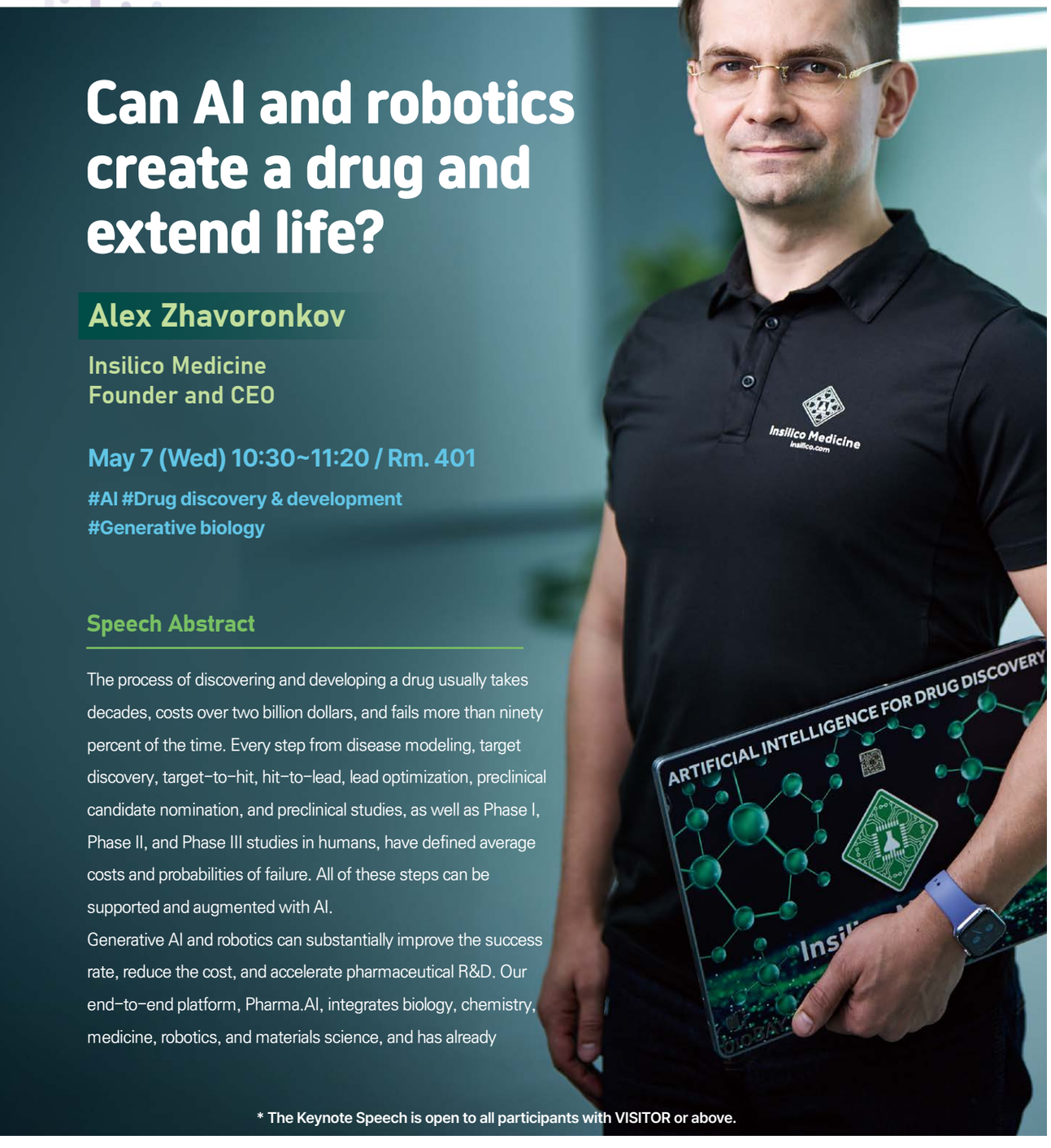


Since its inception in 2006, BIO KOREA has been committed to showcasing Korea's advancements in the bio-health industry on the global stage. By facilitating global technology exchanges and creating business collaboration opportunities, BIO KOREA has worked to elevate Korea's status in the international bio-health market.

Moving forward, we will continue to share cutting-edge trends and foster new business opportunities and international partnerships, striving for Korea to lead the global bio-health industry.

Keynote Speaker

Can AI and robotics create a drug and extend life?



Alex Zhavoronkov

Insilico Medicine
Founder and CEO

May 7 (Wed) 10:30~11:20 / Rm. 401

#AI #Drug discovery & development
#Generative biology

Speech Abstract

The process of discovering and developing a drug usually takes decades, costs over two billion dollars, and fails more than ninety percent of the time. Every step from disease modeling, target discovery, target-to-hit, hit-to-lead, lead optimization, preclinical candidate nomination, and preclinical studies, as well as Phase I, Phase II, and Phase III studies in humans, have defined average costs and probabilities of failure. All of these steps can be supported and augmented with AI.
Generative AI and robotics can substantially improve the success rate, reduce the cost, and accelerate pharmaceutical R&D. Our end-to-end platform, Pharma.AI, integrates biology, chemistry, medicine, robotics, and materials science, and has already produced over 20 preclinical candidates, and a completed Phase 2a study. To accelerate experimental validation, we established a fully-automated robotics lab, LifeStar1, and developed a multi-agent research platform, DORA, capable of generating research outputs including reports and manuscripts. In this talk, I will cover the applications of AI and next-generation laboratory robotics in therapeutic target discovery, small molecule generation, and aging research. I will review several case studies and the current state of the industry, while discussing its limitations and development opportunities. I will also highlight successful collaborations with global pharmaceutical companies, research institutions, and government agencies that demonstrate the real-world impact and scalability of our technologies.

* The Keynote Speech is open to all participants with VISITOR or above.

Professional Experience

Alex Zhavoronkov, PhD, is the founder and CEO of Insilico Medicine (insilico.com), a leading clinical-stage biotechnology company developing next-generation generative artificial intelligence and robotics platforms for drug discovery. Since 2014, he has invented critical technologies in the field of generative artificial intelligence and reinforcement learning (RL) for the generation of novel molecular structures with the desired properties and the generation of synthetic biological and patient data. He also pioneered the applications of transformers and other deep learning technologies for the prediction of human biological age using multiple data types, transfer learning from aging into disease, target identification, and signaling pathway modeling. Under his leadership, Insilico raised over $400 million in multiple rounds from expert biotechnology, healthcare, and financial investors, opened R&D centers in 6 countries and regions, and partnered with multiple pharmaceutical, biotechnology, and academic institutions. Since 2021, the company nominated more than 20 preclinical candidates, started 6 human clinical trials, and entered Phase II with an AI-discovered novel target and AI-designed novel molecule.

Prior to founding Insilico, he worked in senior roles at ATI Technologies (GPU company acquired by AMD). Since 2012, he has published over 200 peer-reviewed research papers with over 30 papers in the field of generative adversarial networks, generative reinforcement learning, and multi-modal transformers, and 3 books, including “The Ageless Generation: How Biomedical Advances Will Transform the Global Economy” (Macmillan, 2013). He serves on the advisory or editorial boards of Trends in Molecular Medicine, Aging Research Reviews, Aging, and Frontiers in Genetics, and founded and co-chairs the Annual Aging Research and Drug Discovery (11th Annual in 2024), the world’s largest event on aging research in the biotechnology industry. He is the adjunct professor of artificial intelligence at the Buck Institute for Research on Aging.

BIOKOREA 2025 International Convention

Conference Topic

Innovative Biotechnology
New Drug Modality. Clinical Trial,
Preclinical - Alternative Toxicology Solutions,
Regenerative Medicine, Anti-aging and Rejuvenation

Bio-Convergence Technology
AI-based New Drug Development,
Bio-Digital Convergence Technology,
Space Biotechnology, Brain-Computer Interface

Business & Development
Global Bio Governance,
Open Innovation - Pharmaceuticals

BUSINESS PARTNERING

Venue
Partnering Center, Hall C(3F), COEX

Date & Time
May 7(Wed) 10:00~17:00
May 8(Thu) 10:00~17:00
May 9(Fri) 10:00~16:00

Go to
Partnering Center

Business Partnering Partners

AMGEN
Johnson&Johnson
sysmex
Boehringer Ingelheim
Lilly
MSD
novo nordisk
Roche
SK bioscience
Takeda

EXHIBITION

Venue
Hall C(3F), COEX

Exhibition Categoris
Pharma, Medical Device,
Digital Health, Investor,
Academic/Non-Profit,
Professional Services and
Consulting etc.

INVEST FAIR

Date
May 7(Wed) ~ May 8(Thu) 2025

Venue
Rm.318(3F), COEX

Session Topic
1. New Horizons: Shifting Bio Investments to the Middle East and Asia
2. Breaking Barriers: Winning Strategies in Western Bio Markets

WELCOME RECEPTION

Date & Time
May 7(Wed) 2025, 18:00

Venue
The Platz(2F), COEX

Participating
Approximately 350 exhibitors, business partnering participate, and guest speakers

PARTNERING RECEPTION

Date & Time
May 8(Thu) 2025, 17:00

Venue
The Platz(2F), COEX

Participating
Approximately 200 business partnering participate

May 7 (Wed)

Program	Time	Title	Venue
Registration	08:00~17:00	All Pass, Conference Pass, Visitor	Hall E Lobby
Official Event	10:00~11:20	Opening Ceremony & Keynote Speech	Rm. 401
	18:00~21:00	Welcome Reception	The Platz
Business Partnering	10:00~17:00	1:1 Partnering	Partnering Center(Hall C)
Invest Fair	13:30~17:00	New Horizons: Shifting Bio Investments to the Middle East and Asia	Rm. 318
Exhibition	10:00~17:00	Bio-Health Technology & Product Promotion	Hall C
Conference	13:30~17:00	S1. AI-Driven Drug Development: A Journey Towards Viable Solutions	Rm. 401
	13:30~17:00	S2. The Great Connection of the 21st Century: Brain-Computer Interface (BCI)	Rm. 307
	13:30~17:00	S3. Advanced Regenerative Medicine: The Beginning of a New Medical Paradigm	Rm. 308
Open Session	13:00~17:30	OS1. Golden Triangle Life Science Open Innovation: Korea-UK-Japan Trilateral Collaboration	Rm. 300
	13:00~17:00	OS2. Workshop on Strategic Collaboration between Korea and Saudi Arabia: Propelling the Growth of Global Biohubs	Rm. 327
	13:00~17:00	OS3. Healthy Aging: Advancing Science for Longevity	Rm. E1
	14:00~15:30	OS5. 2025 Spring Bio-health Policy and Research Forum	Rm. E4
	15:00~17:10	OS6. Advancing Biopharmaceutical Research, Manufacturing, and Workforce Development	Rm. E5
Company Presentation	13:30~17:00	Johnson & Johnson	Rm. 317

※ This program is subject to change depending on internal circumstances.

May 8 (Thu)

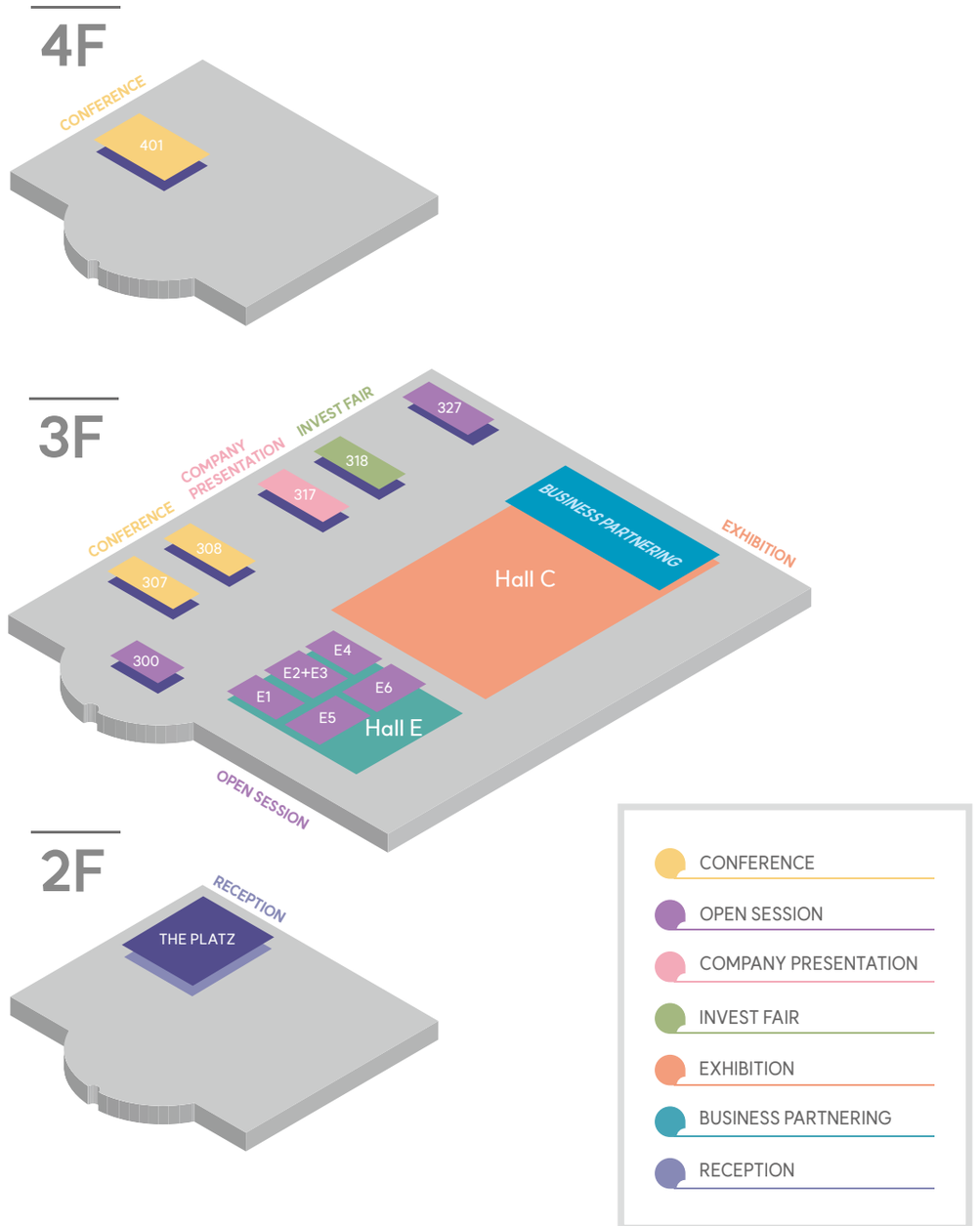
Program	Time	Title	Venue
Registration	08:00~17:00	All Pass, Conference Pass, Visitor	Hall E Lobby
Official Event	17:00~20:00	Partnering Reception	The Platz
Business Partnering	10:00~17:00	1:1 Partnering	Partnering Center(Hall C)
Invest Fair	10:00~17:00	Breaking Barriers: Winning Strategies in Western Bio Markets	Rm. 318
Exhibition	10:00~17:00	Bio-Health Technology & Product Promotion	Hall C
Conference	09:30~11:40	S4. The Key to Innovation: Global Open Innovation Strategy	Rm. 401
	13:00~17:00	S5. The Rise of New Modalities: A Game Changer in Drug Development	Rm. 401
	09:30~11:40	S6. Global Bio Governance 2025: Change and Future	Rm. 307
	13:30~16:00	S7. Strategies for Sustainable Global Biopharmaceutical Approval	Rm. 307
	09:30~11:45	S8. Strengthening the Competitiveness of Domestic Regenerative Medicine by Discovering Outstanding New Technologies for Cutting-edge Regenerative Medicine	Rm. 308
	13:30~16:50	S9. Life Sciences in Space: A New Horizon for Biohealth	Rm. 308
Open Session	13:30~14:20	OS9. Canada's Thriving Life Sciences: Innovation and Collaboration from British Columbia to Beyond	Rm. 300
	14:30~16:25	OS10. Global ATMP Forum	Rm. 300
	14:00~16:25	OS11. 2025 Joint Session on Regenerative Medicine Institution Designation and Regenerative Medical Treatment System	Rm. 327
	14:00~16:50	OS12. Current Status and Strategy of the BioBigData.Korea	Rm. E1~E4
	13:40~17:00	OS13. Global Pharma Supply Chian from Industry Perspective	Rm. E5
	14:00~16:05	OS14. 2025 BioHealth Commercialization Promising Technology Briefing Session	Rm. E6
Company Presentation	10:00~12:10	AMGEN	Rm. 317
	13:30~14:30	ST PHARM	
	14:40~15:40	ACROBiosystems	
Luncheon Session	12:00~13:00	Global BIO Connection ①	Rm. 307
	12:00~13:00	Global BIO Connection ②	Rm. 308

※ This program is subject to change depending on internal circumstances.

May 9 (Fri)

Program	Time	Title	Venue
Registration	08:00~15:00	All Pass, Conference Pass, Visitor	Hall E Lobby
Business Partnering	10:00~16:00	1:1 Partnering	Partnering Center(Hall C)
Exhibition	10:00~16:00	Bio-Health Technology & Product Promotion	Hall C
Conference	09:30~12:00	**S10.** Innovative Aging Control Technologies: Immunity, Diagnostics, and Evaluation Platforms	Rm. 401
	13:30~15:30	**S11.** The Present and Future of Reverse-aging Technologies	Rm. 401
	09:30~12:00	**S12.** Evolving Global Trends and New Technologies in Clinical Trials	Rm. 307
	13:00~16:00	**S13.** Beyond Innovation: The Path to Successful Clinical Adoption and Market Expansion of Digital Therapy	Rm. 307
	09:30~15:35	**S14.** Alternative Toxicity Testing: Our Choice and Challenges for Leading the Future Bio Market	Rm. 308
Open Session	09:30~11:30	**OS15.** AI Research Cases Utilizing Healthcare Data from the National Institute of Health	Rm. 300
Company Presentation	10:00~11:00	MSD	Rm. 317
	11:10~12:10	SYSMEX	

※ This program is subject to change depending on internal circumstances.



02

Issue · Trend and Conference Preview

Conference Session

Innovative Biotechnology | Bio-Convergence Technology | Business & Development

May 7 (Wed)

Time	Rm.401	Rm.307	Rm.308
AM	Keynote Speech		
PM	**AI-based New Drug Development** S1. 13:30~17:00 AI-Driven Drug Development: A Journey Towards Viable Solutions	**Brain-Computer Interface** S2. 13:30~17:00 The Great Connection of the 21st Century: Brain-Computer Interface (BCI)	**Regenerative Medicine** S3. 13:30~17:00 Advanced Regenerative Medicine: The Beginning of a New Medical Paradigm

May 8 (Thu)

Time	Rm.401	Rm.307	Rm.308
AM	**Open Innovation - Pharmaceuticals** S4. 09:30~11:40 The Key to Innovation: Global Open Innovation Strategy	**Global Bio Governance** S6. 09:30~11:40 Global Bio Governance 2025: Change and Future	**Regenerative Medicine** S8. 09:30~11:45 Strengthening the Competitiveness of Domestic Regenerative Medicine by Discovering Outstanding New Technologies for Cutting-edge Regenerative Medicine
		[Luncheon] Global BIO Connection	
PM	**New Drug Modality** S5. 13:00~17:00 The Rise of New Modalities: A Game Changer in Drug Development	**Global Bio Governance** S7. 13:30~16:00 Strategies for Sustainable Global Biopharmaceutical Approval	**Space Biotechnology** S9. 13:30~16:50 Life Sciences in Space: A New Horizon for Biohealth

May 9 (Fri)

Time	Rm.401	Rm.307	Rm.308
AM	**Anti-aging and Rejuvenation** S10. 09:30~12:00 Innovative Aging Control Technologies: Immunity, Diagnostics, and Evaluation Platforms	**Clinical Trial** S12. 09:30~12:00 Evolving Global Trends and New Technologies in Clinical Trials	**Preclinical - Alternative Toxicology Solutions** S14. 09:30~15:35 Alternative Toxicity Testing: Our Choice and Challenges for Leading the Future Bio Market
PM	**Anti-aging and Rejuvenation** S11. 13:30~15:30 The Present and Future of Reverse-aging Technologies	**Bio-Digital Convergence Technology** S13. 13:00~16:00 Beyond Innovation: The Path to Successful Clinical Adoption and Market Expansion of Digital Therapy	

※ This program is subject to change depending on internal circumstances.

2025 BIO KOREA International Convention

Drug Development with AI: A Journey Toward Feasible Solutions

Sharing Tangible Results Leveraging AI with Converging Technologies and New Possibilities in the Drug Development Ecosystem

By | **Junhee Pyo_Vice Chief, Convergence AI Institute for Drug Discovery Korea pharmaceutical and Bio-pharma Manufacturers Association(KPBMA)**

Date & Time : May 7(Wed) 2025, 13:30~17:00

Venue : COEX Rm. 401

Coordinating : Korea pharmaceutical and Bio-pharma Manufacturers Association(KPBMA)

*The content of this article represents the author's opinion and may differ from the official views of the BIO KOREA Organizing Committee.

The Biopharmaceutical Industry is currently undergoing a revolution, thanks to innovative adoption of Artificial Intelligence (AI). AI is providing unprecedented speed and accuracy in the drug development process, serving as a game-changer across various stages of drug development—from target discovery, candidate generation and optimization, and clinical trial design to personalized patient treatment. AI significantly reduces both the cost of, and time required for drug development by enabling precise, data-driven approaches. It is opening a new paradigm in the pharmaceutical sector.

Trends in AI-Driven Drug Development and the Global Market Outlook

Traditional drug development is a highly complex process, an industry where new medicines typically take an average of 10-15 years and cost over 20.6 billion USD or 3 trillion KRW to develop. However, the introduction of AI has enabled massive decreases in time and cost across areas such as target discovery, candidate discovery, drug design, and clinical trial optimization. As a result, global pharmaceutical and biotech companies are adopting AI as an essential tool in drug development, with rapid expansion in venture investments and R&D applications.

Global Market Outlook

The AI drug development market is growing at an average annual rate of over 30% and is expected to reach approximately 6.9 billion USD or 10 trillion KRW by 2030. IT giants such as Google's DeepMind, Amazon's AWS, and NVIDIA are developing AI-driven drug development technologies and platforms, collaborating with global pharmaceutical companies.

Recently, Insilico Medicine has achieved milestones in innovative drug development using AI. From 2021 to 2024, the company identified 22 new drug candidates using AI, with ten candidates receiving Investigational New Drug Application (IND) approval and advancing to clinical trials.

The Nobel Prize in Chemistry 2024 was awarded to scientists who have developed an AI model predicting complex protein structures, highlighting the transformative role of AI as a critical digital tool in drug development and marking a significant shift in research paradigms.

These achievements demonstrate that AI and connecting technologies are unlocking new possibilities in the drug development ecosystem, and these innovative approaches are expected to have a profound impact on the future of the biopharmaceutical industry.

How AI Transforms the Drug Development Process

1. Target Discovery Using Omics Data and Protein Structure Prediction

AI integrates and analyzes hundreds of thousands of genomic, proteomic, and metabolomic datasets to identify drug targets, uncovering disease mechanisms with far greater precision than traditional empirical approaches.

By analyzing gene expression patterns in specific diseases, AI can pinpoint key disease-causing proteins. Google's DeepMind's AlphaFold3 has sparked a revolution in predicting the 3D structure of proteins. This AI model has also enhanced the accuracy of drug target discovery and enabled detailed analysis of protein-drug interactions, a critical aspect of drug development, based on the precise prediction of drug binding sites.

2. Drug Design Utilizing Generative AI and AI Agent Technology

Generative AI leverages deep learning and generative models to create new compounds or drug structures based on existing data.

AI agents, equipped with self-learning capabilities, go beyond data-driven predictions by incorporating experimental results to design optimal drug candidates. Evolutionary algorithms are gaining attention for continuously improving candidate structures and automatically optimizing efficacy and safety.

AI agent-driven drug development can achieve high accuracy with significantly fewer experiments compared to traditional methods, contributing to reduced R&D costs.

3. AI-Driven Autonomous Labs and Robotics

The introduction of AI-based robotic automation systems has dramatically increased the efficiency of drug research.

Institutions such as Massachusetts Institute of Technology (MIT), Stanford University, and the University of Toronto have developed AI-driven autonomous labs operating 24/7, rapidly identifying new drug candidates. AI technology is being utilized to conduct experiments through robotics and automation platforms. It instantly analyzes result data and identifies optimal subsequent experimental combinations.

4. Quantum Computing in Drug Development

Quantum computing can solve complex molecular dynamics simulations that are beyond the capabilities of traditional supercomputers.

Quantum computers enable far more precise drug development by simulating quantum-level reactions of drug candidates.

Companies such as Google, IBM, and Rigetti Computing are actively researching quantum computing applications in drug development, anticipating groundbreaking achievements when utilizing AI.

Challenges and Solutions in AI-Driven Drug Development

1. Data Quality and Accessibility

AI accuracy heavily depends on the quality of training data. Ensuring reliable data acquisition and standardized data sharing are crucial.

Building bio-data sharing platforms is essential to address 'data silo' situations, where data is isolated in separate systems, making it difficult to share, access, or analyze across groups.

2. Regulatory and Legal Issues

Key discussion points are ethical concerns in AI-driven drug development, along with protection measures of patent rights and intellectual property rights for AI-generated drug candidates.

The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) are establishing guidelines for AI drug development, and South Korea also needs to refine its legal framework.

3. Reliability and Validation

To enhance the reliability of AI-developed drug candidates, biological experiments and clinical trials are necessary, requiring integrated AI-experimental models. Without established validation systems for AI-driven drug development, regulatory barriers in the drug approval process may increase.

The Future of AI-Driven Drug Development: Paradigm Shift

The rapid advancement of generative AI and the 2024 Nobel Prize-winning protein structure prediction technology are fundamentally transforming the paradigm of AI-driven drug development. As AI continues to integrate with various emerging technologies, drug development will accelerate further.

In this session, we will delve into how AI is reshaping the drug development process, explore the latest applications and future potential, and also discuss legal issues related to patents and data. We invite you to join us on this journey to envision the future of drug development through AI and converging technologies and to discover any and all possible solutions together.

SESSION 01

AI-Driven Drug Development: A Journey Towards Viable Solutions

Sharing Practical Achievements and New Possibilities in the Drug Development Ecosystem through AI and Converging Technologies

May 7 (Wed), 13:30~17:00 / Rm. 401

More detail ▲

The application of AI technology in drug development is significantly reducing the immense time and costs involved, enhancing efficiency and driving continued global investment. By 2030, the global AI-driven drug discovery market is expected to grow at an annual rate of 30%, reaching approximately 10 trillion KRW. Global big tech such as Google, Amazon, and Nvidia are actively developing AI platforms for drug discovery, providing them to pharmaceutical companies or engaging in collaborative research efforts. With the 2024 Nobel Prize in Chemistry awarded to scientists who developed AI-powered 3D protein structure prediction technology, the AI-driven drug discovery sector is anticipated to experience explosive growth, ushering in a new era of paradigm shifts in research methodologies. This session will delve into how AI is transforming the drug development process, explore real-world applications and future potential, and address key legal issues related to patents and data governance. Together, we will engage in an in-depth discussion to identify practical and implementable solutions in this rapidly evolving landscape.

Featured Speakers

01 Speaker

Brandon Sutherland, Director

Research Operations, University of Toronto, Acceleration Consortium

* Director of the Acceleration Consortium at the University of Toronto, a global collaborative initiative engaging academia, government, and industry
* Oversees research and development efforts aimed at accelerating the design and discovery of advanced materials and molecules for applications in renewable energy, consumer electronics, pharmaceuticals, and other sectors

Tianjing Zhang, Developer Relations Manager

APAC Lead, Healthcare Start-ups, NVIDIA

02 Speaker

* A global U.S.-based semiconductor design, manufacturing, and service company, and a leading enterprise in AI chips.
* Unveiled the generative AI model "BioNeMo" for accelerating drug discovery at the world's largest AI conference, GTC Conference (2024).

Bridging Minds and Machines in the 21st Century: The Monumental Rise of Brain-Computer Interfaces

Global Innovation Trends and the Future Outlook of Brain-Computer Interface Technology

By | **Chang-Hwan Im_Professor, Department of Biomedical Engineering Hangyang University**

Date & Time : May 7(Wed) 2025, 13:30~17:00

Venue: COEX Rm. 307

Coordinating : Department of Biomedical Engineering, Hangyang University

*The content of this article represents the author's opinion and may differ from the official views of the BIO KOREA Organizing Committee.

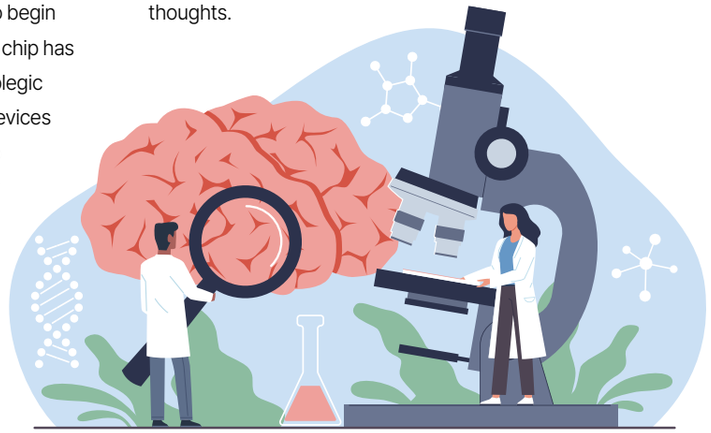
Why Global IT Leaders are Interested in the Human Brain

Elon Musk, CEO of *Tesla* and Head of the U.S. Department of Government Efficiency (DOGE), founded brain engineering tech-startup *Neuralink* in 2016. In 2023, the startup secured FDA approval to begin clinical trials of its brain chip, 'Telepathy'. The chip has successfully been implanted in three quadriplegic patients, enabling them to control external devices and communicate through thought alone. To date, *Neuralink* has reportedly received over 480 million USD, or 700 billion KRW, in investments—more than half of which came from Musk's personal funds. Musk has stated that he aims to implant the Telepathy chip in 20,000 people by 2030. More recently, *Neuralink* announced plans to develop technology that restores vision by implanting chips in the brains of patients with vision loss, following its successes with remedying mobility in quadriplegic patients.

In the U.S., brain engineering companies are already conducting clinical trials for brain chips, such as at *Synchron* and *Precision Neuroscience*. *Synchron* has reportedly obtained over 10 million USD in investment from venture capital firms led by Jeff Bezos and Bill Gates. Another global IT giant, *Meta*, organized an in-house research team in 2017 to develop brain-computer interface technology and has continued its research and development through a company it has since acquired, CTRL-labs.

In Europe, French company *Clinatec* is conducting clinical trials on humans with an implantable brain chip, 'WImagine', which can measure brain signals and stimulate the brain. In 2023, the Swiss Federal Institute of Technology Lausanne released a video of a paralyzed patient walking again after receiving a 'WImagine' implant.

In China, shortly after *Neuralink* announced the successful implantation of its 'Telepathy' chip in 2024, a patient implanted with a neural interface system named 'NEO' demonstrated the ability to control a robotic arm using only their thoughts.



Brain-Computer Interface (BCI) is a technology that reads signals generated by the brain to control external devices or enable external communication. BCI has been actively researched at the laboratory level since the early 1970s, primarily in the U.S. and Europe, but its commercialization was still considered far off. However, with *Neuralink's* rapid success in human clinical trials backed by substantial funding, the industrialization of BCI is becoming a reality. BCI is expected to have a significant impact not only on industries but also on society, welfare, and the economy. The technology can enhance mobility and communication for quadriplegic patients, enable the social reintegration of individuals with disabilities, and improve productivity among the elderly.

BCI Market Status and Outlook

Most BCI technologies remain in the pre-commercialization stage, but non-invasive BCI technologies, those that do not require surgery, are already being commercialized. According to Allied Market Research's 2021 report, the BCI industry was estimated to be worth 1.48 billion USD in 2021. With a robust 13.9% compound annual growth rate, the size of the industry is expected to reach 5.46 billion USD by 2030. The BCI market is anticipated to grow further, driven by its applications in healthcare (e.g., diagnosis, treatment, and rehabilitation of brain diseases), military and security, and gaming and entertainment. The brain-computer interface sector is swirling with high expectations, driven by advancements in neuro-engineering, AI, and wearable technologies, as well as aging populations and rising healthcare demands. This is expected to attract further investment.

In South Korea, research on passive BCI targeting the general public is active, with major corporations showing significant interest. In 2022, *Hyundai Mobis* publicized 'M.Brain', an earpiece-type brainwave measurement system that detects when drivers become distracted, and provides appropriate warnings. 'M.Brain' was piloted on public buses in Gyeonggi Province, reportedly reducing instances of driver inattentiveness by 25.3%. In 2023, *LG Electronics* released 'Brid.zzz', an ear-EEG (Electroencephalography) device that analyzes brainwave signals during sleep and improves sleep quality through sound stimulation. *SK Biopharmaceuticals* developed 'Zero Wired', a brainwave measurement device in the form of earphones, that can predict epileptic seizures, allowing for timely intervention. This device has been named a CES 2023 Innovation Honoree. *Samsung Electronics* also unveiled 'ID.EARS', an earbud-type brainwave measurement device, at CES 2024. As new features and apps are added to these wearable brain signal monitoring devices, the market size is expected to expand continuously.

[Image] BCI-based wearable devices by Korean companies: From left to right: Hyundai Mobis' M.Brain, LG Electronics' Brid.zzz, and SK Biopharmaceuticals's Zero Wired

BCI can also be used to diagnose brain health in the general population and establish appropriate care strategies. Both *BWAVE* Inc. and *Omni C&S* have announced new technologies that analyze brainwave signals measured by wearable systems to quickly and accurately diagnose users' brain health. Meanwhile, domestic efforts are underway to commercialize invasive BCI technology, which requires a device to be implanted into the brain to measure neural signals, with *Gbrain* and *Next Human* leading the way. *Gbrain* obtained clinical trial approval from the Ministry of Food and Drug Safety in 2024 for its brain-implantable neural interface system

and announced plans to develop it for BCI applications. *Next Human*, founded in 2025, is expected to emerge as a competitor to *Neuralink* by integrating the latest technologies through a team of domestic BCI experts.

Challenges for the Development of the Domestic BCI Industry

The BCI sector is predicted to see substantial market growth in the coming decade. Given the situation, domestic companies need long-term and systematic R&D investments to remain competitive in the BCI industry. Large-scale government R&D programs should support both basic and applied research while fostering collaboration between public research institutions, universities, and private companies. Although South Korea has numerous research institutions working on BCI application technologies, the interdisciplinary nature of BCI—requiring the convergence of brain science, neural engineering, and robotics—demands a collaborative approach. This involves combining basic research capabilities (e.g., neuroscience, biomedical engineering, and AI) with application capabilities (e.g., product development and commercialization) through industry-academia-research collaboration. It is crucial to maximize mutual benefits through cooperative R&D consortia, joint research institutes, and testbed operations, while also strengthening investment, incubation, and acceleration programs for startups.

Invasive BCI systems, classified as Class IV medical devices, require overcoming regulatory barriers for successful commercialization. To join the global BCI market, it is essential to streamline approval processes for BCI technologies and establish separate tracks for clinical trials to facilitate market entry. Additionally, active involvement in international standardization efforts—such as BCI signal protocols, data formats, and interface standards—combined with international cooperation, will help domestic companies expand globally.

Creating public demand is also necessary to expand the domestic market. BCI solutions should be actively introduced in public service areas such as rehabilitation therapy, assistive devices for those with relevant disabilities, and education and training, with pilot projects being implemented. Furthermore, identifying application models across industries—such as healthcare (e.g., brain disease diagnosis and rehabilitation), defense (e.g., drone and robot control), gaming, entertainment, and education—and providing continuous support will enable the domestic industry to achieve sustainable growth through a robust local market.

Lastly, BCI technology raises concerns about potential privacy breaches and the leaking of sensitive medical information during the analysis of neural signals. So, efforts to introduce legal and ethical guidelines are necessary. Public discourse to address societal concerns is also essential, with processes such as citizen participation forums, seminars for experts, and public hearings to gather opinions from various stakeholders. It is also needed to increase public interest and acceptance through first-hand experience-based events and science museum exhibitions, while communicating BCI's potential value and risks in a balanced way via mass media and educational programs. By establishing detailed policies, laws, systems, budgets, and R&D plans based on these considerations, South Korea can significantly contribute to the advancement and industrialization of BCI technology.

SESSION 02

The Great Connection of the 21st Century: Brain-Computer Interface (BCI)

Global Innovation Trends and Future Technological Prospects of Brain-Computer Interface (BCI)

May 7 (Wed), 13:30~17:00 / Rm. 307

More detail ▲

The global competition in the brain-computer interface (BCI) market is heating up, driven by Elon Musk's Neuralink. Neuralink has attracted investments totaling $600 million to date, while its competitor, Synchron, has secured significant funding from venture capital firms led by Bill Gates and Jeff Bezos. In November of last year, Precision Neuroscience, a spin-off from Neuralink, announced its success in raising 130 billion KRW. These companies have already obtained FDA approval for clinical trials and are progressing toward the commercialization of BCI technology for human use. Efforts to commercialize BCI technology have also begun in South Korea, with startups being established one by one. This session aims to introduce global innovation trends in BCI technology, as well as the current state of BCI industrialization in Korea and future technological prospects.

Featured Speakers

01 Speaker

Chang Hwan Im, Professor
Department of Biomedical Engineering, Hanyang University

* Section leader for the establishment ofthe 4th Brain Research Promotion Basic Plan of Korea
* Associate editor of five international journals, including Brain-Computer Interfaces and Frontiers in Human Neuroscience

Bo Hong, Professor
Biomedical Engineering, Tsinghua University

02 Speaker

* A professor at Tsinghua University's School of Biomedical Engineering, is leading the development and clinical trials of the NEO wireless minimally invasive brain-computer interface device, which aims to assist spinal cord injury patients in regaining motor functions.

Advanced Regenerative Medicine, The Beginning of a New Medical Paradigm

By | **Samira Choi_Senior Researcher, Regenerative Medicine Acceleration Foundation (RMAF)**

Date & Time : S3. May 7(Wed) 2025, 13:30~17:00
S8. May 8(Thu) 2025, 09:30~11:45

Venue : COEX Rm. 308

Coordinating : Korean Fund for Regenerative Medicine (KFRM), Regenerative Medicine Acceleration Foundation (RMAF), Council for Advanced Regenerative Medicine(CARM)

*The content of this article represents the author's opinion and may differ from the official views of the BIO KOREA Organizing Committee.

At BIO KOREA 2025, advanced regenerative medicine has once again emerged as a key topic in bio-health innovation. In recent years, the global regenerative medicine industry has experienced rapid growth, driven by increased investment and institutional support, leading to the development of groundbreaking technologies. This year's conference aims to explore global trends in regenerative medicine and discuss future directions through two dedicated sessions. The first session will focus on regulatory trends and policy responses in major countries, including South Korea. In the second session, researchers in the field will introduce the latest technological advancements with the aim of fostering networking among researchers.

Global Trends in the Advanced Regenerative Medicine Industry

As of 2024, the global advanced regenerative medicine market is valued at approximately $28.9 billion, growing at an annual rate of 20.7% from $11.3 billion in 2019. Major countries are expanding R&D investments and strengthening support policies, recognizing regenerative medicine as a strategic industry.

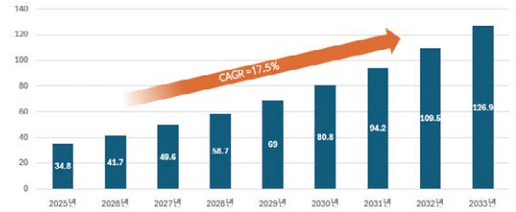
The United States has been actively investing in regenerative medicine R&D, with the NIH allocating $3.9 billion annually as of 2022. To further support bio-innovation, the government established ARPA-H, while the FDA is expediting commercialization through regulatory programs such as fast-track approvals.

In the United Kingdom, the Cell and Gene Therapy Catapult (CGTC) plays a key role in advancing cell and gene therapies. Recently, two new specialized research centers have been launched to accelerate gene therapy innovations.

Japan has long institutionalized regenerative medicine policies, enabling over 100,000 patients to receive regenerative therapies annually. The country has also developed bio-clusters in Kobe, Kyoto, and Osaka, which serve as hubs for technological innovation and commercialization.

Driven by increased investments in basic research, clinical trials, government support policies, and expedited regulatory approvals, the regenerative medicine market is projected to grow at an annual rate of 17.5%, reaching $34.8 billion in 2025 and $126.9 billion by 2033.

(Unit: US$ billions)



Source: Regenerative Medicine Market Report by Type, Application, End User, and Region 2024-2032, IMARC, 2024. Processed by Regenerative Medicine Acceleration Foundation

Significance of the Amendment to the "Act on the Safety and Support for Advanced Regenerative Medicine and Advanced Biological Products"

Regenerative medicine utilizes human cells, making it fundamentally different from traditional pharmaceuticals. This distinction necessitates a separate safety management and support system, which led to the enactment of the Act on the Safety and Support for Advanced Regenerative Medicine and Advanced Biological products in 2019. The act came into effect in 2020. After four years of implementation, it was revised in 2024 to expand clinical research indications beyond rare, severe, and intractable diseases to include all conditions. The revised act, which took effect on February 21, aims to provide broader access to regenerative medicine treatments.

A key feature of the amendment is the Advanced Regenerative Medicine Therapy system, which allows regenerative medicine technologies that have been validated in clinical trials to be used in severe, rare, and intractable diseases after review by the Advanced Regenerative Medicine and Advanced Biological Products

Review Committee. This initiative is expected to offer new treatment options to patients with no alternatives, reducing the need for overseas medical travel and ensuring safer access to regenerative therapies.
Furthermore, advancements in basic research will contribute to the accumulation of clinical evidence through translational research, ultimately leading to the development of advanced biopharmaceuticals and industry growth.
Meanwhile, Japan institutionalized regenerative medicine through the Act on the Safety of Regenerative Medicine (ASRM) in 2014. After 10 years of implementation, Japan amended the act to incorporate new technologies into regenerative medicine and enhance safety regulations.
This session will provide insights into South Korea and Japan's policy frameworks and explore recent regulatory changes and future directions.

Industry Perspectives on Changes in the Regenerative Medicine Landscape and Response Strategies

The FDA has already approved over 20 cell and gene therapies, accounting for 10% of all newly approved drugs in 2024. While regenerative medicine is gaining global recognition for its technological and commercial potential, several challenges still hinder the transition from research breakthroughs to commercialized therapies.
This session will examine the evolving landscape of regenerative medicine and national strategies from the perspective of global industry leaders. Representatives from leading organizations, including Japan's Forum for Innovative Regenerative Medicine (FIRM), Canada's Centre for Commercialization of Regenerative Medicine (CCRM), and Sweden's CCRM Nordic, will share their insights on industry trends and strategic agendas for growth.
These organizations play a key role in connecting researchers, businesses, governments, and related entities, making them valuable benchmarks for South Korea as it seeks to enhance its global competitiveness in regenerative medicine.

Innovative Therapies and Emerging New Technologies

Technological advancements in gene therapy, immunotherapy, artificial blood, and blood-derived products are accelerating at an unprecedented pace.
In the second session, leading regenerative medicine researchers will highlight cutting-edge research with high clinical applicability and commercialization potential. They will also share their perspectives on the innovation and the future of the field.
As the session's first speaker, Professor Stella T. Chou from the University of Pennsylvania, a world-renowned expert in artificial blood, will present on " Induced Pluripotent Stem Cell (iPSC)-Based Red Blood Cell Production Technology." This innovative approach leverages iPSCs to generate red blood cells suitable for clinical applications, providing a breakthrough alternative for patients requiring blood transfusions. This research is expected to be a pivotal milestone in the development of next-generation blood-based regenerative therapies.
Additionally, the Advanced Regenerative Medicine Relay Showcase will feature South Korea's most promising regenerative medicine technologies, highlighting R&D achievements. By promoting investment opportunities, fostering strategic partnerships and building collaborative networks, this initiative aims to establish a strong foothold for commercialization, drive industry growth, and facilitate global market expansion.
Due to its technological complexity and patient-specific nature, regenerative medicine requires extensive global collaboration. The Bio Korea 2025 conference is designed not only to showcase technological advancements but also to explore policies, industry trends, and international cooperation strategies.
Through this event, we hope to facilitate meaningful discussions on how South Korea can establish itself as a global leader in regenerative medicine.

SESSION 03

Advanced Regenerative Medicine: The Beginning of a New Medical Paradigm

May 7 (Wed), 13:30~17:00 / Rm. 308

More detail ▲

With regards to the full-scale implementation of the Advanced Regenerative-Bio Act Amenment(effective as of February 2025), this session will provide the main contents of the Amendment, guidelines and indicators after the Act's enforcement, and examine the macro and micro impacts on the bio industry. We will introduce major issues, including implications for stakeholders such as government, researchers, companies, and patients, and analyze the impact of legal and institutional changes on the field of regenerative medicine; thereby expecting to provide a networking platform for stakeholders in the medical community, researchers, and industry to discuss new opportunities and challenges, and ultimately contribute to strengthening the sustainability and global competitiveness of the regenerative medicine.

Featured Speakers

01 Speaker

Yoshitsugu Shitaka, Chairperson
FIRM/Astellas Pharma Inc.

* Chairperson of a non-profit consortium dedicated to advancing the regenerative medicine and cell therapy industry in Japan.
* Plays a leading role in policy development and market activation through close collaboration with government, academia, and industry

Jim Lund, Chief Business Development Officer
Center for Commercialization of Regenerative Medicine Nordic

02 Speaker

* Chief Business Development Officer (CBDO) of CCRM Nordic, a Sweden-based leading organization at the forefront of commercializing regenerative medicine and driving technological innovation across Europe

SESSION

08

Strengthening the Competitiveness of Domestic Regenerative Medicine by Discovering Outstanding New Technologies for Cutting-edge Regenerative Medicine

Technology Showcase for Outstanding Korean Regenerative Medicine Technologies

May 8 (Thu), 09:30~11:45 / Rm. 308

More detail ▲

This session will introduce the innovative technologies and achievements of promising companies and researcher-centered projects active in the Korean regenerative medicine field, and provide a venue for cooperation by forming a network with investors, the medical community, and researchers. This will revitalize the regenerative medicine ecosystem and strengthen global competitiveness. Through the technology showcase, we will inform the public and industry of the technology and potential of Korean regenerative medicine, promote commercialization by attracting investment and establishing cooperative partnerships, and seek to develop the regenerative medicine industry ecosystem and build a stepping stone for global expansion. In addition, to address the persistent imbalance between blood supply and demand for transfusion caused by demographic shifts such as declining birth rates, population aging, and the impact of infectious diseases like COVID-19, advanced healthcare nations are actively pursuing research on the generation of transfusion-grade red blood cells (RBCs) and platelets from stem cells. In Korea, a pioneering R&D initiative was launched in 2023 under the Multi-Ministerial Research Support Program. This initiative is focused on advancing the clinical translation and mass production of stem cell-derived cultured RBCs and platelets. The program aims to disseminate the core proprietary technologies developed over the past three years and share its technological advancements with the global scientific community.

Featured Speakers

01 Speaker

Stella Chou, Professor

Pediatrics, Transfusion Medicine, University of Pennsylvania School of Medicine

* Utilizing induced pluripotent stem cells (iPSCs) to model blood diseases and develop innovative technologies for customized red blood cell production.

Hyung Cheol Kim, Head of R&D Center

R&D Center, Curocell

02 Speaker

* Head of the Research and Development Center at Curocell, a biotechnology company specializing in the development of cancer immunotherapies using immune cells
* Submitted a reimbursement application (2025) for LIMCAR-T, the first domestically developed CAR-T (Chimeric Antigen Receptor T-cell) therapy in Korea

Global Trends and Implications in Biopharmaceutical Technology Licensing

By | **Yong U Kim_Director, Pharma & Bio Industry Department, Korea Health Industry Development Institute(KHIDI)**

Date & Time : May 8(Thu) 2025, 09:30~11:40

Venue : COEX Rm. 401

Coordinating : Korea Health Industry Development Institute(KHIDI), Global Biopharmaceutical companies

*The content of this article represents the author's opinion and may differ from the official views of the BIO KOREA Organizing Committee.

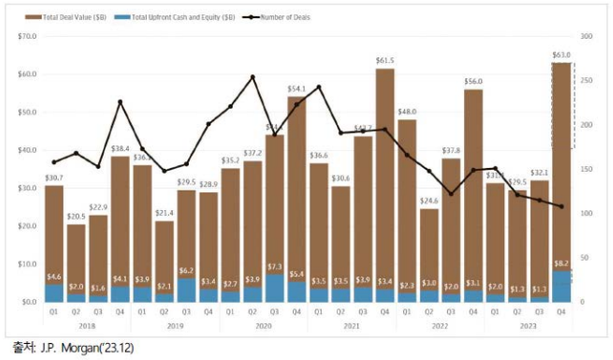
The Global Tech Race and the Transformation of Biopharma

The global pharma-biotech industry is shifting, centered around technology licensing. As the drug development paradigm moves towards open innovation, global pharmaceutical firms are actively seeking novel drug candidates and technologies from external sources. This trend stems from multiple factors, including the expiration of patents on very popular, so-called 'blockbuster' drugs, as well as the pressure to lower prices, and rising R&D costs.

Following the implementation of the Inflation Reduction Act (IRA) in the USA, major pharmaceutical enterprises are focusing on securing new growth drivers to mitigate revenue losses from price negotiations. With 45 blockbuster drugs slated to go off-patent by 2032—resulting in an estimated $212.7 billion in lost sales—Big Pharma is increasingly relying on mergers and acquisitions and licensing deals to expand their pipelines.

Current Trends in the Global Pharma-Biotech Licensing Market

Despite a decline in the number of licensing deals, the individual scale of a given deal has grown significantly. As of 2023, the number of licensing agreements dropped to around 100, yet the total deal value remained robust at $156 billion, and a landmark $22 billion antibody-drug conjugate (ADC) licensing deal between Daiichi Sankyo and Merck in Q4 2023 further underscored this trend.



출처: J.P. Morgan('23.12)

<Figure 1: Annual Pharma-Biotech R&D Partnerships and Licensing Volume/Value ($ billions)>

Amid these shifts in the market, three key trends are shaping the landscape of pharmaceutical licensing:

1. An increased number of transactions involving drug discovery platforms and preclinical-stage technologies.
2. A shift towards improving existing technologies or developing novel therapies.
3. The increasing dominance of bio-pharmaceutical transactions, with licensing deals focused on oncology, cardiovascular treatments, and other high-demand areas.

Emerging Modalities Gaining Traction

The most actively traded modalities in the global licensing market include antibody-drug conjugates (ADCs), targeted protein degradation (TPD), and radiopharmaceutical therapy (RPT). ADC combines antibodies with cytotoxic drugs to precisely target cancer cells and minimize side effects. Leading players such as Daiichi Sankyo, Merck, and Roche are aggressively licensing ADC technologies, signaling sustained market growth.

Unlike traditional small-molecule targeted drugs, Targeted Protein Degradation (TPD) directly degrades disease-causing proteins, maximizing therapeutic efficacy. Pfizer, Merck, and Amgen are actively licensing TPD technologies, with Korea's Orum Therapeutics also making waves in global exports.

Radio-pharmaceutical Therapy (RPT) utilizes radioactive isotopes to destroy tumor cells with high precision. Radioactive isotopes are bound to specific targets to effectively destroy tumor cells with higher efficacy compared to conventional anticancer drugs. Janssen and Lilly have recently entered this space, while SK Biopharmaceuticals is advancing RPT-based drug development.

The Domestic Licensing Landscape and Key Takeaways

Korean pharma-biotech firms are actively engaging in technology transfers and partnerships, securing 108 licensing-out deals worth approximately KRW 47.7 trillion ($35.5 billion) between 2020 and 2024. Leading domestic licensing-out companies—including Alteogen, LigaChem Biosciences, Daewoong Pharmaceutical, GC Cell, Voronoi, and Chong Kun Dang—are leveraging differentiated platform technologies such as ADCs, subcutaneous injection formulation modification technology, and Blood-Brain-Barrier (BBB) penetration technology, striking deals with global giants.

To sustain growth, Korean players must adopt strategic approaches. First, they need to utilize licensing as a pathway to internalize R&D capabilities through collaboration with global big pharma, not just as a one-time transaction. Second, domestic firms need to secure R&D funding via licensing-out and constant innovation amid global economic uncertainty. Third, the Korean government should provide long-term support, regulatory improvements for global partnership, and fund establishment schemes.

Conclusion and Outlook

Pharma-biotech licensing has evolved beyond mere technology transactions into a core pillar of drug development. As global pharmaceutical conglomerations intensify licensing strategies to secure pipelines, Korean companies should strengthen their competitive edge through differentiated platform technology and an innovative industry pipeline that aligns with this trend. With coordinated efforts between the Korean government, the industry, and research institutions—backed by sustained R&D investment and global networking—Korea's pharma-biotech sector is poised for a leap forward on the world stage.

SESSION

04

The Key to Innovation: Global Open Innovation Strategy

May 8 (Thu), 09:30~11:40 / Rm. 401

More detail ▲

In the rapidly evolving pharmaceutical and biotechnology industries, open innovation has become a key strategy for driving innovation, accelerating drug development, and maximizing resource efficiency. Beyond simple research and development (R&D) collaborations, open innovation serves as an essential factor for sustainable growth and industry leadership. To remain competitive in this rapidly changing environment, not only global pharmaceutical companies but also small and mid-sized biotech firms must actively leverage various forms of open innovation, including licensing, joint R&D, partnerships with startups, digital healthcare, and AI-driven technologies. To effectively utilize open innovation, companies must establish strategic direction, build collaborative models, conduct technology evaluation and licensing strategies, and understand contractual and regulatory considerations. Thorough preparation is essential for fostering successful global partnerships. This session will explore the latest trends in open innovation within the global pharmaceutical and biotech industries. By examining successful case studies, we will delve into practical strategies for collaboration, licensing, and joint R&D, providing actionable insights for industry professionals.

Featured Speakers

01 Speaker

Magnus Björsne, CEO
AstraZeneca BioVentureHub

* CEO of AstraZeneca's bio-venture incubator, established in Gothenburg, Sweden
* Supports collaboration and growth in life sciences by providing AstraZeneca's talent and infrastructure to startups and academic institutions in the fields of pharmaceuticals, deep tech, digital innovation, and sustainable technologies

Oliver Kast, Global Head Oncology Business Development and Licensing
Boehringer Ingelheim International

02 Speaker

* Boehringer Ingelheim Korea established a Business Development and Licensing (BD&L) department to foster open innovation with domestic pharmaceutical companies and biotechs
* Actively collaborates with Korean researchers to identify innovative new drug candidates and support their entry into the global market

Next Generation Modalities - Taking on the challenge of a breakthrough in global new drugs

By | **Yeong-min Park, CEO, Korea Drug Development Fund(KDDF)**

Date & Time : May 8(Thu) 2025, 13:00~17:00

Venue : COEX Rm. 401

Coordinating : Korea Drug Development Fund(KDDF)

*The content of this article represents the author's opinion and may differ from the official views of the BIO KOREA Organizing Committee.

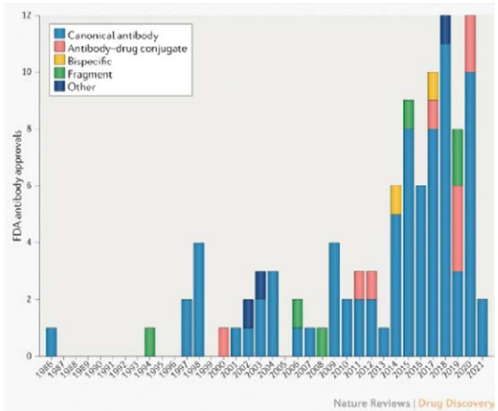
The medical sector is where we most keenly feel the changes and progress brought about by scientific and technological innovation. Among these, the development of new drugs is key to realizing the dream of extending life in the face of countless, seemingly insurmountable diseases, such as cancer or rare diseases. The emergence of next-generation modalities, rooted in ongoing innovation and technological advancements, offers humanity hope for addressing the unmet medical needs that still remain. These next-generation modalities are being boldly developed to overcome the mechanistic or physiochemical limitations of existing approved drugs, and have progressed to a point where the strengths of individual modalities are reflected in technological convergence.

Of course, there is pressure to succeed, as there is little data accumulated on these next-generation modalities and high risks involved in their development. However, players ranging from global pharmaceutical giants to biotech firms continue to take on the challenge due to the potential profits of success. Global deals are actively being signed to secure the relevant assets.

Therapeutic antibody technology, once considered a revolutionary new modality, matured and achieved commercialization after first being approved by the FDA in 1986 (product name: OKT3). By 2021, the 100th monoclonal antibody drug was approved, and it has since come to play a pivotal role, connecting low-molecular-weight compounds. Monoclonal antibodies accounted for 20% (10 cases) and bispecific antibodies (BsAb) made up 6% (3 cases) of all FDA-approved drugs in 2024. These antibody-based modalities, which began with monoclonal antibodies, have since developed and expanded to include multispecific antibodies (MsAb), such as bispecific (BsAb) and trispecific antibodies (TsAb), as well as other anticancer drugs, antibody-drug conjugates (ADC), dual-drug ADCs, and degrader-antibody conjugates (DAC).

In particular, spurred by the anticipated mechanistic effects of antibody-based modalities, 2023 witnessed ADC account for the largest deal of the year and approximately 70% of key antibody pharmaceutical deals. Furthermore, in 2024, bispecific^1 and trispecific^2 antibody modalities were included in both the top 10 global biopharmaceutical deals and the top 10 M&A deals. The demand for these modalities is also evident in the most recent deal trends of global firms. Korean drug development companies are also focusing on such modalities, resulting in multispecific antibodies and antibody-based new drug modalities accounting for roughly 20% of the Korea Drug Development Fund's sponsored projects (as of 2024). We have high hopes that these will be key drivers and opportunities for future global new drug development.

[FDA antibody approvals: 1986~2021]



Source: Nature Reviews Drug Discovery

RNA treatments, cell and gene therapy, PROTAC, degraders such as molecular glue degraders (MGD), and radiopharmaceuticals were also among the next-generation modalities included in global deals in 2024, and they are being developed as potential anticancer drugs as well.

The success of developing new drugs with next-generation modalities is also a field where the "little giant" biotech can create a miracle that goes beyond the principle of proportionality in economies of scale. According to an analysis of FDA approvals between 2022 and October 2024, biotech's success rate for new drug approvals increased from 30% of FDA-approved items (34 out of 112) to 48% (76 out of 159) between 2014 and 2016. Moreover, the number of next-generation modalities approved for biotech firms (18 approvals) is on par with that of pharmaceutical firms (19 approvals). These figures prove that global new drug development based on breakthrough technology is not just a possibility—it can be a reality. It gives me hope that the determination and pride of Korea's new drug developers will ensure that their struggles will come to fruition. The Korea Drug Development Fund examines both the domestic and international environments and provides comprehensive support to domestic new drug developers, enabling them to develop innovative next-generation modalities. This will help ensure that Korea's new drugs succeed globally and contribute to building new growth engines for our country.

[TOP 10 Biopharma M&A of 2024]

No	Acquirer	Target	Target focus	Deal value	Month
1	Novo Holdings	Catalent	**Contract manufacturing services** for medicines	$16.59bn	Feb.
2	Vertex	Alpine Immune Sciences	ALPN-303 (bet/APRIL antagonist) in **phase 2** for IgAN, **SLE** and **cytopenia**	$4.98bn	Apr.
3	Gilead	CymaBay Therapeutics	**FDA-approved** Livdelzi (seladelpar), a selective PPARδ agonist for **PBC**	$4.3Bn	Feb.
4	Eli Lilly	Morphic Therapeutics	Oral integrin therapies, including MORF-057 in **phase 2b** for **IBD**	$3.2Bn	Jul.
5	Merck & Co.	Eyebiotech	Vulcan-toxic trapezitic antibody Restoret in **phase 1b/2a** for **DME** and **wet AMD**	$3.0Bn	May
6	Novartis	MorphoSys	**Phase 3** BET inhibitor pelabresib for JAK inhibitor-naïve **myelofibrosis**	$2.9Bn	Feb.
7	H.Lundbeck	Longboard Pharmaceuticals	5-HT_{2C} agonist bexicaserin in **phase 3** for **Dravet syndrome**	$2.6Bn	Oct.
8	Ono Pharma.	Deciphera Pharmaceuticals	**Marketed** kinase inhibitor Qinlock (ripretinib) for **GIST**	$2.4Bn	Apr.
8	AstraZeneca	Fusion Pharmaceuticals	**Radioconjugates** for cancer, including FPI-2265 in **phase 2** for **mCRPC**	$2.4Bn	Mar.
10	Sanofi	Inhibrx	Recombinant AAT augmentation therapy INBRX-101 in **phase 2** for **AATD**	$2.2Bn	Jan.

[Top 10 Biopharma Partnership of 2024]

No	Company	Partner	Therapeutic area	Deal focus	Deal value	Month
1	Sarepta Therapeutics	Arrowhead Pharmaceuticals	Metabolic, neurology, respiratory	**Clinical & Non-clinical** programs in **rare muscle, central nervous system & lung disease, & new targets in other rare disease**	$12,820M	Nov.
2	Kailera Therapeutics	Jiangsu Hengrui Pharmaceuticals	Endocrine, metabolic	Jiangsu Hengrui's **GLP-1 candidates**	$8,035M	May
3	Novartis	Shanghai Argo	Cardiovascular	2 cardiorenovascular programs based on Argo's **RNAi platform**	$4,165M	Jan.
4	Bristol Myers Squibb	Prime Medicine	Autoimmune/immunology, oncology	**Reagents for** ex vivo **CAR-T cell therapies** using Prime's prime editing technology	$3,595M	Sep.
5	Merck & Co.	LaNova Medicines	Oncology	LaNova's LM-299, a **phase 1 bispecific antibody targeting PD1 and VEGF**	$3,290M	Nov.
6	Novartis	Dren Bio	Oncology	**Bispecific antibody** for cancer using Dren Bio's **targeted myeloid engager & phagocytosis platform**	$3,000M	Jul.
7	Novartis	PTC Therapeutics	Neurology	PTCrx phase 2 oral Huntington's disease therapy, PTC512	$2,900M	Dec.
8	Viatris	Idorsia Pharmaceuticals	Autoimmune/immunology, cardiovascular	Idorsia's **phase 3** assets, selatogrel ($P2Y_{12}$ inhibitor) & cenerimod(**S1P1 receptor modulator**)	$2,750M	Feb.
9	Novartis	Schrödinger	Not specified	Multiple development candidates & expanded access to Schrödinger's **computational platform**	$2,420M	Nov.
10	Novartis	Monte Rosa Therapeutics	Autoimmune/immunology	Monte Rosa's **phase 1** MRT-6160 for immune-mediated conditions & other VAV1 **molecular glue degraders**	$2,250	Oct.

Source: Nature.com/ Processed by the R&D Planning Team

[Top 10 Oncology licensing/R&D deals for solid cancers in 2024]

Partners	Candidate/modality	Upfront and milestone payments
Merck & Co. Inc., LaNova Medicines	Merck gains a global license to develop LM-299, a PD-1xVEGF bi-specific antibody in phase 1	$588 million upfront; $2.7 billion in milestones
BioNTech, Autolus	BioNTech gains the option to use Autolus' clinical and manufacturing infrastructure for claudin-6-targeted CAR-T cell BNT211, in phase 1 for solid tumors	$250 million upfront; $392 million in milestones
Novartis, PeptiDream	PeptiDream will discover peptides to be developed into peptide-drug conjugates (radionuclides) with Novartis	$180 million upfront; $2.71 billion in milestones
Novartis, Arvinas	Novartis gets worldwide rights to develop and commercialize PROTAC androgen receptor protein degrader	$150 million upfront; $1.01 billion in milestones
BeOne Medicines (formerly Beigene), CSPC Pharmaceutical Group	Beigene gets rights to a methionine adenosyltransferase 2A (MAT2A)-inhibitor for solid tumors including glioblastoma, pancreatic cancer and NSCLC	$150 million
Eli Lilly, Radiometrix Oncology	Eli Lilly enters a small-molecule RLT research partnership with Radiometrix and has the option to acquire the company	$140 million upfront; $1 billion if acquisition option exercised
Sanofi, RadioMedix/Orano Med	Sanofi gets worldwide rights to commercialize Pb-212-based RLT AlphaMedix for neuroendocrine tumors	$110 million upfront; $243 in milestones
Gilead Sciences, Merus	Research collaboration to develop antibody-based tri-specific T-cell engagers using Merus' Trioclonics platform	$81 million upfront; $1.5 billion in milestones
Ideaya Biosciences, Jiangsu Hengrui Pharmaceuticals	Ideaya gets worldwide (excluding Greater China) rights to DLL3 targeting ADC in phase 1 for NSCLC and NETs	$75 million upfront; $970 in milestones
Ligand Pharmaceuticals, Agenus	Financing deal giving Ligand access to royalties from Agenus' CTLA-4-targeted botensilimab (BOT) with anti-PD-1 balstilimab (BAL), in the clinic for colorectal cancer	$75 million upfront; $400 in milestones

ADC, antibody-drug conjugate; CAR, chimeric antigen receptor; CTLA4, cytotoxic T-lymphocyte associated protein 4; DLL3, delta-like protein 3; NET, neuroendocrine tumor; NSCLC, non-small-cell lung cancer; Pb-212, lead-212; PD-1, programmed cell death protein 1; R&D, research and development; RLT, radioligand-based therapy; VEGF, vascular endothelial growth factor

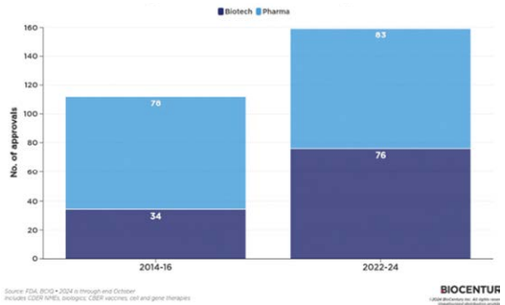
[Top 10 Oncology M&A for solid cancers in 2024]

Buyer, seller	Acquired assets	Value
Ono Pharmaceutical, Deciphera Pharmaceuticals	Small molecule Qinlock (ripretinib) approved for gastrointestinal stromal tumors (oral switch)	$2.4 billion
AstraZeneca, Fusion Pharmaceuticals	RLTs; lead phase 2 for prostate cancer	$2 billion; $400 million in contingent payments
Johnson & Johnson, Ambrx Biopharma	ADCs; lead phase 2 candidate is HER2-targeted	$2 billion
Genmab, ProfoundBio	ADCs; lead Rina-S (rinatabart sesutecan) for solid tumors in phase 2	$1.8 billion
Boehringer Ingelheim, Nerio Therapeutics	Small-molecule inhibitors of immune checkpoint tyrosine phosphatases N1 and N2, pre-clinical	$1.3 billion
Novartis, Mariana Oncology	RLT programs: actinium-based lead, pre-clinical, small-cell lung cancer	$1 billion; $750 million in milestones
BioNTech, Biotheus	Bi-specific ADCs including a PD-L1xVEGF-A candidate in phase 3	$800 million upfront; $150 million in additional payments
Merck & Co. Inc., Harpoon Therapeutics	Tri-specific antibody lead MK-6070 and other T-cell engagers	$680 million
Pharmacosmos, G1 Therapeutics	G1's Cosela (Trilaciclib) approved for decreasing chemotherapy-induced myelosuppression in lung cancer	$405 million
XOMA Royalty Corp, Kinnate Biopharma	Phase 1 pan-RAF exarefenib for BRAF- and NRAS-driven alterations	$110 million upfront

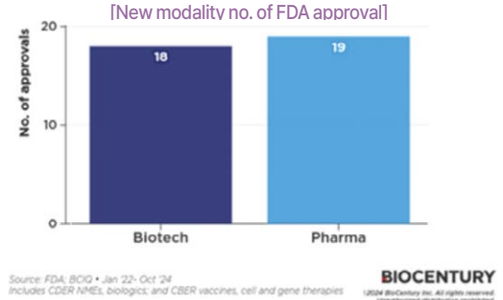
ADC, antibody-drug conjugate; BRAF, serine/threonine-protein kinase B-raf; HER2, receptor tyrosine-protein kinase erbB-2; M&A, merger and acquisition; NRAS neuroblastoma RAS (rat sarcoma) viral oncogene homolog; PD-L1, programmed cell death ligand 1; RAF, rapidly accelerated fibrosarcoma; RLT, radioligand-based therapy; VEGF-A, vascular endothelial growth factor A. Source: DealForma.

Source: Nature.com

[The growth of biotech-sponsored FDA approvals]



[New modality no. of FDA approval]



Source: BIOCENTURY

SESSION
05

The Rise of New Modalities: A Game Changer in Drug Development

May 8 (Thu), 13:00~17:00 / Rm. 401

More detail ▲

The rise of new modalities is creating a major turning point across the pharmaceutical and biotech industries, going beyond the traditional framework of drug development.Innovative treatment approaches such as CAR-T, mRNA, gene and cell therapies, and antibody-drug conjugates (ADCs) are rapidly advancing, moving past the conventional focus on small molecules and biologics.This session brings together leaders from global pharmaceutical companies, law firms, investment firms, and promising domestic biotech ventures to explore the core concepts and latest trends in new modalities. The discussion will delve into how these approaches are expanding the paradigm of drug development, and examine the challenges and opportunities faced during the research, development (R&D), and commercialization stages.

Featured Speakers

01 Speaker

Friedemann Janus, SVP

Head of Business Development & Licensing, Co.Lab, Regional and Divestitures, Bayer

* Senior Vice President responsible for Regional Business Development, Licensing, Open Innovation, and Divestments within Bayer's Pharmaceuticals Division
* Spearheads Bayer's innovation strategy, including the establishment of Bayer Co.Lab in Berlin to support life science startups

Koji Yashiro, Director

Business Development and Licensing, MSD

02 Speaker

* As the Director of Business Development and Licensing at MSD Asia Pacific, he leads search and evaluation efforts focused on early-stage assets in Japan and Korea.

Biosecure Act Article

By | **Sean Kim_Partner, Ice Miller LLP**

Date & Time : S6. May 8(Thu) 2025, 09:30~11:40
S7. May 8(Thu) 2025, 13:30~16:00

Venue : COEX Rm. 307

Coordinating : Dongguk University College of Pharmacy, Ice Miller LLP, U.S. Embassy & Consulate in the Republic of Korea

*The content of this article represents the author's opinion and may differ from the official views of the BIO KOREA Organizing Committee.

BIOSECURE Act article

As a life sciences company doing business in the United States, it is important to not only be aware of the latest trends in the industry, but also any potential (and actual) developments in the law that may impact the business. With the recent emergence of China as a noteworthy contender in the biotech space, the proposed BIOSECURE Act (H.R. 7085) received a lot of attention last year. This proposed legislation sought to place restrictions on companies that contracted with a "biotechnology company of concern," or used such biotechnology equipment or services. The bill explicitly identified five Chinese "biotechnology companies of concern"[1]: "Beijing Genome Institute (BGI), MGI Tech Solutions (MGI), Complete Genomics, WuXi AppTec, and WuXi Biologics, and any subsidiary, parent affiliate or successor of such entities." If passed, the Act would prohibit U.S. federal funding (for example, loans, grants, and contracts) in connection with obtaining or procuring biotechnology equipment or services produced or provided by a "biotechnology company of concern."

The Proposed Legislation and its Amendments

Introduced in January 2024 by bipartisan members of the United States House of Representatives, Rep. Raja Krishnamoorthi (D-IL.) and Rep. Mike Gallagher (R-WI.), of the House Select Committee on the Strategic Competition between the United States and the Chinese Communist Party (House Select Committee on the CCP),[2] the proposed legislation sought to accomplish two main objectives: to prevent entities receiving federal funding from utilizing biotechnology equipment and services from companies linked to foreign adversaries, including those in the People's Republic of China (PRC), and to protect U.S. genetic data from being accessed by the Chinese Communist Party (CCP)[3].

The proposed legislation's definition of "biotechnology companies of concern" include any entity that: (1) is "subject to the jurisdiction, direction, control, or operates on behalf of the government of a foreign adversary," (i.e., PRC, Cuba, North Korea, Russia, and Iran)[4]; (2) is "involved in the manufacturing, distribution, provision, or procurement of a biotechnology equipment or service"; and (3) "pos[es] a risk to the U.S. national security..."[5]

The definition of "biotechnology equipment or services" was broad, including any machine, equipment, software, data storage, consulting services, support services, or disease detection that involves "research, development, production or analysis" related to "biological materials."[6]

With China's emergence as a strong contender in the biotech space, both as a service provider and potential partner, the potential effect from the passage of such a bill would have affected not only those companies that fall under the definition of a "biotechnology company of concern," but also ones that do business (or want to do business) with such companies, as the U.S. government is a strong source of funding in the industry, including through government contracts and grants.

The proposed legislation for the BIOSECURE Act passed the House of Representatives through a 306-81 vote on September 9, 2024, but has not yet passed the U.S. Senate, which is necessary for the bill to be presented to the President for signature.

Despite bipartisan support, the BIOSECURE Act faced opposition, including from both Senator Rand Paul (R-KY) and Representative Jim McGovern (D-MA), who voiced concerns about its extensive restrictions on "biotechnology equipment and service." They worried that the Act would severely disrupt existing supply chains and potentially cause drug shortages, as industry surveys indicated an insufficient number of non-Chinese Contract Development and Manufacturing Organizations (CDMOs) capable of replacing the services currently provided by the designated companies of concern.[7] These concerns persisted even after the proposed Act was amended (H.R. 8333) to provide an approximately eight-year "grandfathering" transition period for severing ties with the affected PRC firms.

The bill was further amended to clarify that "biotechnology equipment or services" would not include those that "were formerly, but no longer, produced or provided by biotechnology companies of concern"[8] and that it would only govern federal contracts under the Federal Acquisition Regulation. Other criticisms focused on the Act's inadequate notification requirements for companies of concern and insufficient due process provisions for appealing their designations.

S. 3558, the Senate's version of the BIOSECURE Act that failed to progress, did not include the grandfathering period but clarified that the Act would not apply to existing arrangements with named biotechnology companies of concern that were in effect as of the legislation's effective date. Unlike the House version, S. 3558 did not specify which types of federal contracts would fall under its purview.

The bill was not presented for a vote at the Senate before the new Congressional term began in 2025, and with the new Republican-led Congress and Trump administration, its future is unclear.

Outlook and Potential Impact

Nonetheless, the amended House version of the BIOSECURE Act (H.R. 8333) (or another similar bill) may resurface in 2025 or beyond, with two main factors supporting its potential revival. First, the legislation enjoys relatively strong bipartisan support in a Republican-controlled Congress. Second, it could align with the broader policy agenda, including measures to protect U.S. domestic jobs and manufacturing. This development indicates a shift in governmental approach to international collaboration and national security within the life sciences sector.

Companies in the life sciences are monitoring this bill and assessing the potential risk/s of either continuing to do business with Chinese biotech companies and/or potentially serving as an alternative source. For example, some companies in the life sciences industry appear to be exploring alternatives to PRC firms, possibly in preparation for potential regulatory changes and to address geopolitical risks in their operations. If enacted, the ultimate impact and scope of the BIOSECURE Act will depend on multiple factors: Congress' final drafting of the legislation, federal agencies' interpretation and implementation of its provisions, and the private sector's response to the new regulatory framework.

Ultimately, the bill's passage (or a similar bill's passage) will depend in part on the new Congress and Trump administration's agenda and priorities, including with the relationship between U.S. and China, national security concerns, US-manufacturing, and issues impacting the biotech/life sciences. We are continuing to monitor developments to this bill and/or potential alternative proposals by Congress or the new Trump administration.

1 https://www.congress.gov/118/bills/hr8333/BILLS-118hr8333rfs.pdf
2 https://www.congress.gov/bill/118th-congress/house-bill/8333
3 Clause 2(b) of the bill.
4 10 U.S.C. 4872(d) (2024).
5 https://www.congress.gov/118/bills/hr8333/BILLS-118hr8333rfs.pdf page 9
6 Section 1(k)(2)(C) of H.R. 8333.
7 https://health-isac.org/wp-content/uploads/11.4.24_WP_ImpactsoftheBIOSECUREActontheGlobalBioTechIndustry.pdf (bottom of page 5-6)
8 Section (c)(3)(A) of H.R.8333.

SESSION 06

Global Bio Governance 2025: Change and Future

With a Focus on Policy, Regulation, Economy, and Approval

May 8 (Thu), 09:30~11:40 / Rm. 307

More detail ▲

Since the inauguration of President Trump in 2025, the America First policy has been reinforced, bringing rapid changes to the global bio-governance landscape. The revision of the U.S. Biosecure Act and discussions surrounding the repeal of the Inflation Reduction Act (IRA) are directly impacting the regulatory environment and investment strategies of global biotech companies. These shifts are expected to further intensify technological competition, particularly among the U.S., Europe, and China.

In response, countries worldwide are adjusting their strategies across key areas of the biotech industry, including policy, regulation, economic frameworks, and drug approvals. South Korean pharmaceutical and biotech companies must develop optimal strategies to navigate these changes and successfully enter the global market.

This session will provide a comprehensive analysis of how the Trump 2.0 administration is shaping bio-health industry policies, regulatory frameworks, and drug pricing policies. It will also examine global biotech investment trends and strategies for securing biopharmaceutical approvals. The discussion aims to offer strategic insights for Korean biotech firms to achieve sustainable competitiveness in this rapidly evolving global environment. Additionally, it will explore opportunities for South Korea's innovative biotech sector to expand its presence on the global stage.

Featured Speakers

01 Speaker

Ernesto Chanona,CEO

American Business Development

* CEO of a U.S.-based company specializing in B2B business development
* Former Vice President at CSSi LifeSciences, a global regulatory consulting firm

Jorge A. Goldstein, Director

Sterne, Kessler, Goldstein, and Fox PLLC

02 Speaker

* Founder of Sterne, Kessler, Goldstein & Fox PLLC, a prominent U.S. law firm renowned for its strong expertise in intellectual property law, particularly in the areas of patents, trademarks, and copyrights

SESSION 07

Strategies for Sustainable Global Biopharmaceutical Approval

Expanding into Global Markets Through Collaboration and Innovation

May 8 (Thu), 13:30~16:00 / Rm. 307

More detail ▲

The global biopharmaceutical industry faces the dual challenge of ensuring regulatory compliance while maintaining sustainable management (ESG) in an increasingly complex regulatory landscape. Compliance with current Good Manufacturing Practice (cGMP) is no longer just a legal requirement; it has become a critical component of ESG management, encompassing environmental sustainability, social responsibility, and transparent corporate governance.

To remain globally competitive, biotech companies must adopt eco-friendly production processes, prioritize quality and safety, strengthen ethical management, and ensure regulatory compliance. Meeting the standards of major regulatory agencies such as the FDA, EMA, and MFDS—while integrating ESG principles—will be key to ensuring long-term sustainability.

This session will explore how cGMP certification aligns with ESG management and the strategies that biotech firms can implement to achieve sustainable growth in global markets. It will also feature case studies of successful cGMP approvals and best practices in global ESG management. Through these insights, biotech companies can learn how to build global trust by linking regulatory compliance with ESG initiatives and develop practical strategies for sustainable growth.

Featured Speakers

01 Speaker

Charles Ahn, President

Aegis Beacon Consulting, Inc.

* A senior expert with over 30 years of global Good Manufacturing Practice (GMP) experience, including roles at the FDA and as a consultant in the pharmaceutical industry.

In Hwa Choi, Executive Director

Healthcare Access Innovation Team, KRPIA

02 Speaker

* Has over 20 years of experience in health policy, specializing in market access (MA) and regulatory affairs (RA)

03 Speaker

Min Woo Na, Vice President

Business Development-AP, PHARMASPHERE

* As the Vice President of Asia Pacific at PharmaSphere, LLC, he leads the company's new business programs in the region, leveraging his expertise in supply chain management, quality management, and regulatory affairs.

Low Earth Orbit Economy and Space Bio/Health technology

By | **Kyu-Sung Kim_Professor, Dept. of Otolaryngology-Head & Neck Surgery, Inha University Hospital**
Director, Inha Research Institute for Aerospace Medicine
President, Korean Aerospace Medical Society

Date & Time : May 8(Thu) 2025, 13:30~16:50

Venue : COEX Rm. 308

Coordinating : Korean Aerospace Medical Society

*The content of this article represents the author's opinion and may differ from the official views of the BIO KOREA Organizing Committee.

The Low Earth Orbit (LEO) environment, once seen as a challenge to overcome, is now evolving into a space of opportunity. In the 1970s, LEO was primarily a domain of competition and exploration. However, with the advent of human spaceflight, the 1980s marked the beginning of a new era of cooperation and utilization, symbolized by the International Space Station (ISS), a collaborative project involving multiple countries.

Building on decades of experience, the New Space era has enabled the private sector to leverage microgravity, space radiation, and extreme atmospheric conditions for biomedical research and development. Scientists are now exploring and utilizing the mechanisms of cell and tissue behavior, gene expression, protein synthesis, and stem cell differentiation in space to achieve groundbreaking advancements in drug discovery, manufacturing, and validation. There are also active efforts to apply the findings to improve human health, including efforts to combat diseases such as musculoskeletal degeneration and cancer as well as developing new medical technologies. These developments are not only driving innovation in bio-health research but also creating new opportunities for entrepreneurship and investment.

The LEO space economy refers to an expanding economic ecosystem encompassing commercial, scientific, and technological activities in low Earth orbit. Unlike past government-led space programs, the New Space era is increasingly driven by dynamics in the private sector, where LEO evolves into a thriving ecosystem that generates value. As the International Space Station is set to retire in 2030, multiple private space stations are expected to begin operations, fostering industries such as space tourism, health services, biomedical research, and manufacturing. Beyond space exploration, LEO is poised to become a major economic hub that integrates satellite services, telecommunications, and other space-based infrastructure.

Looking ahead, LEO will play a critical role in lunar and Mars exploration as part of NASA's Artemis program, which aims to establish a sustainable human presence beyond Earth. As the gateway to deep space, LEO will serve as a key staging base for future missions throughout the solar system.

While South Korea has made significant advancements in space technology, particularly in launch vehicles, satellites, and payloads, research utilizing LEO's unique environment, including human spaceflight and microgravity-based studies, remains underdeveloped. However, since the 2000s, South Korea has experienced remarkable economic growth alongside significant advancements in biomedical science, a foundational technology in the bio-health sector. As a latecomer to the emerging LEO economy, these strengths can serve as valuable assets in narrowing the gap and securing a competitive edge on the global stage.

This session will explore the latest developments in space bio-healthcare utilizing LEO, discuss South Korea's potential role in this emerging sector, and provide insights into available space research facilities and international collaboration opportunities. By deepening industry understanding of space-based biomedical research, we aim to inspire Korean bio-health companies to expand into space R&D and join the ranks of leading space nations, making meaningful contributions to the international space community in the future.

SESSION
09

Life Sciences in Space: A New Horizon for Biohealth

Innovation and Challenges in the Low Earth Orbit Environment

May 8 (Thu), 13:30~16:50 / Rm. 308

More detail ▲

In the low Earth orbit (LEO) economy, key sectors are expected to include space tourism and related healthcare services, space-based research and development focusing on biotechnology and advanced materials, and space-based manufacturing technologies. Compared to advancements in launch vehicles, satellites, and payloads, South Korea's progress in human spaceflight and LEO utilization research—particularly leveraging microgravity environments—has been relatively delayed. Now, with advancements in technological capabilities within the bio-health industry, these strengths should be leveraged as a resource for South Korea to secure a competitive position in the emerging LEO economy. Through this session, we aim to explore and examine the current state of LEO-utilized bio-healthcare and discuss future directions to position South Korea as a key player in this evolving field.

Featured Speakers

01 Speaker

Kyu-Sung Kim, Director

Inha Research Institute for Aerospace Medicine, Inha University Hospital

* Professor at Inha University College of Medicine and Director of the Aerospace Medical Science Research Center, designated as a key research institute in science and engineering
* Conducting a Korea-U.S. collaborative study with a NASA-affiliated organization to address cognitive decline induced by space environments

Koichi Wakata, Astronaut

Astronaut Office, Axiom Space

02 Speaker

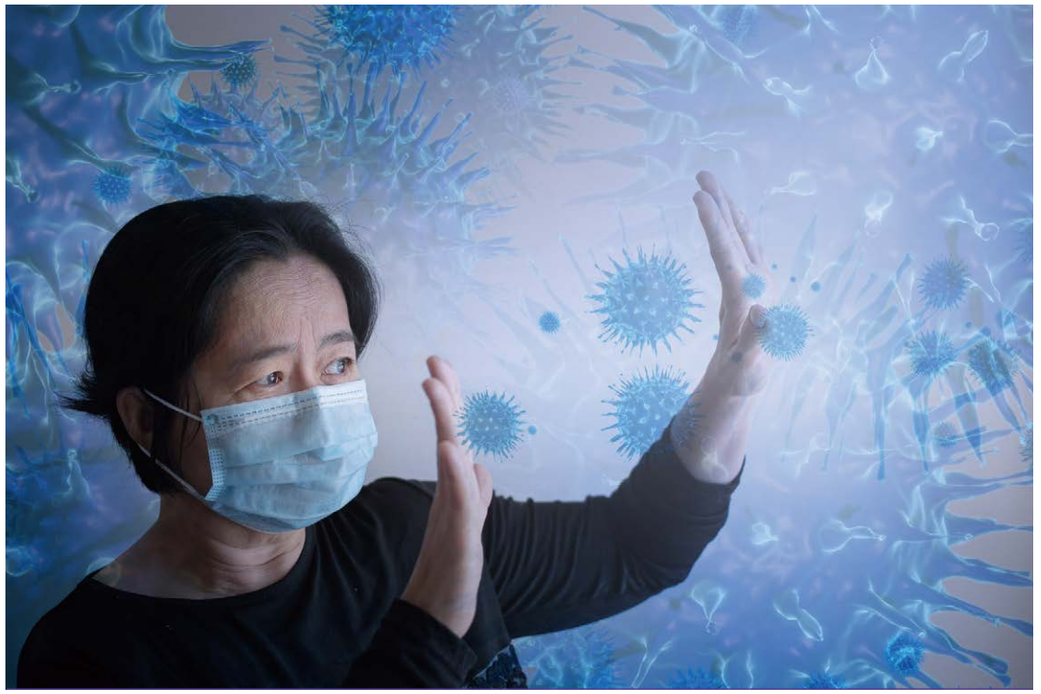
* Conducted various life science and bio-related experiments aboard the International Space Station (ISS)
* Collaborated with the U.S. space company Axiom to advance life science and bio research in space

2025 BIO KOREA International Convention

The Present and Future of the Anti-Aging and Reverse Aging Industries

"Healthspan, Not Lifespan, is the Key: Big Pharma's Full-Scale Entry"

By | **Kyung A Cho Ph.D**
Professor, Department of Biochemistry,
Chonnam National University Medical School
CEO, MediSpan Inc.



Date & Time : S10. May 9(Fri) 2025, 09:30~12:00
S11. May 9(Fri) 2025, 13:30~15:30

Venue : COEX Rm. 401

Coordinating : MediSpan Inc., The Korean Society for Gerontology, Korea Advanced Institute of Science and Technology(KAIST)

*The content of this article represents the author's opinion and may differ from the official views of the BIO KOREA Organizing Committee.

Healthspan Expansion is Crucial: Establishing the Aging Research Industry

The average human lifespan has been steadily increasing. However, the focus of aging research has shifted from simply living longer to maintaining a healthy life for as long as possible. As the world continues to experience an increasingly aging population, age-related diseases such as cancer, cardiovascular diseases, and metabolic disorders are surging in number. Maintaining a healthy physical state and early prevention of these diseases have emerged as new goals for the global healthcare industry.

Accordingly, research on aging has evolved from simple life extension technologies to healthspan extension, driving rapid growth in related industries. The development of anti-aging treatments is thriving, while preventive aging control technologies and personalized health management systems are becoming major market segments. According to global market research firms, the anti-aging and reverse aging market is growing at an annual rate of 8-10%, with rapid advancements in anti-aging therapeutics, diagnostic technologies, and preventive solutions.

What is Reverse Aging?

Reverse aging refers to restoring biological functions that have declined with age, effectively rejuvenating cells, tissues, or systems to a more youthful state. Unlike anti-aging, which aims to slow or prevent the onset of age-related decline, reverse aging actively targets the reversal of existing aging phenotypes through cellular reprogramming, immune modulation, tissue regeneration, and metabolic resetting. This paradigm shift seeks not only to halt but to undo aging-related damage.

Global Investment in Aging Research Expands: Big Pharma's Direct Entry Begins

Aging research is no longer just a basic science but has transformed into a massive industry. In the past, research was led by life science startups and academia, but now governments, global investors, and major pharmaceutical corporations are directly engaging in R&D to accelerate the clinical development of anti-aging therapeutics.

The U.S. National Institute of Health (NIH) has designated aging research as a national strategic initiative, investing over 125 million USD annually. The European Union (EU) is strengthening its support for research on aging through the Horizon 2020 program. Additionally, the U.S. Advanced Research Projects Agency for Health (ARPA-H) has selected studies on aging as a core focus, proactively supporting regenerative medicine and anti-aging technology development.

Global investors are also pouring significant funds into aging research. The Hevolution Foundation, based out of Saudi Arabia, invests over 1 billion USD annually in aging research and drug development, while global competitions such as the XPRIZE Longevity competition foster innovation. This has accelerated the growth of aging control technologies, with large pharmaceutical companies and tech firms directly entering the anti-aging industry.

Among these developments, the most notable is the full-scale entry of global pharmaceutical companies into anti-aging therapeutics. Novartis has partnered with BioAge Labs to explore aging-related biomarkers and therapeutic targets, initiating a research collaboration worth up to 530 million USD. Pfizer and Eli Lilly are also advancing AI-based aging biomarker research and personalized therapeutics, continuously expanding their research scope.

Aging research is no longer a future technology but an ongoing revolution in the healthcare industry. Global pharmaceutical firms and research institutions' direct involvement in developing anti-aging treatments boost commercialization prospects.

The Evolution of Aging Treatment Technologies: From Traditional Drugs to Innovative Approaches

Aging control technologies are advancing across three main areas: cellular, molecular, and systemic factors. In the past, the primary approaches were senolytics—a class of drugs targeting the elimination of senescent cells—and metabolic regulation, such as modulating the mTOR (mechanistic Target Of Rapamycin) and AMPK (AMP-activated Kinase). More innovative strategies have emerged, including cellular reprogramming, tissue regeneration, and organ replacement technologies.

Aging research is expanding beyond controlling senescent cells to functional rejuvenation, focusing on restoring age-related decline in immune, muscular, and cognitive functions. The XPRIZE Foundation is promoting such research by offering substantial prizes in a global competition to develop technologies that rejuvenate the physical and cognitive functions of the elderly.

Since the COVID-19 pandemic, improving aged immune systems has become a critical issue in aging research, gaining attention in research focused on enhancing responses to new infectious diseases and seasonal illnesses. Clinical trials are underway to evaluate the immune-boosting effects of known anti-aging medications, such as rapamycin, senolytics, and metformin, in elderly populations, with models combining these drugs with vaccines to demonstrate immune recovery.

Meanwhile, gene editing (CRISPR) and iPSC (induced Pluripotent Stem Cell) technologies are being integrated into aging treatments, with active research on repairing damaged tissues or replacing aged organs. U.S.-based eGenesis is developing organs derived from pig tissues compatible with the human immune system using gene editing, while Renewal Bio is researching customized artificial organs using embryonic stem cells.

These technological advancements indicate that aging treatments shift from drug-based control mechanisms to fundamentally regenerating tissues and restoring

functions. Moving forward, the combination of technologies utilized to reverse cellular aging and the approaches used to modulate immune and metabolic functions are expected to lead to more comprehensive anti-aging strategies.

Commercialization of Aging Research: South Korea's Need for a Swift Market Entry

As anti-aging therapeutics enter clinical trials at an accelerated pace, the commercial potential of aging research is growing. However, developing biomarkers to measure aging progression accurately is essential for anti-aging medicine development. Currently, the Biomarkers of Aging Consortium and ASTM Standards Task Group are working on standardizing aging biomarkers, while AI-based aging diagnostic technologies are becoming increasingly precise. If these studies prove fruitful, objective criteria for evaluating the efficacy of anti-aging therapeutics will be established, and clinical trials will progress more rapidly.

A number of countries, including Singapore, Saudi Arabia, Japan, and China, are at the forefront of global efforts in advancing aging research and supporting related policies. Since aging control technologies require more research and funding than traditional disease treatments, overseas research budgets and venture investments are being supported through large-scale national R&D projects and funds. However, South Korea lags behind global competitors in investment and has fallen short of a full technological entry into aging research and drug development. Government support programs for aging-related research and technology development are also significantly lacking compared to other countries.

For South Korea to quickly enter the global market, it needs to expand support for basic aging research and technology commercialization, strengthen collaborations with global pharmaceutical companies and research institutions, and improve clinical research and regulatory frameworks for anti-aging therapeutics.

The anti-aging therapeutics market is projected to be one of the fastest-growing sectors in the global healthcare industry within the next decade. For South Korea to secure competitiveness in this market, immediate and proactive measures are necessary. Aging research is no longer a distant future technology but the center of medical innovation that we must embrace today.

SESSION 10

Innovative Aging Control Technologies: Immunity, Diagnostics, and Evaluation Platforms

May 9 (Fri), 09:30~12:00 / Rm. 401

More detail ▲

Aging research has shifted its focus from merely extending lifespan to promoting healthy longevity. This session explores key technologies for aging modulation, covering immune-based aging control, precision diagnostics, and next-generation evaluation platforms. Discussions will include immune system modulation for aging intervention, AI-driven diagnostics and biomarker analysis, and novel platform technologies for evaluating aging therapeutics. This session aims to highlight the latest advancements and practical applications in aging research, paving the way for innovative strategies to bring aging control technologies closer to real-world implementation.

Featured Speakers

01 Speaker

Dmitry Bulavin, Director
IRCAN INSERM

* Affiliated with the French National Institute of Health and Medical Research (INSERM) and involved in projects such as the Interaging initiative, which aims to strengthen aging research through international collaboration.

Kyung A Cho, Professor/CEO
Chonnam National University/ Medispan

02 Speaker

* Research elucidating the therapeutic effects on aging-related metabolic disorders has been published in the high-impact journal Aging Cell, a leading publication in the field of aging.

SESSION

11

The Present and Future of Reverse-aging Technologies

May 9 (Fri), 13:30~15:30 / Rm. 401

More detail ▲

For over half a century, scientists have pursued technologies to alter the fate of living cells: from somatic cell nuclear transfer (SCNT) and cell fusion to cellular reprogramming. Today, these advancements have led to groundbreaking reverse-aging technologies that challenge the natural aging process, as well as cancer-reversal technologies that seek to restore cancer cells to their normal state.

Unlike traditional anti-aging approaches, reverse-aging technology aims to rejuvenate aged cells, restoring them to a youthful and healthy state. This innovation holds the potential to address a wide range of age-related diseases, offering new solutions for the aging population.

This session will explore the latest developments in reverse-aging technologies, examine their impact on human health, and discuss future directions in the field.

Featured Speakers

01 Speaker

Kwang-Hyun Cho, Professor

Department of Bio and Brain Engineering, Korea Advanced Institute of Science and Technology (KAIST)

* Developed a fundamental technology for cellular rejuvenation that reverses aged human dermal fibroblasts into younger cells. (2020)
* Identified a molecular switch capable of inducing cancer reversibility at the moment normal cells transform into cancer cells. (2025)

BG Rhee, Chairman CEO

GI Innovation

02 Speaker

* Member of the National Advanced Strategic Industry Committee
* Keynote Speaker at the AI Biohealthcare Drug Discovery Summit (ABDD Summit) in 2024

Shifting Global Trends and Emerging Technologies in Clinical Trials

By | **Ryungwoo Kang_Director, Policy Research Center, Korea National Enterprise for Clinical Trials (KoNECT)**

Date & Time : May 9(Fri) 2025, 09:30~12:00

Venue : COEX Rm. 307

Coordinating : Korea National Enterprise for Clinical Trials (KoNECT)

*The content of this article represents the author's opinion and may differ from the official views of the BIO KOREA Organizing Committee.

The global clinical trial landscape in 2025 is

rapidly evolving, driven by advancements in technology and changes in regulatory environments. The development of artificial intelligence (AI) and digital technologies, the increasing emphasis on patient-centric approaches, and shifts in regulatory policies are bringing about a new paradigm in clinical trials. In particular, following the COVID-19 pandemic, the adoption of remote monitoring and decentralized clinical trials (DCTs) has accelerated, significantly expanding the scope and methods of clinical research.

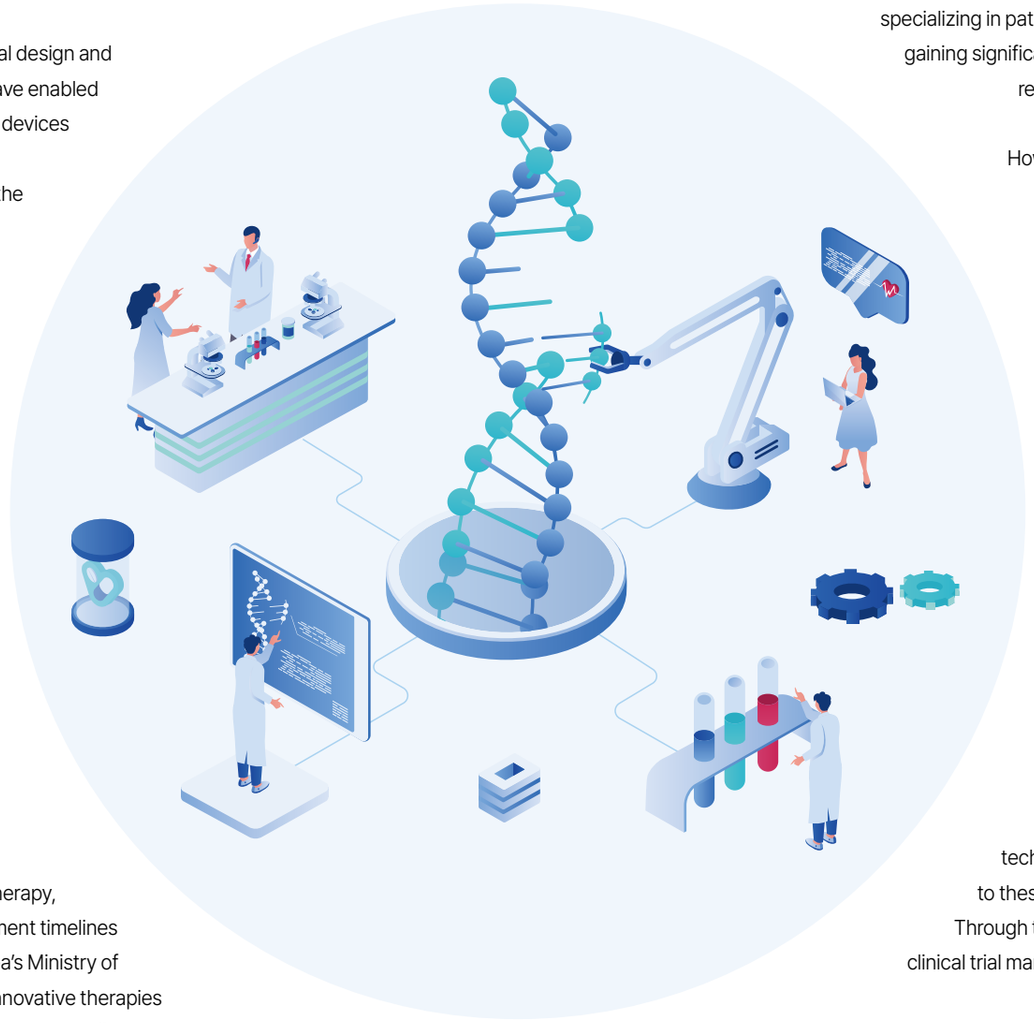
The advancement of AI and big data technologies is revolutionizing clinical trial design and patient recruitment processes. Machine learning algorithms powered by AI have enabled more precise and efficient patient selection. Additionally, the rise of wearable devices and IoT technologies allows real-time data collection and analysis, facilitating continuous monitoring of clinical trial safety and efficacy, thereby enhancing the overall quality of clinical trials.

As a result, the importance of patient-centric clinical trial designs is gaining greater emphasis. To enhance patient convenience and participation, technologies such as remote monitoring and electronic Informed Consent (eConsent) are being widely adopted. These approaches reduce patient burden, boost participation rates, and improve data collection efficiency.

Regulatory frameworks are also evolving

to keep pace with these changes. Leading regulatory agencies, including the FDA and EMA, are continuously refining guidelines to facilitate the adoption of new technologies and methodologies. In particular, the development of regulatory frameworks for utilizing Real-World Data (RWD) and Real-World Evidence (RWE) is transforming clinical trial design and evaluation approaches.

The U.S. FDA is expediting the development and review of drugs that meet critical medical needs through programs such as Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review. These programs shorten development timelines and enable essential treatments to reach patients faster. Similarly, South Korea's Ministry of Food and Drug Safety (MFDS) is facilitating the accelerated market entry of innovative therapies through a conditional approval system. Under this system, treatments for severe or rare diseases receive conditional approval based on Phase 2 clinical trial results, with a requirement to submit Phase 3 trial data later. This approach enables patients to access innovative treatments sooner.



In response to these trends, global pharmaceutical companies are reshaping their clinical trial strategies. Leading firms such as Pfizer, Roche, and Novartis are adopting AI-driven clinical trial design and targeted patient selection-recruitment systems while establishing decentralized clinical trial platforms to conduct more efficient and comprehensive studies.

Venture capital firms are also showing strong interest in companies pioneering clinical trial innovation through AI, machine learning, and wearable technologies. In particular, startups specializing in patient recruitment, real-time data analysis, and remote monitoring solutions are gaining significant attention. These technologies not only improve clinical trial efficiency and reduce costs but also enable more precise and comprehensive data collection.

However, these innovative approaches also present potential challenges. Issues such as data security and privacy protection, equity issues stemming from disparities in access to digital technologies, and the need to validate the reliability and efficacy of emerging technologies remain challenges that need to be addressed.

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In this context, the global clinical trial landscape in 2025 is

being shaped by regulatory shifts and technological advancements. The expedited programs of the MFDS and FDA are accelerating the development of innovative therapies, while advancements in DCTs and digital therapeutics (DTx) are significantly enhancing the efficiency and accessibility of clinical trials. These transformations are paving the way for patient-centric trial designs and improved health outcomes. Looking ahead, the clinical trial sector is expected to further accelerate these innovations, driving faster and more effective drug development as well as enhanced patient care.

In this session, we will delve into the latest global trends and innovative technologies in clinical trials and examine how domestic companies are adapting to these changes. Additionally, we will discuss regulatory shifts and future outlooks. Through this discussion, participants will gain valuable insights into the evolving global clinical trial market and acquire the strategic knowledge necessary to navigate this dynamic landscape.

SESSION
12

Evolving Global Trends and New Technologies in Clinical Trials

Emerging Trends and Innovations in Global Clinical Trials: Navigating an Evolving Landscape for Successful Drug Development

May 9 (Fri), 09:30~12:00 / Rm. 307

More detail ▲

The global clinical trial landscape is rapidly evolving, driven by regulatory changes from major agencies the growth of emerging markets (Asia, the Middle East, and South America), and cost-saving strategies. To help companies effectively navigate these shifts, this session will provide the latest insights into global clinical trial trends and strategic approaches. Additionally, it will explore how advanced technologies, such as AI-driven trial design, decentralized clinical trials (DCT), real-world data (RWD) and real-world evidence (RWE) utilization, and digital patient recruitment and retention strategies, are transforming clinical trials to enhance efficiency and success rates. The session will also discuss collaboration models with global CROs, pharmaceutical companies, and biotech firms. By doing so, it aims to showcase Korea's clinical trial capabilities and innovative technologies to international stakeholders while offering domestic companies practical strategies to strengthen their global competitiveness.

Featured Speakers

01 Speaker

Ben Phillips, Consultant
Consulting, Syneos Health

* Syneos Health launched a new Decentralized Clinical Trial (DCT) site network to accelerate the adoption of DCTs and support the delivery of high-quality digital health technology solutions (2023)

Shawn Lee, Senior Manager
Regulatory Affairs and Strategy, Harvest Integrated Research Organization (HiRO)

02 Speaker

* HiRO, a global Contract Research Organization (CRO), signed a Memorandum of Understanding (MOU) with Bundang CHA Hospital to conduct joint research aimed at streamlining clinical trial processes and improving operational efficiency (2024)

From Clinical Evidence to Practical Therapeutic Tools: Realizing the Innovation of Digital Therapies

By | **Chul-Hyun Cho_Professor, Department of Psychiatry, Korea University Anam Hospital**
Director, Smart Healthcare Research Group, Korea University Anam Hospital
Academic Director, Korean Society for Digital Therapy

Date & Time : May 9(Fri) 2025, 13:00~16:00

Venue : COEX Rm. 307

Coordinating : The Korean Society for Digital Therapy

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The Rise of Digital Therapy and Paradigm Shift

Digital technology is driving innovation across the entire healthcare sector. In particular, digital therapy is gaining attention as an innovative approach that provides treatment interventions based on clinical evidence. Beyond simple health management applications, digital therapy is recognized as a medical intervention that delivers tangible therapeutic effects. Like new drug development, it must undergo rigorous clinical trials to demonstrate its efficacy and safety. A key category in this field is medical devices known as digital therapeutics (DTx), which has emerged as a clinically validated digital solution for more advanced treatment interventions. In the United States and Europe, digital therapeutics are already being used to treat various conditions, including sleep disorders, depression, and diabetes. In Korea, approvals for digital therapeutics by the Ministry of Food and Drug Safety (MFDS) are also increasing.

However, limiting digital therapy to the scope of a medical device overlooks its full potential. Instead, it should be seen as a transformative tool that enhances the patient treatment journey by integrating technological advancements with user experience to optimize therapeutic outcomes. This article explores the present and future of digital therapy from multiple perspectives, including medicine, technology, policy, industry, healthcare administration, design, regulation, and the experiences of both patients and healthcare providers. Additionally, it proposes strategies for driving successful innovation in this evolving field.

A Multifaceted Approach to Digital Therapeutic Innovation

1. Medical Approach: Digital Therapy as Evidence-Based Treatment

Digital therapy has the potential to be applied across various medical domains, including prevention, treatment, management, prognosis improvement, and caregiver support. However, establishing clinical evidence is crucial to demonstrating its reliability and effectiveness in these areas. While the required level of evidence may vary, digital therapy that lacks validation for patient safety and therapeutic efficacy is unlikely to gain medical credibility.

Digital therapy can be combined with existing treatments to enhance patient outcomes. With real-time monitoring capabilities, it enables personalized care tailored to individual patient needs. In mental health care, for example, digital therapy can track emotional responses in real-time and deliver timely interventions. In chronic disease management, continuous data analysis allows for tracking treatment progress and adjusting interventions accordingly.

The advancement of digital therapy also extends to preventive care and post-treatment follow-up. Examples include digital interventions for improving lifestyle habits in patients at risk of cardiovascular disease, personalized solutions to enhance cognitive function in dementia patients, and digital platforms offering psychological support for cancer patients. To maximize its impact across various medical fields, rigorous research and evidence-based validation are essential. Equally important is the development of digital therapeutic solutions tailored to each stage of treatment, alongside the establishment of appropriate regulatory frameworks. To successfully integrate digital therapy into healthcare systems, its roles must be clearly defined based on disease-specific needs and purpose-driven objectives. This foundation will enable the development of a more structured approach to evidence collection and approval processes through targeted policy efforts. Establishing digital therapy as a trusted medical intervention requires active collaboration among healthcare professionals, research institutions, and continuous clinical research.

2. Technological Approach: Precision Digital Therapy Based on AI, IoT, and Big Data

Digital therapy is rapidly emerging as a key enabler of precision medicine by integrating artificial intelligence (AI) and big data technologies. Recent AI advancements go beyond basic data analysis, continuously monitoring patients' daily conditions, curating personalized treatments, and improving adherence to digital interventions. Additionally, AI plays a crucial role in the real-time analysis of patient responses, leveraging biometric and behavioral data to enhance engagement and continuously optimize therapeutic efficacy.

The advancement of wearable devices and Internet of Things (IoT) technology has become a key driver of digital therapy. Real-time monitoring enables continuous tracking of patients' health conditions and timely therapeutic interventions when needed. To maximize effectiveness, these technologies should be designed as a user-centered closed-loop system that seamlessly integrates healthcare providers, patients, and caregivers, ensuring ongoing improvements. Notably, the combination of AI and wearable technology can significantly enhance early disease detection and preventive interventions, paving the way for more proactive and personalized health management.

However, the effective utilization of AI and IoT technologies in digital therapy requires careful attention to legal and ethical considerations. Key concerns include safeguarding personal health data, ensuring the reliability of AI-driven treatment decisions, and clarifying legal responsibility for automated therapeutic interventions. Therefore, alongside technological advancements, the development of robust regulatory frameworks and ethical guidelines is essential to ensure safe implementation.

3. Policy Approach: Institutional Support and Regulation for Digital Therapy

For digital therapy to become a sustainable solution within the healthcare system, institutional support and a robust legal foundation are crucial. While the United States and Europe have established evaluation criteria for digital therapeutics, Korea's Ministry of Food and Drug Safety (MFDS) has also issued relevant guidelines. However, the criteria for assessing the efficacy and safety of digital therapy differ from those for traditional medical devices and pharmaceuticals. This underscores the need for a new regulatory framework tailored specifically to digital therapy. Achieving this will require collaboration among the government, medical institutions, and industry to develop policies for clinical evidence collection, certification standards, and reimbursement systems for digital therapy.

For digital therapy to be effectively adopted, a clear regulatory definition and an innovative approach are essential. Unlike traditional medical devices and pharmaceuticals, digital therapy is software-driven and constantly evolving, necessitating a regulatory framework that addresses these unique characteristics. First, to drive change through regulation, the evaluation criteria for digital therapy must be redefined. It is impractical to apply the same standards used for conventional medical devices and pharmaceuticals, so a flexible regulatory approach that validates effectiveness through real-world evidence is required. Second, given that AI-driven digital therapy evolves through algorithmic updates, a dynamic regulatory model that includes continuous monitoring and updates is crucial. For example, when AI refines its algorithms based on new treatment data, a system should be in place to report and evaluate these updates in real-time to regulatory authorities. Third, the "Regulatory Sandbox" approach should be actively employed to accelerate introducing new digital therapeutic technologies into the market. This approach allows for controlled, experimental applications, enabling limited market deployment for a designated period while gathering clinical data. By adopting these measures, innovative digital therapy solutions can enter the market more quickly and achieve broader adoption.

4. Industrial Approach: Market Growth and New Business Opportunities

The digital therapy industry is rapidly expanding and establishing itself as a key sector in the global healthcare market. A wide range of digital therapy solutions, including digital therapeutics (DTx), are being actively researched and developed by pharmaceutical companies, medical device manufacturers, IT firms, and startups, with continued growth in investment anticipated. As with any emerging field, successes and failures are expected to coexist. Currently, the global digital therapy market is thriving in diverse areas, such as mental health management, chronic disease prevention and treatment, lifestyle improvement, and neurological disorder therapies. Notably, the United States and Europe have already introduced several digital therapy solutions to the market, while Korean companies and research institutions are actively collaborating to develop related products.

From an industrial perspective, the sustained growth and widespread adoption of digital therapy require not only increased research and development (R&D) investment but also supportive policies and infrastructure to facilitate commercialization. A critical aspect of this is securing data that demonstrates the efficacy and economic value of digital therapy, as such evidence forms the foundation for integrating digital therapy into insurance reimbursement systems. This integration will not only improve patient access but also enable companies to establish sustainable business models, ensuring the ongoing expansion of the digital therapy industry.

5. Public Health Administration Approach: Integrating Digital Therapy into the Healthcare System

For digital therapy to be effectively integrated into real-world medical settings, a systematic approach from a public health administration perspective is essential. Establishing the necessary infrastructure is a prerequisite for hospitals and medical institutions to actively adopt and implement digital therapy solutions. Additionally, comprehensive education and clear guidelines must be provided to ensure healthcare professionals can effectively use digital therapy in clinical practice. To fully incorporate digital therapy into the existing healthcare system, it is crucial to enhance healthcare professionals' understanding of these solutions and empower them to offer appropriate treatment options to patients.

Moreover, standardizing digital therapy is crucial. While various digital therapy solutions are being developed across multiple platforms, the lack of standardized data and interoperability remains a significant challenge. To address this, collaboration among medical institutions, government bodies, and industry stakeholders is necessary to establish standardized frameworks that facilitate the seamless integration of digital therapy into healthcare systems, particularly electronic medical record (EMR) systems. At the same time, safeguarding patient medical data and ensuring privacy are of utmost importance. Since digital therapy inherently involves the real-time collection and analysis of patients' health data, implementing robust legal and technological safeguards is essential. To build patient trust, it is critical to establish strong security systems and clear regulatory guidelines governing data usage.

6. Design Approach: Enhancing User Experience (UX) and Accessibility

The success of digital therapy hinges significantly on user experience (UX) and accessibility. To ensure that diverse users—including patients, healthcare professionals, and caregivers—can easily navigate these solutions, intuitive user interface (UI) design and accessibility-focused strategies are crucial. A user-centered design approach is foundational to digital therapy's effectiveness. To maintain patient engagement over time, digital therapy must be designed for continuous use and offer personalized features. For example, in mental health management apps, integrating real-time emotional state analysis with tailored feedback can enhance the experience. Ultimately, delivering a seamless and refined user experience is a pivotal factor in determining the success or failure of digital therapy.

In addition, factors that contribute to the long-term sustainability of digital therapy must be carefully considered. Incorporating gamification elements or utilizing user behavior analysis to boost motivation can be powerful strategies. For instance, in chronic disease management apps, users could earn rewards for achieving their goals, or community features could be introduced to offer social support. However, due to the inherent limitations of gamification and reward systems in the medical field, it is crucial to explore innovative applications that can address these challenges and provide strong justifications for their integration.

Moreover, it is essential to improve accessibility for digitally vulnerable populations. Elderly individuals, people with disabilities, and others who face challenges in using digital technology are particularly vulnerable in the context of digital therapy, highlighting the need to address health inequalities. When designing digital therapy to be more inclusive, features such as voice recognition, text enlargement, and simplified navigation should be prioritized to ensure accessibility for these groups.

7. Patient (User)-Centered Approach: Enhancing the Acceptance of Digital Therapy

The ultimate goal of digital therapy is to enhance patient health, and achieving this requires a patient-centered approach. Digital therapy must clearly define its role and the extent to which it can contribute to improving patient health, while simultaneously addressing gaps or deficiencies in conventional medical care. To achieve this, it is crucial to actively engage with patients and listen to their feedback. Increasing patient acceptance of digital therapy is essential, particularly since it differs from conventional treatments by requiring active user participation. This makes an intuitive, user-friendly design all the more important, ensuring patients can use the therapy without feeling overwhelmed. To further enhance engagement, methods to improve patient adherence are necessary, such as AI-based personalized notifications, feedback systems, and motivation programs that encourage continuous use.

In addition, safeguarding data privacy and security is a critical consideration. Establishing clear guidelines on personal information protection and data security will help build trust, allowing patients to confidently incorporate digital therapy into their daily routines.

An Integrated Approach to Achieve Innovation in Digital Therapy

Digital therapy is emerging as a critical tool to overcome the limitations of modern healthcare and realize patient-centered precision medicine. As discussed in this article, the successful innovation of digital therapy requires an integrated approach that includes medical, technological, policy, industrial, healthcare

administration, and design perspectives.
Digital therapy, based on clinical evidence, should complement and enhance, rather than replace, existing treatments. Precision interventions utilizing AI and IoT technologies enable personalized healthcare, and regulatory innovations must create a system that ensures safety and efficacy while accommodating rapid technological advancements.
For the sustainable growth of the digital therapy ecosystem in Korea, collaboration among diverse stakeholders is crucial. Healthcare professionals must enhance their understanding of digital therapy and actively work to integrate it into clinical practice. The industry should prioritize the development of reliable products, emphasizing user-centered design and evidence-based approaches. Meanwhile, the government and regulatory bodies must create a balanced regulatory framework that fosters innovation while maintaining safety and efficacy. Above all, the active participation and feedback of patients will be essential in driving the continued advancement of digital therapy.
Digital therapy, which evolves from clinical evidence into practical therapeutic tools, is poised to play a pivotal role in the future of healthcare. By integrating innovative approaches that combine technology, medicine, and design, digital therapy is expected to become an integral part of clinical practice, ultimately enhancing patients' quality of life and improving healthcare system efficiency. For successful implementation in medical settings, active participation and trust-building among healthcare professionals are essential. Achieving this requires a thorough review of how previous technologies and treatments have been introduced and established in medicine, drawing insights from past trials and errors. Above all, it is crucial to secure robust clinical evidence through high-quality research, while also presenting results that highlight the practical benefits of digital therapy, including economic advantages, to more effectively persuade healthcare professionals.
Additionally, educational programs and guidelines for healthcare professionals on validated digital therapies are necessary. To ensure digital therapy is integrated into clinical practice, healthcare professionals must be supported in understanding and using these tools appropriately. For digital therapies with proven effectiveness, proactive promotion by developers is key to encouraging adoption. Furthermore, tools that foster interaction between healthcare professionals and patients are vital for ensuring digital therapy becomes a standard part of clinical practice. Digital therapy should be designed to complement healthcare professionals' workflows and be seamlessly integrated into treatment and consultation processes.
Digital therapy represents more than just technological innovation—it is fundamentally transforming the healthcare paradigm. For digital therapy to become a core component of the healthcare system, it must integrate clinical evidence, technological advancements, regulatory innovation, industrial growth, and a patient-healthcare professional-centered design in a cohesive manner. Collaboration among the medical field, industry, and policymakers is essential to fully realize the potential of digital therapy and ensure its continued advancement.

SESSION 13

Beyond Innovation: The Path to Successful Clinical Adoption and Market Expansion of Digital Therapy

Key Requirements and Strategies for Clinical Utility and Market Success of Digital Therapy

May 9 (Fri), 13:00~16:00 / Rm. 307

More detail ▲

Despite its potential to transform healthcare, digital therapies have yet to achieve widespread clinical adoption and market success. This session explores the key factors that move digital therapy beyond innovation into practical implementation. Discussions will cover strategies to ensure clinical efficacy and usability, challenges in integrating digital therapy into healthcare systems, ways to enhance acceptance among patients and providers, and sustainable business models for market viability. By bringing together experts from various fields, this session aims to provide actionable insights and strategic directions for the future of digital therapeutics in both clinical and commercial settings.

Featured Speakers

01 Speaker

Jonas Albert, Partner
fBeta GmbH

* Jonas Albert is a Managing Consultant at fbeta and is responsible for projects related to reimbursement and business models for digital health innovations. In this role, he has already supported 24 of the currently 54 listed DiGA.

Sean G. Kang, CEO
WELT corp.

02 Speaker

* The digital biomarker and digital therapeutics company has announced that its product, "WELT-I," has been officially designated as Korea's second approved digital therapeutic

Innovation and Challenges in Next-Generation Toxicity Assessment Driven by AI and Organoids

By | **Hyang-Ae Lee_Principal Researcher, Korea Institute of Toxicology**
Associate Professor, University of Science & Technology

Date & Time : May 9(Fri) 2025, 09:30~15:35

Venue : COEX Rm. 308

Coordinating : Korea Institute of Toxicology

*The content of this article represents the author's opinion and may differ from the official views of the BIO KOREA Organizing Committee.

As drug development grows more complex and ethical and legal regulations on animal testing are tightened, the need for more precise and reliable toxicity assessment technologies is growing. Traditional animal testing faces limitations due to high costs, long research timelines, and physiological differences from humans, which restrict predictive accuracy. As a result, in vitro-based toxicity assessment platforms and AI-driven toxicity prediction models are emerging as next-generation solutions across various fields, including drug development, medical device evaluation, and regenerative medicine.

In response to these changes, global regulatory agencies are actively advancing legislation and standardization efforts. In line with this, the European Union (EU), the U.S. Food and Drug Administration (FDA), and South Korea's Ministry of Food and Drug Safety (MFDS) are expanding the adoption of non-animal testing methods. Notably, the FDA introduced the FDA Modernization Act 2.0 in 2022, eliminating the mandatory requirement for animal testing in the drug approval process and officially recognizing alternative testing methods. The EU has also been expanding the use of non-animal testing approaches beyond its existing ban on cosmetic animal testing to include drug development processes. However, industry adoption of these methods has been slower than anticipated, with critical challenges remaining, including regulatory uncertainty, a lack of standardized data, and compatibility issues with existing evaluation systems, which remain key challenges to be addressed.

Industry and Technological Trends in Alternative Toxicity Assessment

Alternative toxicity assessment technologies are advancing with a focus on in vitro-based evaluation systems and AI-driven toxicity prediction models, aiming to overcome the limitations of traditional animal testing and improve predictive reliability. These technologies are being adopted across various industries, including drug development, chemical safety assessment, and medical device research, contributing to reduced research time and costs while enhancing assessment accuracy. In particular, the integration of in vitro evaluation techniques that closely mimic human tissues, combined with AI-powered predictive models, is enabling more reliable toxicity assessments, surpassing the accuracy of conventional animal testing.

In vitro-based evaluation systems are technologies that enhance the precision of toxicity assessments by creating environments similar to human tissues in laboratory settings. Representative examples include organoid-based models, Organ-on-a-Chip technology, and 3D bioprinting technology. Organoid-based models utilize induced pluripotent stem cells (iPSCs) to culture three-dimensional tissues that resemble specific organs, allowing for toxicity assessments in a more physiologically relevant environment compared to traditional monolayer cell cultures. In particular, various organoid models for the heart, liver, kidneys, and lungs have been developed, and drug toxicity analyses using these models are actively being conducted. Organ-on-a-Chip technology replicates human tissue environments using microfluidic systems, enabling more precise toxicity assessments that take into account interactions between organs. This technology contributes to more accurate predictions of pharmacokinetics and organ-specific toxicity of drug candidates, with active research underway in the development of Multi-Organ-on-a-Chip systems. 3D bioprinting technology constructs multilayered cellular structures using living cells, creating environments that more closely resemble human tissues than traditional 2D cell cultures. This allows for more precise assessments of tissue responses to drug administration and is applicable not only to tissue-specific toxicity evaluations but also to the development of personalized therapeutic approaches.

Alongside this, AI-based toxicity prediction models enhance the accuracy of preclinical toxicity assessments by leveraging large-scale toxicity databases, enabling automated evaluation of drug candidates. Machine learning (ML) and deep learning-based toxicity prediction models analyze vast chemical compound datasets to develop systems capable of autonomously predicting the toxicity of new drug candidates. This approach enables faster and more accurate toxicity predictions than traditional experimental methods, with extensive research focusing on structure-based toxicity prediction at the molecular level. The AI-organoid fusion model integrates extensive in vitro experimental data with AI analysis to improve the accuracy of toxicity predictions and enable more precise assessments. By combining experimental data with existing toxicity databases, this model aids in selecting optimal drug candidates during the drug development process.

Recent studies have led to the development of predictive platforms that combine AI with in vitro models, enabling more precise toxicity assessments of drug candidates and reducing clinical trial failure rates. Efforts are also being made to standardize in vitro experimental data and collaborate with regulatory agencies to enhance the accuracy of AI-driven toxicity predictions. These technological advances not only accelerate and improve the accuracy of toxicity assessments but also reduce costs and enhance reliability compared to traditional animal models. In particular, the integration of AI-based toxicity prediction models with in vitro evaluation systems is transforming the paradigm of drug development and toxicity assessment, with data-driven evaluation methods increasingly becoming standardized. Moving forward, the development of multi-data integration platforms that incorporate in vitro evaluation models and AI-based toxicity analysis technologies is expected to enable even more precise predictions.

Global Market Trends and the Role of Key Companies

The alternative toxicity testing market is rapidly expanding, driven by cost reductions in drug development, stricter regulations, and enhanced reliability through technological advancements. It is expected to record high annual growth rates in the future. In particular, the integration of in vitro evaluation models and AI-based toxicity prediction systems is enabling more precise and faster toxicity analysis compared to traditional methods. Leading global companies are accelerating the commercialization of alternative toxicity testing technologies and enhancing collaborations with pharmaceutical companies and research institutions to validate reliability. Notably, Emulate Inc. from the United States is leading the development of Organ-on-a-Chip technology and providing advanced in vitro evaluation platforms for drug development and personalized treatment solutions. The Netherlands-based MIMETAS is building an in vitro toxicity testing system using 3D organoid models and developing technologies to create physiologically relevant evaluation environments in the drug development process. Additionally, Insilico Medicine from the United States uses AI-based toxicity prediction models to assess the safety of drug candidates in advance, helping to reduce risks in the drug development process and increase development efficiency. These companies are enhancing the reliability of toxicity evaluations by merging in vitro testing technologies with AI toxicity prediction models, and this technological advancement is expected to become a core element in future drug development and chemical safety assessments.

However, a recent survey by the Pistoia Alliance found that despite the FDA's approval of animal testing alternative models (NAMs), industry adoption remains slow due to regulatory uncertainty. This survey was conducted by a global non-profit organization founded by leaders from AstraZeneca, GSK (GlaxoSmithKline), Novartis, Pfizer, and others, and it involved 350 life sciences professionals. The survey revealed that 77% of respondents still do not incorporate in vitro-based models, such as cell cultures and organoids, in their R&D processes, and 60% cited regulatory uncertainty as the primary barrier to adopting the alternative models.

This reality suggests that the introduction of non-animal testing methods requires a comprehensive approach, not only from a technological standpoint but also in terms of regulatory approval and data standardization. In order for non-animal testing methods to establish themselves as a primary evaluation tool across the biohealth industry in the future, it is essential to enhance scientific validity, standardize data, and strengthen collaboration among global regulatory agencies.

BIO KOREA 2025: Strategy Session for Entering Global Alternative Toxicity Assessment Market

In line with these technological advancements and market changes, the "Session 14: Development and Commercial Success of Alternative Toxicity Assessment Solutions for Entering the Global Biohealth Market" at BIO KOREA 2025 will discuss the global market applicability and commercialization strategies of alternative toxicity assessment technologies. This session will highlight the applications of in vitro organoid platforms and AI-driven predictive toxicity models in various fields such as drug development, medical device evaluation, and regenerative medicine, while also examining strategies for market expansion based on these applications.

In particular, the session will analyze key commercialization processes and success factors through major success stories, and present practical strategies and implementation plans for researchers and companies to effectively target the global market. Through this session, participants will gain insights into strengthening the global competitiveness of next-generation toxicity assessment technologies that leverage AI and in vitro models, while acquiring strategic insights to maximize their global market entry potential.

SESSION
14

Alternative Toxicity Testing: Our Choice and Challenges for Leading the Future Bio Market

Our task for commercializing a new paradigm for bio-research and development systems such as new drugs and alternative animal testing methods

May 9 (Fri), 09:30~15:35 / Rm. 308

More detail ▲

This session will focus on the development and successful commercialization of alternative toxicity assessment solutions for global biohealth market entry, sharing innovative cases of global market expansion. With increasing ethical and legal restrictions on animal testing, rising drug development costs, and limitations in predictive accuracy due to physiological differences between animals and humans, the demand for alternative toxicity assessment technologies is growing. As a result, in vitro organoid-based platforms that mimic human organs and AI-driven predictive toxicity models are emerging as next-generation assessment technologies.

This session will explore the commercialization process and success factors of AI-based toxicity prediction models and advanced toxicity assessment platforms across various fields, including drug development, medical device evaluation, and regenerative medicine, while also examining the potential for global business expansion. Furthermore, practical strategies and approaches for researchers and companies to effectively penetrate the global market will be presented, enhancing the competitiveness of AI and in vitro model-based next-generation toxicity assessment technologies.

Featured Speakers

01 Speaker

Nicholas Geisse, CEO
Curi Bio

* Curi Bio is collaborating with the U.S. National Institutes of Health (NIH) and the National Aeronautics and Space Administration (NASA) on a joint project involving artificial heart-on-a-chip technology. The project involves sending human induced pluripotent stem cell (iPSC)-based cardiac tissue chips into space to study the effects of microgravity on human physiology.

Hanna Oh, Director
Global BD Division, ORGANOIDSCIENCES Ltd.

02 Speaker

* OrganoidScience has been designated by the Ministry of Trade, Industry and Energy of Korea as a company possessing National Strategic Advanced Technology. It is the first company in Korea preparing for an IPO under the special listing program for breakthrough technologies.

2025 BIO KOREA International Convention

Open Session

	Rm.300	Rm.327	Rm.E1	Rm.E2~E3	Rm.E4	Rm.E5	Rm.E6
Day 1 May 7 (Wed)	OS1. Golden Triangle Life Science Open Innovation: Korea-UK-Japan Trilateral Collaboration 13:00~17:30	OS2. Workshop on Strategic Collaboration between Korea and Saudi Arabia: Propelling the Growth of Global Biohubs 13:00~17:00	OS3. Healthy Aging: Advancing Science for Longevity 13:00~17:00	OS4. K-BIC Venture Café 12:00~13:00	OS5. 2025 Spring Bio-health Policy and Research Forum 14:00~15:30	OS6. Advancing Biopharmaceutical Research, Manufacturing, and Workforce Development 15:00~17:10	
Day 2 May 8 (Thu)	OS9. Canada's Thriving Life Sciences: Innovation and Collaboration from British Columbia to Beyond 13:30~14:20 OS10. Global ATMP Forum 14:30~16:25	OS11. 2025 Joint Session on Regenerative Medicine Institution Designation and Regenerative Medical Treatment System 14:00~16:25	OS12. Current Status and Strategy of the BioBigData.Korea 14:00~16:50			OS13. Global Pharma Supply Chian from Industry Perspective 13:40~17:00	OS14. 2025 BioHealth Commercialization Promising Technology Briefing Session 14:00~16:05
Day 3 May 9 (Fri)	OS15. AI Research Cases Utilizing Healthcare Data from the National Institute of Health 09:30~11:30						

Company Presentation

Time	May 7 (Wed) Rm.317	May 8 (Thu) Rm.317	May 9 (Fri) Rm.317
10:00~11:00		AMGEN	MSD
11:00~11:10			Break
10:10~12:10			Sysmex
12:10~13:30	Lunch Break		
13:30~14:30	Johnson & Johnson (14:00~17:00)	ST PHARM	
14:30~14:40		Break	
14:40~15:40		ACROBiosystems	
15:40~15:50			
15:50~16:50			

※ This program is subject to change depending on internal circumstances.

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- Cardiotoxicity Screening by Microelectrode Array

Booth No. J19

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