



KRIBB *focus*

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Advanced Bio & Public Research

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Leap Toward a Sustainable Bioeconomy
The Advanced Bio Initiative

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KRIBB Research and Technology:
Driving the National Bio Strategy

KRIBB PEOPLE

The Global TOP Research Initiative at
KRIBB Aims to Build a New R&BD Platform
for Next-Gen Therapeutics

The Korea Research Institute of Bioscience and Biotechnology (KRIBB) is Korea's leading national research institute specializing in biotechnology.

KRIBB serves as a national hub for bioscience by conducting world-class fundamental research and providing public bio-infrastructure.

01

MISSION, FUNCTION & VISION

MISSION

To conduct bioscience R&D in collaboration with domestic and international partners, and to share research outcomes widely

FUNCTION

Develop and share core technologies in bioengineering and the bioeconomy

► Drive bio convergence, foster future growth, address key bio challenges

Support domestic and global bio R&D infrastructure

► Build infrastructure, advise policy, train talent, and aid bio SMEs

VISION

A Global Leader for Healthy Life and Bioeconomy

W

World-class R&D

Global impact, structured R&D support



A

Accelerating Open Innovation

Open bio R&D hub



V

Vitalizing Bio-industry

Driving innovation in the bioindustry



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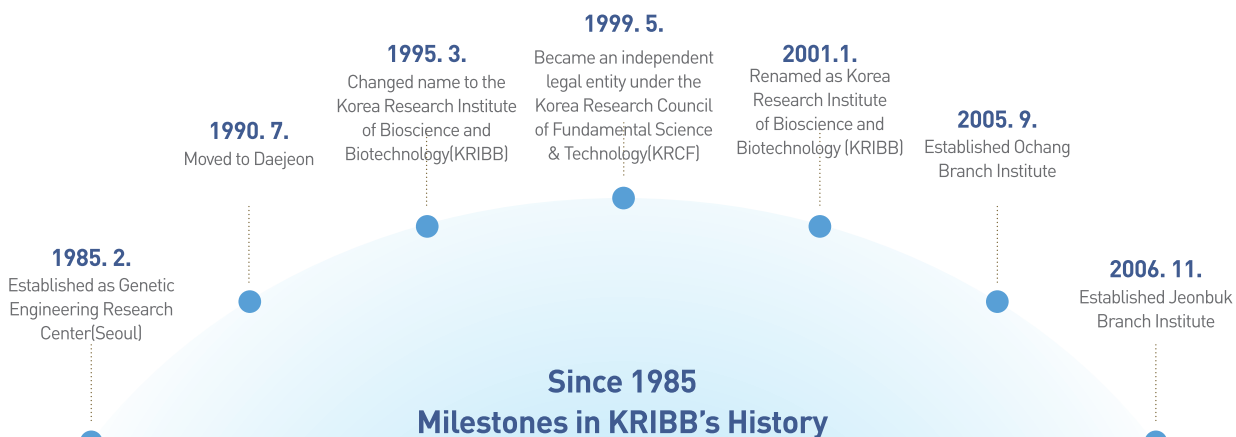
Enhancing Sustainability

Value-driven management



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Advanced Bio & Public Research

Leap Toward a Sustainable Bioeconomy The Advanced Bio Initiative



A new national vision to establish South Korea as a global biotechnology leader by 2035 was unveiled this April. Dubbed the “Advanced Bio Initiative Vision,” the strategy outlines the government’s ambitious plan to position biotechnology as a core driver of national growth—envisioning a “second semiconductor miracle.” This target year aligns with South Korea’s long-term policy cycle, typically structured in five- or ten-year strategic increments, and underscores the urgency to foster a next-generation growth engine as existing export pillars such as semiconductors and shipbuilding approach maturity.

Often cited as the backbone of Korea’s rapid economic ascent, the semiconductor industry transformed the

country into a global tech powerhouse beginning in the late 20th century. The “second semiconductor miracle” analogy thus signals the aspiration to replicate this transformative success—this time through biotechnology. In this context, “advanced bio” refers to the convergence of biological science with frontier technologies such as artificial intelligence, nanotechnology, and robotics. This fusion is not merely an upgrade of conventional biotechnology, but a redefinition of its scope and potential. By embedding computational and physical systems into life science, advanced bio aims to surpass previous limitations and create entirely new industrial categories.

While traditional biotechnology focused primarily on

© Samsung Biologics



Biological systems were once considered too complex and unpredictable to standardize. But advances in biotechnology are changing that—enabling precise control over life processes and opening the door to scalable bio-industrial applications. Pictured: Samsung Biologics’ Songdo campus.

biological processes themselves, the term “advanced bio” signals a shift toward a more integrated approach. By embedding digital, physical, and biological layers, this framework allows for more programmable, scalable, and predictive applications of biology—making it not just a life science, but a new form of engineering.

Biology as the Engineering of a New Era

The distinction between science and engineering has long been recognized: science seeks to explain natural phenomena, while engineering applies knowledge to solve real-world problems. For life sciences, this division was especially pronounced. Biological phenomena are complex and difficult to reduce to simple algorithms, making it hard to predict outcomes and apply findings in practical settings. Even as humanity has studied life for millennia, biology remained the last of the sciences to be industrialized, precisely because of these challenges.

Until recently, biology lacked the predictive precision required for engineering. But this began to change with the convergence of advanced analytical tools, gene-

editing technologies, and information and communication technologies (ICT). Computational methods now enable large-scale biological data analysis and modeling, bringing new levels of predictability to life science research.

This bioengineering revolution is reshaping traditional industries. Medicine and food production have seen dramatic gains in time and cost efficiency. Even chemical manufacturing and materials science are increasingly incorporating biological methods. Unlike chemistry and physics, biology works in ways already familiar to ecosystems. This gives bioengineering an edge in building sustainable industries that align with ecological and climate goals. Recognizing this, many nations have moved to position bioscience as a strategic sector, not only for economic reasons but also for long-term resilience.

A Paradigm Shift Toward Advanced Bio

Biotechnology is still a work in progress, evolving rapidly under varied definitions and expectations. Korea’s April announcement reflects this dynamic shift, framing the future of biotech under the unified concept of “advanced

bio.” This vision is both a response to intensifying global tech rivalries and a commitment to enhancing quality of life through science. Advanced bio technologies offer the potential to transform current industries while shaping the competitive landscape of the future. As a high-risk, high-return domain, it represents the front line of innovation and geopolitical competition.

Today, the global bioeconomy—encompassing biopharmaceuticals, agriculture, and bio-based materials—is projected to exceed USD 10 trillion by 2030, outpacing the total market value of the semiconductor sector. Korea’s strategy emphasizes securing a leading position in this space through rapid technology development, ecosystem expansion, and regulatory modernization.

Recent breakthroughs are reinforcing this urgency. AI and big data are accelerating drug development timelines, making gene and cell therapies increasingly viable. Meanwhile, advanced bio technologies are expanding into diverse fields. In healthcare, personalized precision medicine, regenerative therapies, and anti-aging research are progressing rapidly. In agriculture, synthetic biology is transforming food production systems. In energy and the environment, research into biofuels, biodegradable materials, and environmental remediation is gaining momentum. Bio-based materials are also entering

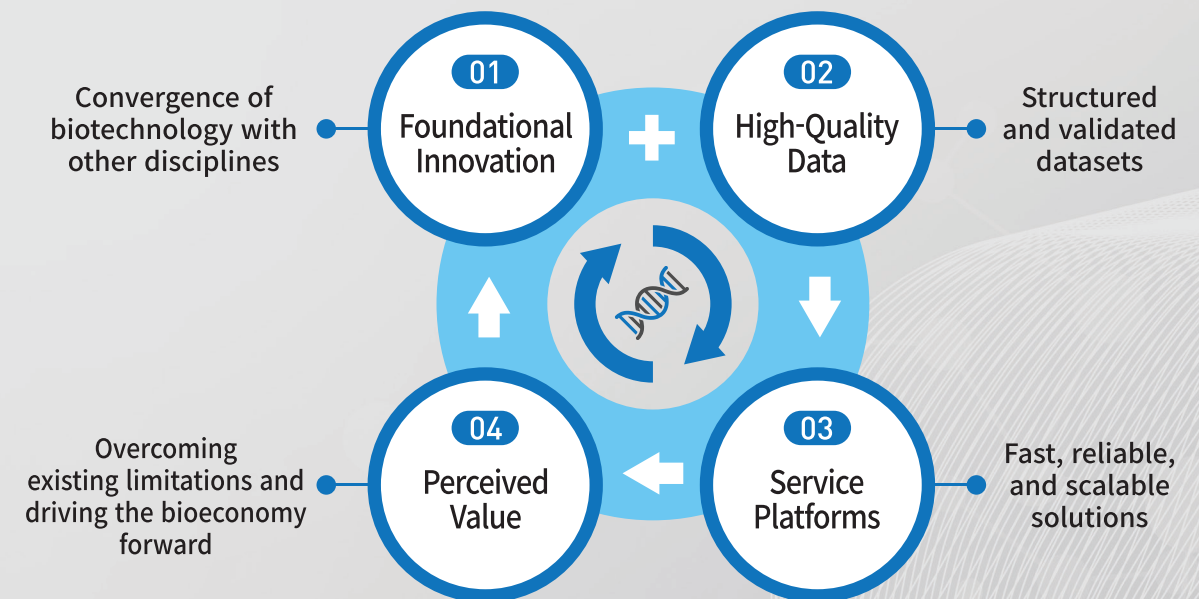
mainstream manufacturing and replacing petrochemical inputs in key sectors.

This evolution goes far beyond simple technological advancement. Advanced bio is transforming fundamental aspects of human life, including disease prevention, food security, and environmental sustainability. It also plays an increasingly vital role in ensuring technological sovereignty and national biosecurity. Recognizing its significance, both the public and private sectors in Korea are investing heavily in nurturing key talent, building world-class research infrastructure, forming international networks, and reforming relevant laws and systems to create a fertile ground for growth.

Value Chains as the Backbone of the Initiative

The Advanced Bio Initiative outlines three overarching drivers of transformation: digitization, platformization, and strategic technology. These shifts are expected to reshape not only the economy, but also societal structures and national security frameworks. Biotechnology is no longer viewed as a single-sector endeavor, but as a cross-cutting enabler of digital industries, defense strategy, and public welfare.

Central to the initiative is the concept of the bio value chain. By integrating innovation-based technologies with high-quality data, the government seeks to create next-



The bioindustry forms a dynamic value chain—where technology flows into data, data powers platforms, and platforms give rise to new services, completing a cycle of continuous innovation.

generation service platforms that generate real-world value. Like assembling a giant puzzle, the initiative envisions connecting diverse elements to form a unified picture.

These elements include everything from core platform technologies—like gene-editing tools and biofoundries—to datasets, regulatory pathways, clinical testing capacity, and industrial production systems. Their integration is essential for translating scientific discovery into scalable, real-world outcomes.

More than a growth strategy, the initiative represents a national blueprint to secure bio-sovereignty and maintain a technological edge that is difficult to replicate. As global markets enter a phase of “bio transition,” Korea’s strategy aims to ensure both technological leadership and public health resilience. At the heart of this strategy is the Korea Research Institute of Bioscience and Biotechnology (KRIBB).

KRIBB’s Role in Powering the Future of Advanced Bio

KRIBB plays a pivotal role in developing core technologies, operating national infrastructure, and shaping the broader bio-ecosystem. As one of Korea’s 25 government-funded

research institutes (GRIs), KRIBB operates independently of universities and private corporations, yet it is directly aligned with national R&D priorities. This allows KRIBB to coordinate stakeholders across sectors while remaining focused on public interest goals.

The institute is not only advancing gene and vaccine development, but also leading the digital transformation of drug discovery and artificial protein engineering. These efforts reflect its dual focus on strengthening existing capacities and pioneering high-potential, exploratory research areas. This includes AI-driven drug development, synthetic biology, and early-phase innovation that may be too risky for private investment.

Recently designated as a host for Korea’s “Global Top Strategic Research Group” initiative, KRIBB is sharpening its focus on next-generation gene therapies. It is also exploring high-potential areas such as anti-aging technologies, regenerative medicine, and digital bio convergence.

To support its mission, KRIBB operates major national platforms, including the National Primate Research

The Pfizer-BioNTech COVID-19 vaccine. The pandemic offered a vivid demonstration of how powerful biotechnology can be when innovation meets urgency.



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Center, the Korea BioInformation Center (KOBIC), and the K-Biofoundry. These resources are vital for improving the competitiveness and sustainability of Korea's biotech sector. The institute's integrated data systems are helping raise the overall quality of domestic life science research.

In parallel, KRIBB has made ecosystem development a strategic priority. Its activities range from facilitating academia-industry-government cooperation and promoting the co-production and use of bio-data, to serving as a policy think tank and helping establish ethical standards in biotechnology. KRIBB's centrality in orchestrating these efforts underscores its unique value as a public research institute.

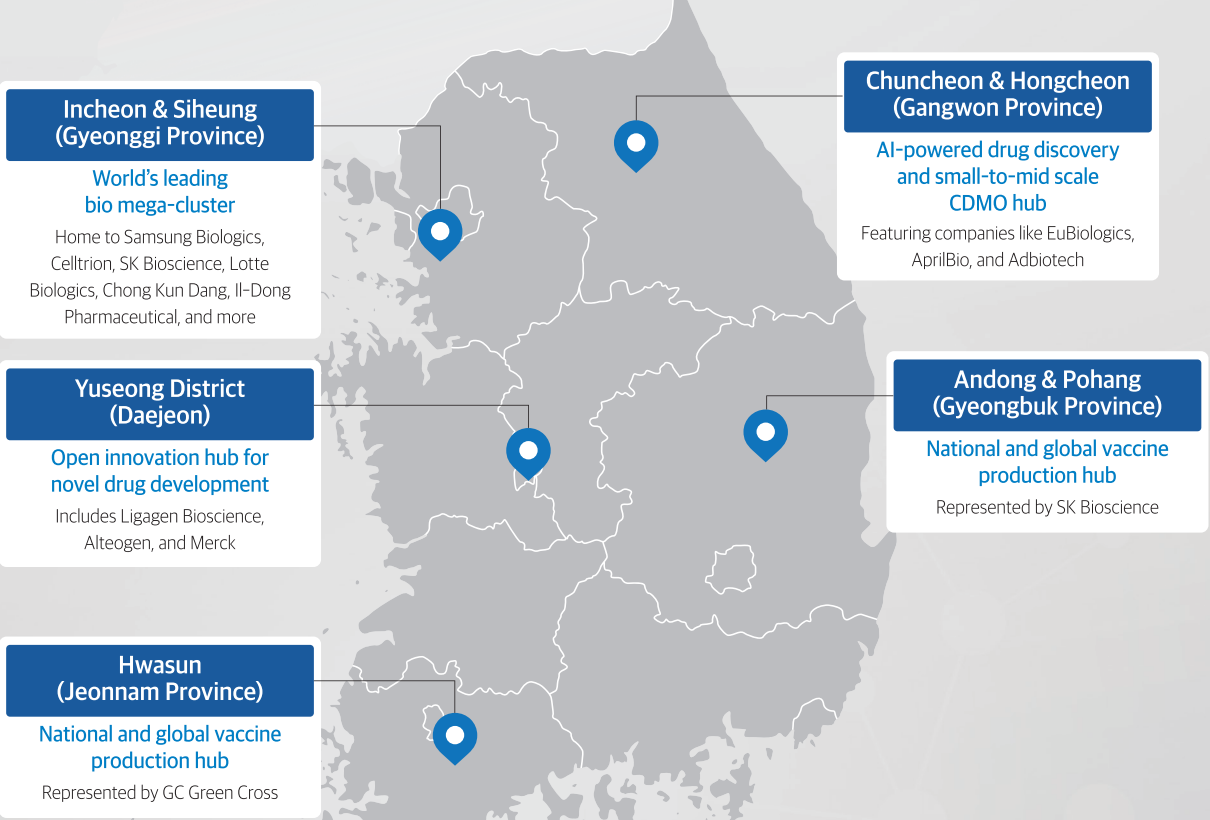
As a government-funded institute, KRIBB occupies a neutral, coordinating position that allows it to align stakeholders across sectors without commercial bias. This

role is particularly critical in areas like early-stage research, ethical standard-setting, and the development of national infrastructure—tasks that require long-term vision and cross-sectoral trust.

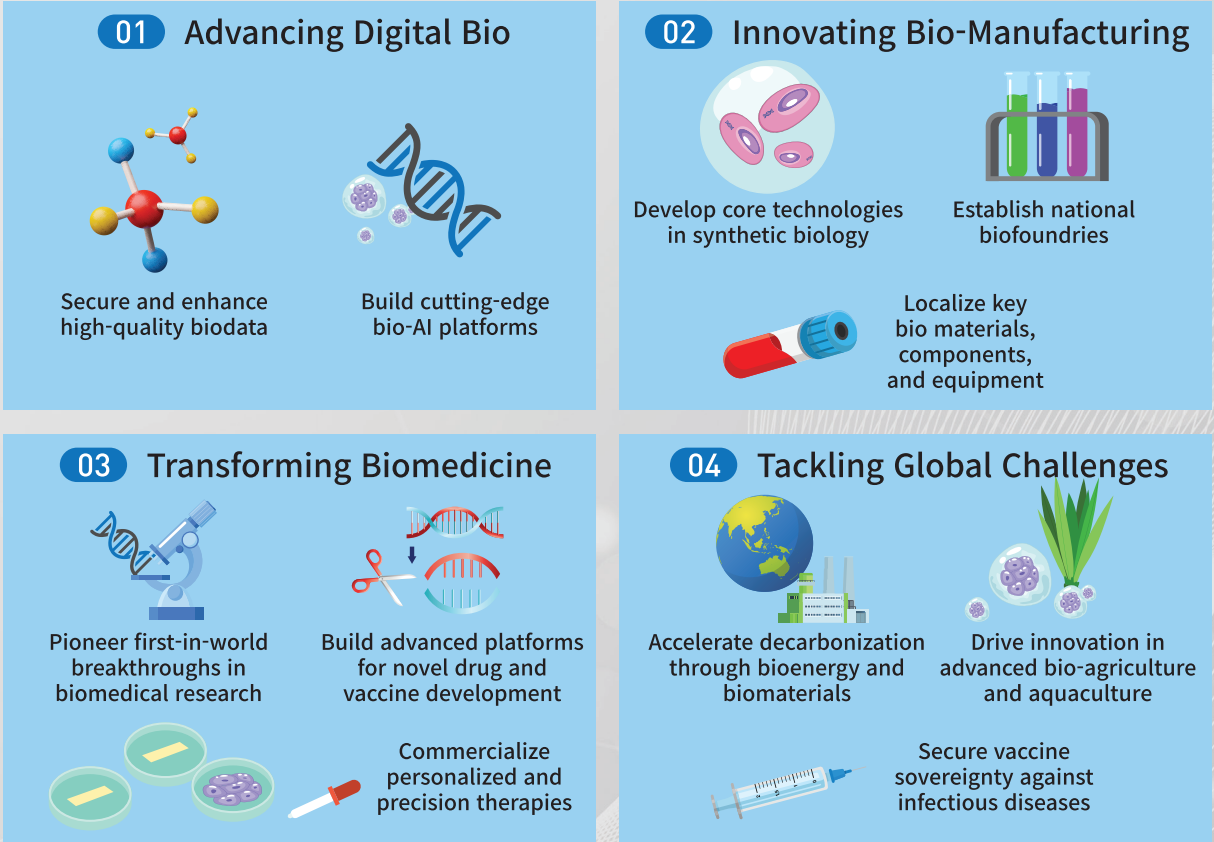
Reimagining the Future of Public Research

Since its founding in 1985, KRIBB has led Korea's biotechnology innovation, establishing itself as an irreplaceable national research institution. Three factors distinguish KRIBB's unique position. First, its cutting-edge infrastructure offers resources that private industry cannot easily replicate, supporting national R&D capacity. Second, KRIBB conducts end-to-end research spanning basic biology to commercialization, helping catalyze the entire industry. Third, it addresses ethical and regulatory issues, advocating responsible development of technologies like

Major Bio Clusters and Strategic Hubs Across Korea
The government plans to build a nationwide bioindustry ecosystem, anchored in five key regional hubs.



Technology Innovation Agenda
to Strengthen the Bio Value Chain



Key Innovation Challenges in Biotechnology. Across 11 priority areas in four major sectors, public-sector research plays a central and driving role.

synthetic biology.

KRIBB also works to ensure that regulation does not stifle innovation. For example, it has collaborated with the Ministry of Food and Drug Safety to standardize the use of organoids as an alternative to animal testing, contributing to OECD guideline development.

KRIBB's role in regulatory science includes not only risk assessment but also the proactive development of flexible, science-based regulatory frameworks. In this spirit, KRIBB often proposes alternative review approaches that can help facilitate the approval of novel technologies while maintaining public safety.

The institute also contributes to Korea's broader

policy efforts to harmonize innovation and regulation. For instance, KRIBB's ethical research frameworks and participation in regulatory sandboxes help shape national standards for high-risk technologies. These roles are critical in helping Korea move from being a fast follower to a first mover in bioscience innovation.

KRIBB's research strategy unit envisions a future where the institute leads the global bioscience frontier, integrating foundational technology development with ethical and sustainable practices. Through comprehensive approaches to research, infrastructure, and governance, KRIBB is laying the groundwork for a more sustainable and globally competitive bioeconomy.

KRIBB Research and Technology: Driving the National Bio Strategy



The passage of the Advanced Bio Initiative and its accompanying legislation marks a turning point in Korea's push to position biotechnology at the center of national strategy. Yet biotechnology, by nature, carries high technical risk and long timelines. Its path to commercialization is neither linear nor easily predictable. This raises a key question: who assumes responsibility for the high-risk segments that private companies are reluctant to take on?

Bridging the gap between basic research and industrial

deployment—spanning data generation, circuit design, production, and regulatory alignment—requires an institutional actor with both technical depth and strategic mandate. That actor is the Korea Research Institute of Bioscience and Biotechnology (KRIBB).

KRIBB is more than an executing agency; it plays a proactive role in designing and operating the very structures that the national strategy envisions. It anchors this effort across three core domains: bioinformatics, synthetic biology, and biopharmaceuticals. Each area



The National Center for Biological Research Resources and Information, located within the KRIBB campus, serves as a key hub for bioinformatics research and talent development.

contributes not only standalone outputs but also integrated functions within the broader advanced bio ecosystem.

Bioinformatics defines the problems through data; synthetic biology engineers solutions at the genetic level; and biopharmaceuticals translate these innovations into real-world therapies. In practice, insights generated through big data analysis inform the design of synthetic biological components, which in turn serve as the foundation for therapeutic development and clinical applications.

This seamless interaction creates a virtuous cycle where each domain enhances the effectiveness and efficiency of the others, exemplifying a truly end-to-end innovation system. Together, they form a contiguous pipeline from analysis to application—a living embodiment of Korea's advanced bio strategy.

Bioinformatics: A Gateway to the Technology Ecosystem

Although the digital transition arrived late in life sciences, it is now reshaping the field. With explosive growth in omics data—genomics, proteomics, metabolomics—biology has become a data-intensive science. From identifying disease mechanisms to predicting health outcomes, data analytics

now drives discovery. Biotechnology no longer begins at the lab bench. It begins with data.

KRIBB recognized this shift as more than a technological trend—it saw a strategic inflection point. Through the Korea BioInformation Center (KOBIC), it has built a national system for aggregating, refining, and analyzing life science data. As the lead agency for Korea's National Bio Big Data initiative, KOBIC manages a precision platform drawing on genomic and clinical data from over one million individuals.

This capability not only supports domestic precision medicine but also positions KRIBB as a contributor to global bio-data initiatives, including international collaborations on data standards, interoperability, and ethical governance frameworks.

According to KOBIC Director Hayeong Jung, "Integrated analysis of genomic, proteomic, and metabolomic data has enabled accurate predictions in diagnostics and drug response. Patient simulation technologies like digital twins are also becoming feasible through the synergy of bioinformatics and AI."

KRIBB has gone beyond data storage to actively increase data utility. In 2024, it launched a dedicated human-derived biobank integrated with enhanced ethical and

security protocols. By aligning with international standards, KOBIC has improved research reliability and reinforced Korea's presence in global data governance.

The center's bioinformatics capability extends into experimental validation as well. Amid growing international demand for non-animal testing, KRIBB is developing an organoid-based toxicity testing platform that simulates liver physiology. Compared to 2D models, the 3D liver organoid offers greater predictive precision.

In collaboration with the Ministry of Food and Drug Safety, KRIBB is driving ISO certification and OECD guideline adoption for the platform—demonstrating its role not only as a technology developer but also as a regulatory thought leader within the global NAM (New Approach Methods) paradigm.

On the international front, KRIBB is also pioneering systems for the ethical use of Digital Sequence Information (DSI)—a key issue in ongoing biodiversity and bioresource negotiations. “Open science,” Jung notes, “must be equitable, not indiscriminate. Clear attribution, depositor rights, and commercial usage terms must accompany

shared digital sequence data.”

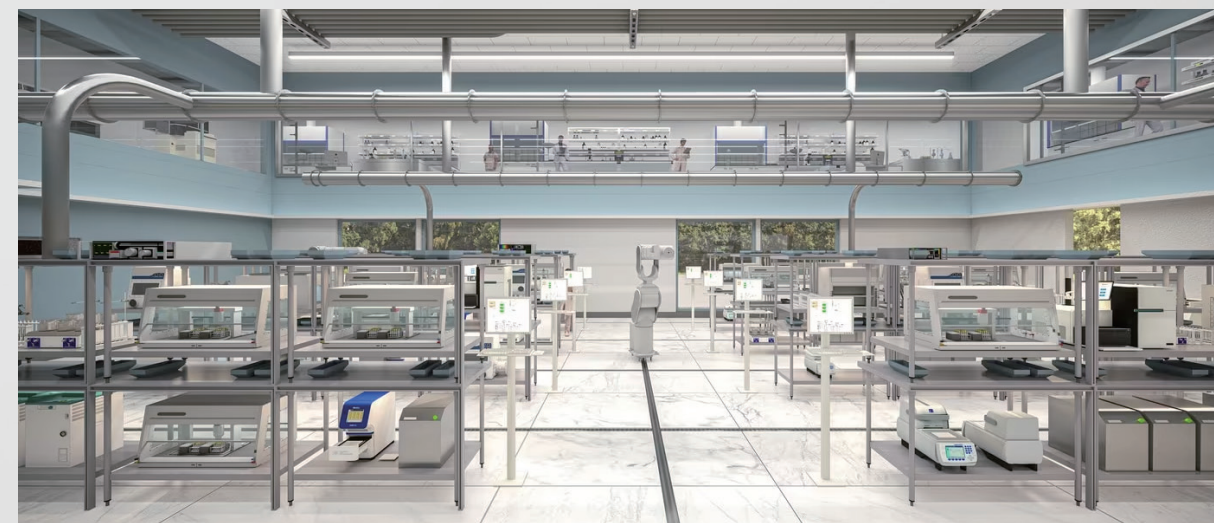
In line with this philosophy, KRIBB became the first institution in Korea to formalize DSI attribution protocols and continues to adapt its platforms to reflect Convention on Biological Diversity (CBD) negotiations. This function—as both technical innovator and policy intermediary—reflects KRIBB's broader role in balancing scientific openness with national information sovereignty.

Ultimately, bioinformatics has become the foundational layer for advanced bioengineering. It drives both the upstream analysis in precision medicine and the downstream design of synthetic biology. The capability KRIBB has built in this domain ensures that Korea's bio R&D pipeline begins on a data-secure, ethically grounded, and globally connected foundation.

From Design to Production: Advancing Synthetic Biology

If bioinformatics provides the blueprint, synthetic biology brings it to life. This field reimagines biological systems as programmable entities—capable of replacing

Control room of the National Center for Biological Research Resources and Information. Comprehensive and structured data forms the starting point of today's bioindustry.



Overview of the pilot biofoundry facility at KRIBB's Synthetic Biology Research Center. This site serves as a foundational research platform for establishing a national public biofoundry.

petrochemical-based manufacturing across sectors. Synthetic biology has rapidly gained strategic value not only for its industrial promise, but also for its alignment with carbon-neutral goals and national security frameworks.

KRIBB has emerged as Korea's leading center of excellence in this field. Its core asset is the biofoundry: an automated, high-throughput platform that handles DNA design, circuit assembly, expression, and production. Developed in partnership with KAIST and modeled with input from Lawrence Berkeley National Laboratory (LBNL)—a global pioneer in synthetic biology infrastructure—the biofoundry reflects international best practices tailored to Korea's innovation context.

Unlike traditional lab-based approaches, KRIBB's biofoundry incorporates AI-driven circuit optimization and robotic automation, enabling high-throughput prototyping with enhanced reproducibility. Its modular architecture and support for domestic SMEs further distinguish it from large-scale industrial foundries abroad, emphasizing accessibility and flexibility for early-phase experimentation.

This platform does more than accelerate experiments. It offers industrial-grade access to bio-manufacturing

capabilities. Small and mid-sized enterprises (SMEs) can prototype engineered biomaterials and scale early production without investing in proprietary facilities. KRIBB's integrated design-production-validation system significantly reduces barriers to entry and enhances commercialization efficiency for the domestic bioeconomy.

In recognition of this capacity, the Korean government designated synthetic biology a National Strategic Technology in 2022 and launched the Synthetic Biology Development Council. KRIBB serves as the research community's co-chair on this council, helping align technical platforms with regulatory and policy frameworks. It is also advancing standardization initiatives that enable cross-sectoral coordination.

In January 2024, KRIBB's biofoundry project passed the national preliminary feasibility review, securing a KRW 126.3 billion budget for construction. A new flagship facility will be built on KRIBB's campus by 2029, serving as a national hub for industrial synthetic biology. It will anchor the Daejeon bio-cluster and serve as a catalyst for local innovation.

According to Dr. Seunggu Lee, “The future of biotech hinges on data—and biofoundries are the only scalable way



KRIBB is actively pursuing international collaboration to strengthen its role as a global hub for synthetic biology. In this photo from June 2023, Dr. Haseong Kim (right) introduces the pilot biofoundry facility to key figures in the global synthetic biology community. From left: Dr. Nigel Mouncey, President of the Society for Industrial Microbiology and Biotechnology (USA); Professor Matthew Chang, National University of Singapore; and Professor Paul Freemont, Imperial College London. The visit focused on exploring in-depth strategies for cross-national collaboration.

to produce high-quality, reproducible biological datasets. In an AI-driven research landscape, whoever controls the data will lead the innovation curve.”

Biopharmaceuticals: From Discovery to Industry

The final node in KRIBB’s strategic triad is biopharmaceuticals. From immunotherapies to gene and cell therapies, biologics represent the fastest-growing segment of the global pharmaceutical industry. Unlike chemically synthesized drugs, biologics engage diseases at the molecular and cellular levels, enabling more personalized and effective treatments.

KRIBB has prioritized translational pipelines that connect laboratory breakthroughs with industrial partners.

KRIBB has prioritized translational pipelines that connect laboratory breakthroughs with industrial partners. Its most notable success to date is the 2021 licensing of an NK cell-based immunotherapy platform to Ingenium Therapeutics for KRW 154.5 billion. Developed through collaboration with Asan Medical Center, the therapy demonstrated triple the survival rate in leukemia patients with reduced side effects and improved scalability compared to traditional

T-cell therapies.

To support such outcomes, KRIBB has institutionalized a full commercialization support system: from technology scouting and licensing to spin-off incubation. To date, it has helped launch 31 start-ups with a combined market cap exceeding KRW 2.2 trillion as of 2022. These include Bioneer (genetic diagnostics), Genofocus (industrial enzymes), and PharmAbcine (antibody oncology)—all rooted in KRIBB-developed technologies.

For instance, Bioneer has leveraged KRIBB’s foundational research in molecular diagnostics to develop real-time PCR kits that are now exported globally. Genofocus, on the other hand, transformed enzyme engineering insights from KRIBB into commercially viable biocatalysts for food and pharmaceutical processing.

These cases highlight how KRIBB’s incubation framework, including IP support, pilot production, and regulatory navigation, provides a launchpad for translating scientific assets into successful ventures.

“Spin-offs are not merely exit strategies,” says Dr. Seungwook Ji. “They are proof points that public research can deliver industrial relevance. KRIBB’s support system

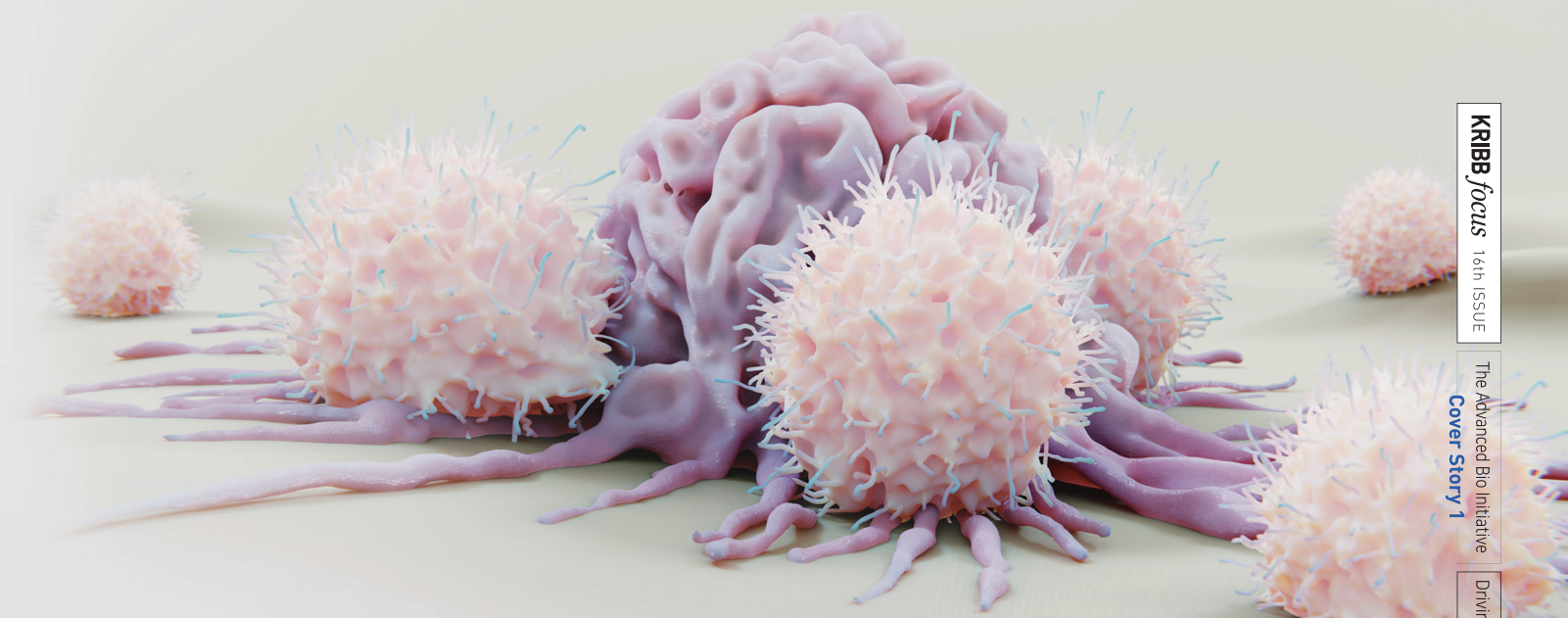


Illustration of a natural killer (NK) cell targeting a cancer cell. NK cells are emerging as a key component in immunotherapy. KRIBB has successfully transferred large-scale technologies based on its research into NK cell applications.

bridges the gap between bench and market, giving our science a viable commercial pathway.”

Precision medicine further enhances this model. KRIBB’s bioinformatics platform, KOBIC, and its human-derived biobank ensure that therapeutic development is grounded in ethically sourced, high-integrity data. This directly supports the design of targeted therapies and disease modeling.

Together, these efforts enable KRIBB to lead in both foundational technology development and application-based innovation. By bridging precision medicine with scalable therapeutics, KRIBB demonstrates what public research can achieve at the frontier of science and society.

Engineering the Bioeconomy: A Strategic Mandate

Biotechnology does not succeed through isolated breakthroughs. It requires a system that can endure trial and error, integrate multiple technical layers, and translate innovation into impact. Public institutions like KRIBB are essential for absorbing early-stage risk and aligning foundational science with national goals. Their role as architects and stabilizers becomes critical to ensuring

the coherence and sustainability of a national innovation strategy.

The results speak for themselves. In bioinformatics, KRIBB leads global digital sequence governance and ethical infrastructure. In synthetic biology, it is building Korea’s first full-scale biofoundry—designed for accessibility, modularity, and data generation. In biopharmaceuticals, it has seeded precision therapies, large-scale technology transfers, and a start-up ecosystem that continues to scale. These are not isolated achievements; they reflect a coherent system intentionally designed and executed by a single institution.

In this role, KRIBB is not just supporting national strategy. It is designing it—evident in its leadership of national initiatives like the Bio Big Data platform, the establishment of Korea’s first industrial-scale biofoundry, and its pivotal role in technology transfer that has seeded a new generation of biotech startups.

These strategic outcomes illustrate KRIBB’s dual identity: both as architect and engine of Korea’s biotechnology future. As the bioeconomy becomes more complex and contested, this dual role will only grow more vital.

The Global TOP Research Initiative at KRIBB Aims to Build a New R&BD Platform for Next-Gen Therapeutics



The Global TOP Research Group for Gene and Cell Therapy officially launched its research activities with a kickoff briefing held on November 22.

From Unmet Need to Strategic Opportunity

Despite immense advances in biotechnology, rare and intractable diseases continue to pose major challenges to public health. As conventional pharmaceuticals fall short in providing durable cures, next-generation therapies based on gene and cell manipulation are emerging as a promising alternative. These novel treatments, by directly targeting the genetic or cellular basis of disease, hold the potential for single-dose curative interventions. In response, countries worldwide are racing to secure early leadership in this transformative field.

In Korea, this shift is being strategically embraced

through the launch of the Global TOP Gene and Cell Therapy Research Group, led by the Korea Research Institute of Bioscience and Biotechnology (KRIBB). The initiative was officially launched in November 2024 at KRIBB's Daejeon headquarters with a kickoff symposium and formal designation under the country's Global TOP program.

The Global TOP program—short for “Target-oriented Platform”—is a national initiative spearheaded by the Ministry of Science and ICT and the National Research Council of Science and Technology. It is designed to secure long-term technological sovereignty by funding

elite research consortia in high-risk, high-impact domains. Under this framework, KRIBB's group aims to develop foundational technologies in gene and cell therapy while also establishing an open, public R&BD (research and business development) system.

The R&BD framework, which extends beyond conventional R&D, seeks to embed commercialization pathways directly into the research process itself. It integrates basic science with early validation and industry-facing translation—creating a structural bridge between public science and private-sector deployment. In this sense, R&BD is not simply an outcome-driven metric but a platform logic that governs how research is conceived, executed, and delivered for maximal real-world impact.

Yet the translation of basic science into clinical-grade therapeutics is a formidable challenge. Candidate materials must undergo rigorous efficacy and safety screening. Systems for production, purification, stabilization, and analytical evaluation must be developed in parallel. For private firms, these tasks carry significant risks and demand long timelines. That is why Korea's Global TOP platform is structured to provide a stable, state-funded institutional backbone—capable of de-risking innovation, absorbing uncertainty, and connecting discovery with deployment.

Building a National Ecosystem for Translational Biotech

The research group is organized as a distributed consortium, linking government-funded research institutes (GRIs), universities, hospitals, and private companies into a single innovation pipeline. KRIBB leads the effort with a focus on core source technologies, while other GRIs—including the Korea Research Institute of Chemical Technology (KRICT), Korea Institute of Toxicology (KIT), Korea Research Institute of Standards and Science (KRISS), Korea Basic Science Institute (KBSI), and Electronics and Telecommunications Research

Institute (ETRI)—contribute specialized capabilities across material science, preclinical validation, metrology, and biosignal analysis.

Importantly, this initiative builds upon over five years of collaboration. Since 2019, KRIBB, KRICT, and KIT had worked together under a proposed national program for personalized therapeutics in rare diseases. Their cooperation matured into a formal “Rare Disease Consortium” that hosted regular seminars and shared data infrastructure, laying the groundwork for deeper integration when the Global TOP opportunity emerged.

That continuity has proven critical in creating a research environment where disciplines converge and institutional trust is already in place. According to Dr. Kyung-Sook Chung, head of KRIBB's Gene and Cell Therapy Strategic Research Division, “The formation of this group is not just the start of a new project—it's the culmination of years of cross-disciplinary trust and coordination.”

Hospitals and clinical researchers are also integral to this platform. Because gene and cell therapies require validation through both preclinical and clinical trials, the initiative actively involves medical institutions in experimental design, data generation, and translational strategy. It also supports researcher-led spin-offs and diverse forms of public-private partnerships. Internally, KRIBB has created a set of modular working groups—designated as NTCs (National Technology Cells)—that align discovery, validation, and application across the participating entities. These NTCs function as thematic integration units, enabling concurrent development across parallel modules while ensuring that each component meets predefined regulatory and industrial interface standards.

AI, International Collaboration, and the Cambridge Connection

One of the most innovative elements of the initiative is its use of artificial intelligence to build an integrated



Collaborative Framework of the Global TOP
Research Group for Gene and Cell Therapy

therapeutic discovery platform. Drawing on large-scale biomedical datasets, the project seeks to streamline the identification, optimization, and testing of gene and cell therapy candidates.

This effort has led to a global partnership with the Milner Therapeutics Institute at the University of Cambridge, known for its leadership in AI-driven biomedical modeling. According to Dr. Namsik Han, Director of AI Research at the Milner Institute, “We’re focusing on digital platforms that integrate non-clinical and clinical data for predictive modeling and vector design. Our role is to help embed these systems as core components of the Korean R&BD platform.”

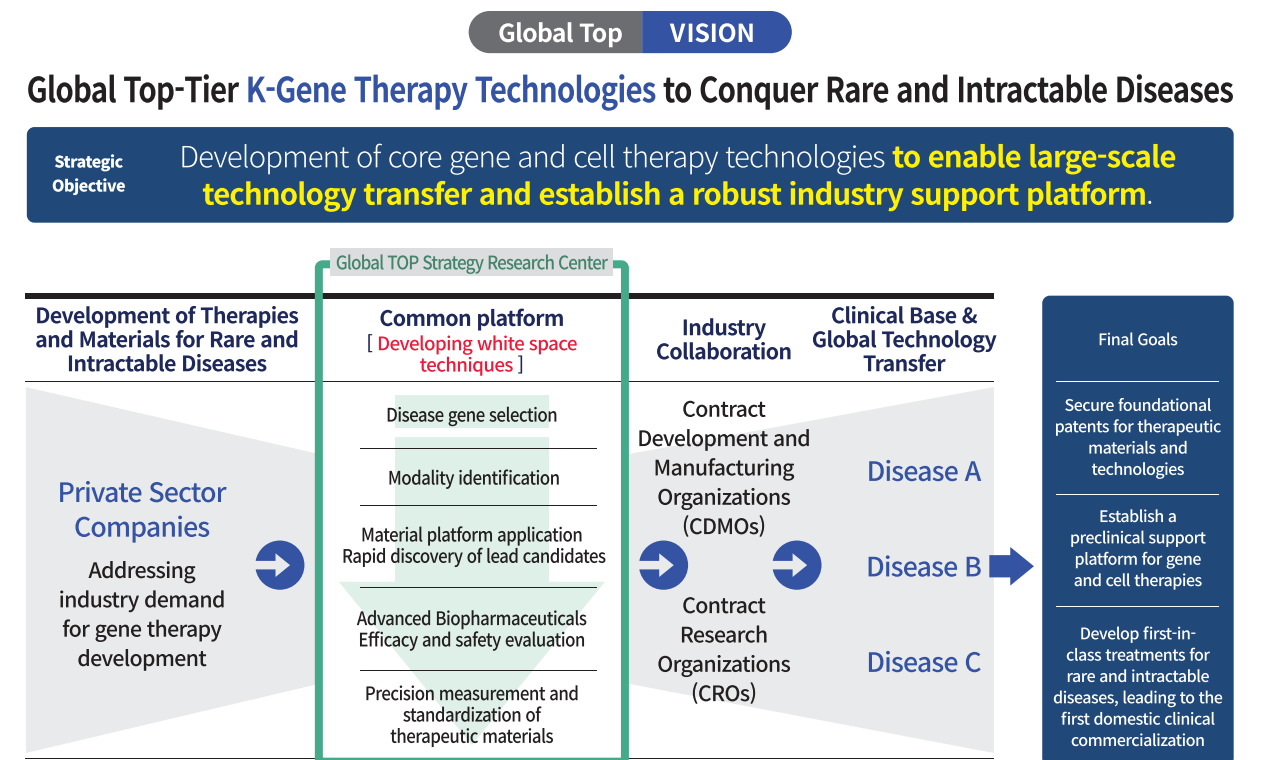
Together, KRIBB and Cambridge are building dual, interoperable AI platforms—one in Korea and one in the UK. These open-access infrastructures are not just about licensing freedom or shared APIs. They are designed as federated platforms, allowing academic, clinical, and industrial actors to connect through shared analytics modules, standardized data layers, and predictive modeling tools—without forcing the physical transfer of sensitive or sovereign datasets. This architecture enables

dynamic collaboration while respecting jurisdictional data governance.


The two sides are also exploring joint researcher exchanges, where Korean scientists can access Cambridge's ecosystem of precision medicine tools and multi-omics analytics, while UK partners can tap into Korea's extensive clinical data and cooperative research networks.

Targets and Timeline: From Public Investment to Private Acceleration

Funded with KRW 85 billion over five years, the initiative has set clear performance goals: at least 10 novel therapeutic candidates, 10 technology transfers to industry, 10 source patents, and two domestically developed biomedical devices by 2028. These candidate therapeutics will primarily target monogenic rare diseases with high unmet needs—areas where gene and cell therapy offer the most immediate potential for curative outcomes. All candidates are expected to reach at least TRL 6 (technology readiness level), meaning preclinical proof-of-concept, within the project's initial funding cycle.



Securing Advanced Gene and Cell Therapy Technologies for Treating Intractable Diseases

 Vision, Goals, and Implementation Framework
of the Specialized Research Group

More broadly, the group aims to seed over 30 deep-tech startups by 2035—anchored not in derivative applications, but in first-principles platform technologies. To do so, the project emphasizes royalty-free licensing models, public-private interface design, and long-term institutional alignment.

“This project is about more than just developing a few promising molecules,” says Dr. Chung. “We’re focused on building a seamless platform that spans discovery, validation, and commercialization—while keeping core source technologies publicly accessible as shared national assets.”

KRIBB President Dr. Jang-Seong Kim emphasizes that this initiative represents not just a research undertaking but a national innovation strategy. “We will do everything in our power to ensure that Korea secures sovereign,

homegrown technologies in gene and cell therapy and produces large-scale public outcomes in the process.”

The Global TOP Gene and Cell Therapy Research Group is not merely a scientific consortium. It is a public platform designed to align deep science with industrial and clinical delivery—bringing together institutional capacity, regulatory flexibility, and international trust. Unlike many national programs that fund research and hope for private uptake, Korea’s model builds the transition into the system—designating responsibility, coordinating stakeholders, and allocating resources from the outset. This integrated approach is what gives the Global TOP initiative its structural uniqueness. As global interest in advanced biologics continues to grow, Korea’s experiment with translational coordination may well become a model for next-generation bioeconomy infrastructure.

KRIBB Scientists Illuminate Global Health Frontiers

As climate change, aging populations, and chronic disease reshape the global health landscape, new tools are needed to understand and counteract emerging biological risks. At the Korea Research Institute of Bioscience and Biotechnology (KRIBB), scientists are turning molecular insight into medical possibility—decoding deadly pathogens, improving cancer diagnostics, and redefining our understanding of liver disease through epigenetics.

In the second half of 2024, three KRIBB researchers were honored as Scientists of the Month for groundbreaking work in their respective fields: Dr. Youngjin Lee for uncovering how *Vibrio vulnificus* disables host immunity, Dr. Taejoon Kang for developing an mRNA-based liquid biopsy platform for early cancer detection, and Dr. Mirang Kim for revealing an epigenetic link between lifestyle and advanced liver disease. While the topics vary, each project exemplifies KRIBB’s institutional mission: transforming fundamental bioscience into translational strategies for public health resilience.



Dr. Youngjin Lee

Decoding a Deadly Pathogen: KRIBB Team Uncovers Immune-Evasion Mechanism of *Vibrio vulnificus*



In the summer of 2024, Korea experienced one of the hottest seasons on record, with national average temperatures reaching 25.6°C—nearly 2 degrees higher than historical norms. This climatic shift has not only disrupted environmental patterns but has also heightened the risk of marine-borne infections. One such threat is *Vibrio vulnificus*, a pathogenic bacterium found in warm seawater. It causes fatal sepsis when it enters the human body via open wounds or consumption of raw seafood.

The case fatality rate for *V. vulnificus* infections hovers between 40 and 50 percent. In 2023 alone, Korea recorded 27 deaths, prompting intensified public health surveillance. While the correlation between ocean

warming and *Vibrio* outbreaks has been widely observed, the molecular basis of its lethality remained largely unexplained—until now.

A research team led by Dr. Youngjin Lee at the Center for Microbiome Convergence at KRIBB has identified the key immune evasion strategy used by *V. vulnificus* to disable host defenses. At the center of this mechanism is the MARTX (Multifunctional-Autoprocessing Repeats-in-Toxin) toxin, a complex protein structure that releases a variety of toxic effectors during infection. Among them, the team focused on two previously uncharacterized components: DUF1 and RID, collectively referred to as “transformer proteins” due to their sequential activation behavior.

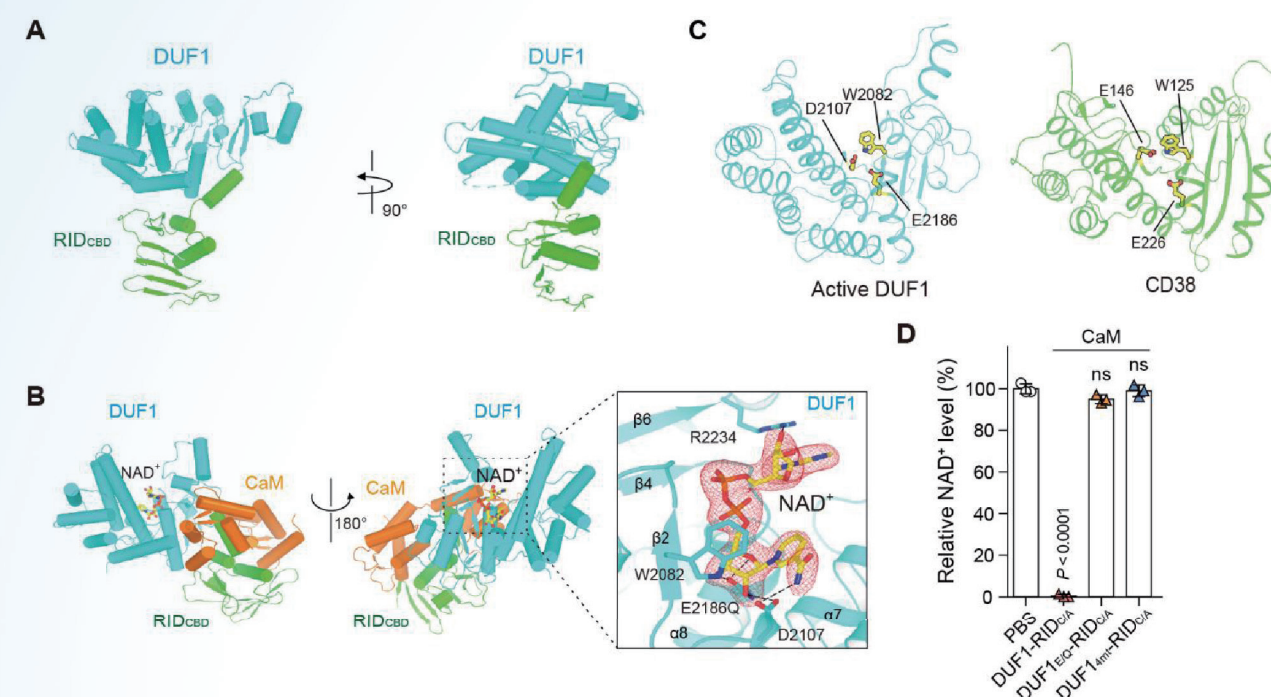
Upon entering the host cell, these transformer proteins bind tightly to the human proteins calmodulin (CaM) and Rac1. This interaction triggers a conformational change that activates an enzyme known as NADase. The enzyme rapidly hydrolyzes NAD⁺, a molecule essential for both cellular metabolism and immune signaling. Simultaneously, the binding disrupts Rac1-mediated signal transduction, impairing cytoskeletal organization and innate immune function.

In vivo experiments using mouse models validated these findings. Mice infected with wild-type *V. vulnificus* expressing NADase showed rapid bacterial proliferation in the bloodstream, spleen, and liver, followed by systemic inflammation and cytokine storm—leading to high mortality. In contrast, mice infected with a genetically modified strain lacking NADase expression showed significantly improved survival and reduced disease progression.

Notably, the study also highlights the pathogen’s use of “conditional activation” as a strategic adaptation. Because NAD⁺ is a crucial cofactor for bacterial survival as well, *V. vulnificus* keeps its NADase activity in an inactive state during transit. Only upon recognizing host molecules does it activate this immune-disabling mechanism, thereby balancing self-preservation with virulence. This form of host-triggered activation echoes strategies seen in other multidrug-resistant bacteria, such as *Pseudomonas aeruginosa*, but the dual inactivation of both NAD⁺ and Rac1 by a single protein complex appears to be unique.

By elucidating this process, Dr. Lee’s team has not only revealed how *V. vulnificus* achieves its devastating effects but also opened new avenues for therapeutic intervention. Targeting the NADase activation step or its interaction with CaM and Rac1 could provide the basis for future drug development—not only for *Vibrio* infections but also for other pathogens that use similar immune sabotage tactics.

The *Vibrio vulnificus* transformer protein (DUF1/RID), shown converting into an NADase enzyme upon binding to human intracellular proteins.



Dr. Taejoon Kang

CRISPR Meets Liquid Biopsy: A New Platform for Early Cancer Detection



Cancer remains the leading cause of death in South Korea, with mortality rates twice that of cardiovascular disease. While therapeutic options have improved significantly in recent decades, the single most decisive factor in cancer prognosis continues to be early detection. Catching malignancies before they metastasize dramatically increases survival odds and reduces treatment complexity. Yet existing diagnostic tools—including imaging and tissue biopsies—often fall short in sensitivity, specificity, or patient accessibility.

Dr. Taejoon Kang and his team at KRIBB's Center for BioNano Research have addressed this diagnostic gap by

co-developing a new platform called SCOPE (Self-amplified and CRISPR-aided Operation to Profile Extracellular Vesicles), in collaboration with Massachusetts General Hospital and Sungkyunkwan University. The platform integrates mRNA profiling with CRISPR-Cas13a technology to detect ultra-low concentrations of tumor-derived genetic material in bodily fluids, enabling non-invasive and high-precision cancer screening.

SCOPE is based on liquid biopsy—a diagnostic method that captures cell-free nucleic acids or extracellular vesicles (EVs) from biofluids such as blood or urine. EVs are nanoscale lipid vesicles secreted by cells, including cancer

cells, and carry molecular information such as mRNA, DNA, and proteins. However, detecting tumor-specific mutations in EVs has historically been limited by their extremely low abundance and the difficulty of distinguishing single-nucleotide variants.

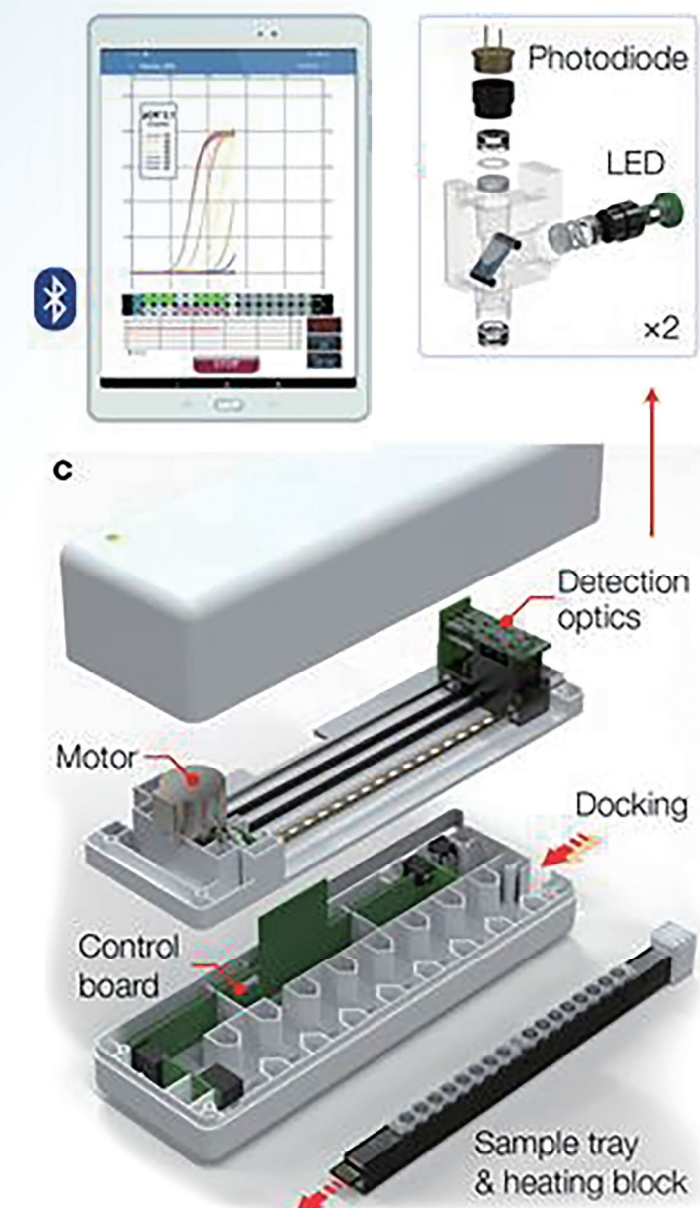
To overcome these challenges, the KRIBB team employed the RNA-targeting CRISPR enzyme Cas13a, which can amplify and selectively cleave RNA sequences with high fidelity. SCOPE enhances the abundance of target mRNA derived from tumor EVs and achieves single-base resolution detection, significantly improving both sensitivity and specificity. In mouse models, the system successfully identified early-stage lung cancer using only 40 microliters of EV-enriched plasma. In clinical samples from colorectal cancer patients, SCOPE detected oncogenic mutations with higher sensitivity than standard PCR assays.

What sets the platform apart is its practicality. SCOPE processes 16 samples simultaneously and produces results in under 40 minutes, making it suitable for point-of-care deployment. In partnership with RevoSketch, a biotech startup, the team has miniaturized the device to further support clinical integration. This opens new possibilities for longitudinal patient monitoring, early recurrence detection, and personalized therapy planning.

The platform also addresses key limitations of tissue biopsies, which are invasive, time-consuming, and often fail to capture the genetic heterogeneity of tumors. Liquid biopsies offer a snapshot of the molecular landscape across primary and metastatic sites without requiring surgical intervention. SCOPE pushes this promise further by making high-precision molecular diagnostics accessible in real-time settings.

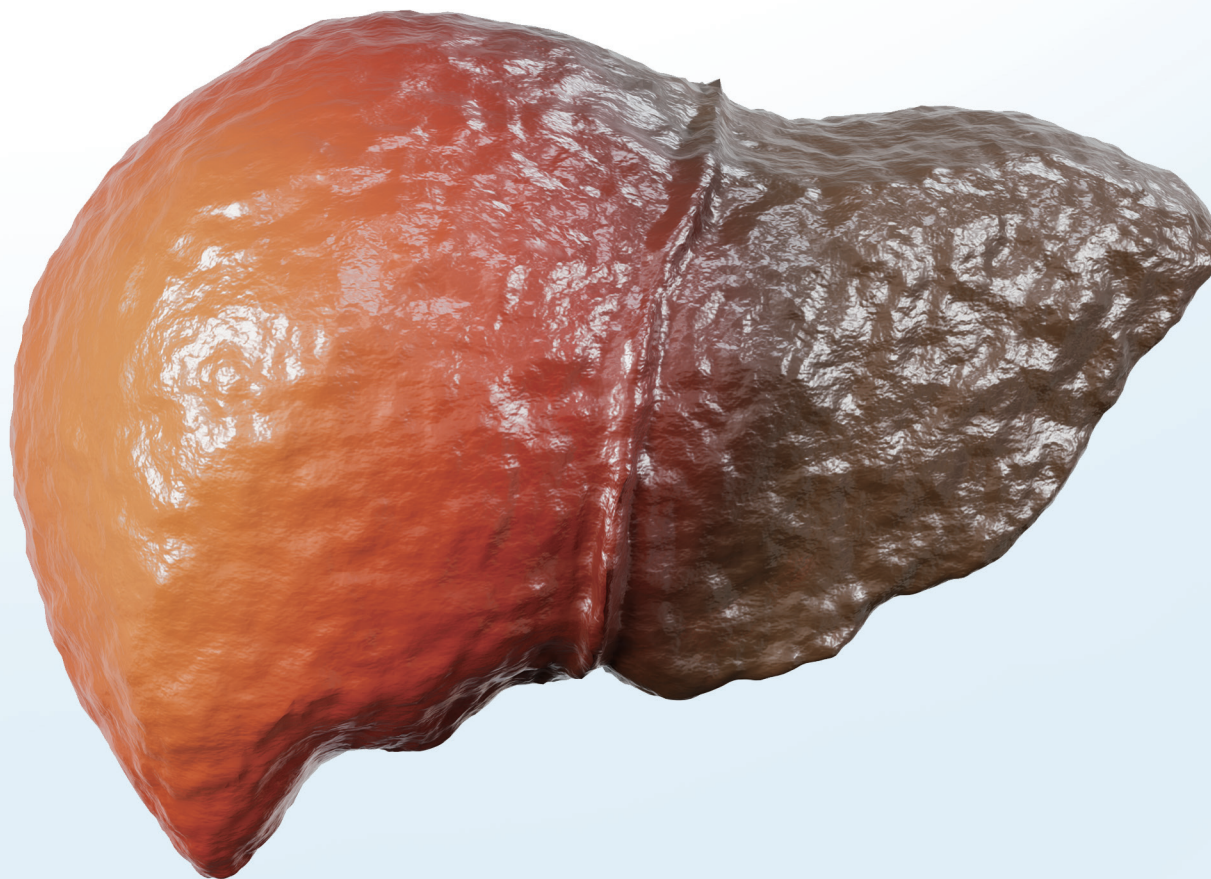
KRIBB and its collaborators are pursuing international patent protection for the platform and are working to refine its usability in clinical workflows. By bridging CRISPR technology with cancer diagnostics, the team has taken a critical step toward democratizing early detection—a turning point not just for cancer research, but for how genomic tools can be deployed at scale in everyday medicine.

The research team collaborated with a domestic molecular diagnostics company to miniaturize the platform equipment, enhancing its usability in real-world clinical settings.



Dr. Mirang Kim

Epigenetics and the Gut-Liver Axis: Decoding the Progression of Metabolic Liver Disease



Fatty liver disease, once considered a benign metabolic anomaly, has emerged as one of the world's most widespread chronic conditions. Today, over 2 billion people globally are affected by what is now clinically termed metabolic dysfunction-associated steatotic liver disease (MASLD), a spectrum that includes simple steatosis, steatohepatitis, fibrosis, and even hepatocellular carcinoma. In South Korea alone, nearly 40 percent of adults over 20 are believed to have some form of fatty liver. Despite its prevalence, effective treatment options remain limited,

especially for advanced forms such as steatohepatitis and fibrosis.

Addressing this urgent unmet need, Dr. Mirang Kim and her team at KRIBB's Research Center for Integrative Aging have identified a key molecular link between lifestyle-driven risk factors and liver disease progression. The study, conducted in collaboration with Boramae Medical Center, explores how poor diet, inactivity, and microbiome imbalance lead to epigenetic alterations that exacerbate metabolic liver dysfunction.

The researchers focused on DNA methylation, a central mechanism in epigenetics whereby chemical groups are added to DNA without altering its sequence, affecting gene expression in response to environmental cues. Analyzing liver biopsy samples from 106 Korean MASLD patients, the team found a strong inverse correlation between DNA methylation patterns and gene expression in complement system genes—a group of innate immune components involved in pathogen clearance and inflammation.

This link between complement genes and hepatic fibrosis is especially significant. While previous studies had hinted at immune dysregulation in fatty liver disease, Dr. Kim's team is the first to demonstrate, in human clinical tissue, a methylation-mediated suppression of complement genes in patients with steatohepatitis. The findings suggest that altered microbiome-derived metabolites may trigger epigenetic silencing of immune genes, creating a permissive environment for inflammation and fibrotic remodeling.

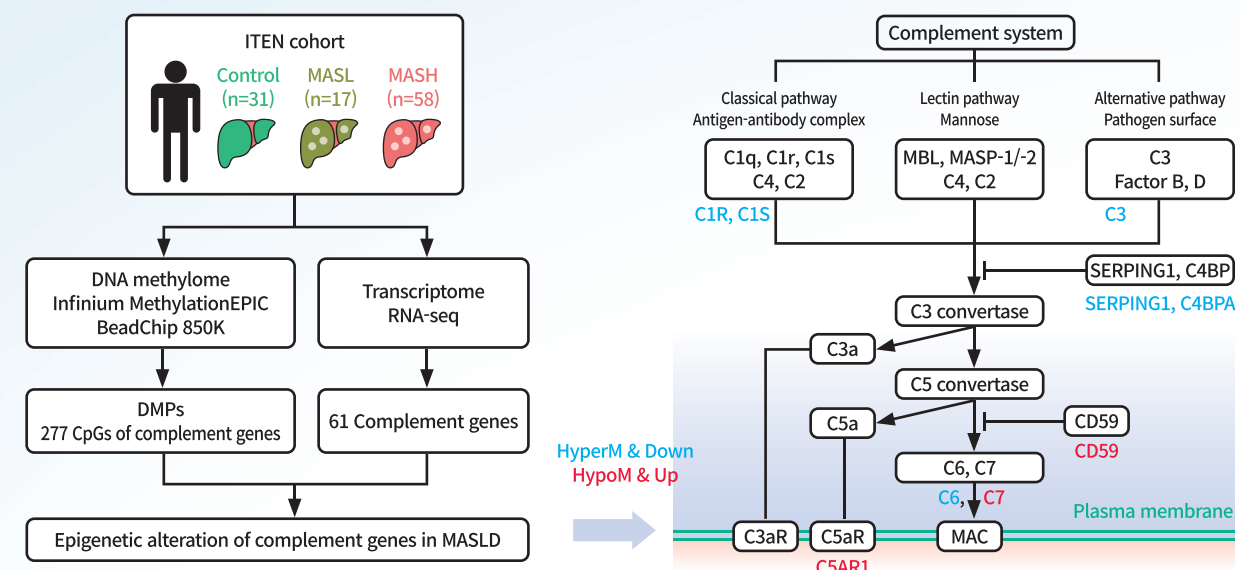
The research further contextualizes MASLD as not merely a metabolic condition but a complex

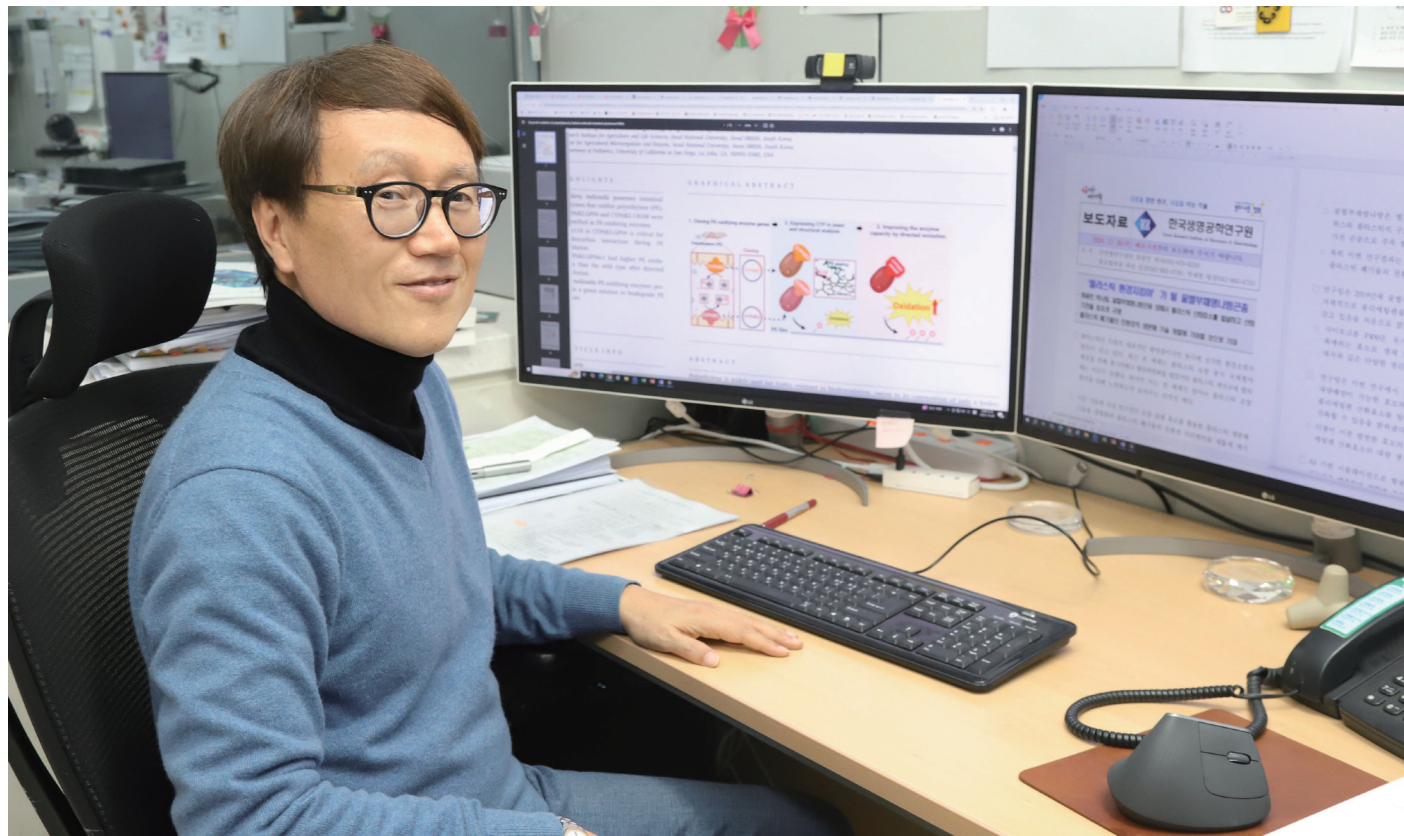
immunometabolic disorder with distinct epigenetic signatures. The team's integrative approach—linking lifestyle, microbiota, immune signaling, and DNA methylation—offers a comprehensive model for understanding how non-alcoholic fatty liver progresses to its more dangerous forms.

Importantly, this work opens new therapeutic avenues. Epigenetic biomarkers could improve early diagnosis and risk stratification, while interventions targeting methylation pathways may offer novel strategies for reversing disease progression. With the global pharmaceutical market for MASLD therapies projected to exceed USD 25 billion, the potential impact is enormous—particularly given that only one treatment (resmetirom) had received regulatory approval as of early 2024.

By uncovering a plausible mechanistic pathway between environmental stress and genetic regulation, Dr. Kim's group has added a crucial missing link to the puzzle of fatty liver disease. Their findings underscore KRIBB's commitment to tackling age-related and lifestyle-driven diseases through molecular precision and translational foresight.

Epigenetic alterations in complement system genes during the progression of metabolic dysfunction-associated liver disease (MASLD)





Galleria mellonella Larva Enzymes Offer Sustainable Solution for Plastic Waste

KRIBB Develops Plastic Oxidation Technology Using Insect-Derived Enzymes

Plastic is often hailed as one of humanity's most revolutionary inventions. However, it has also emerged as a major environmental pollutant, imposing a significant burden on global ecosystems. Despite five rounds of international negotiations aimed at establishing a legally binding agreement to end plastic pollution, the global community has yet to reach a consensus on limiting plastic production. The need for effective plastic reduction technologies is therefore

more urgent than ever.

Amid this challenge, a research team led by Dr. Choong-Min Ryu at the Infectious Disease Research Center of the Korea Research Institute of Bioscience and Biotechnology (KRIBB) has developed a new method for plastic oxidation and degradation using enzymes derived from the gut of the *Galleria mellonella* moth, commonly known as the greater wax moth. The study offers a concrete

technological pathway toward the eco-friendly treatment of plastic waste and has attracted attention for its potential applications.

The team identified cytochrome P450 enzymes in the gut of the moth that are capable of oxidizing plastic. They successfully expressed these enzymes heterologously in yeast and insect cells, confirming two distinct oxidases that react with polyethylene. In parallel, they



established stable culture conditions for efficient enzyme production.

Using AI-based molecular simulations, the researchers predicted the binding affinity between the enzymes and plastic substrates, and further pinpointed key amino acid residues responsible for binding. This approach significantly deepened their understanding of the enzyme's structural features and catalytic mechanisms. Additionally, through random mutagenesis, they generated enzyme variants with improved oxidative efficiency.

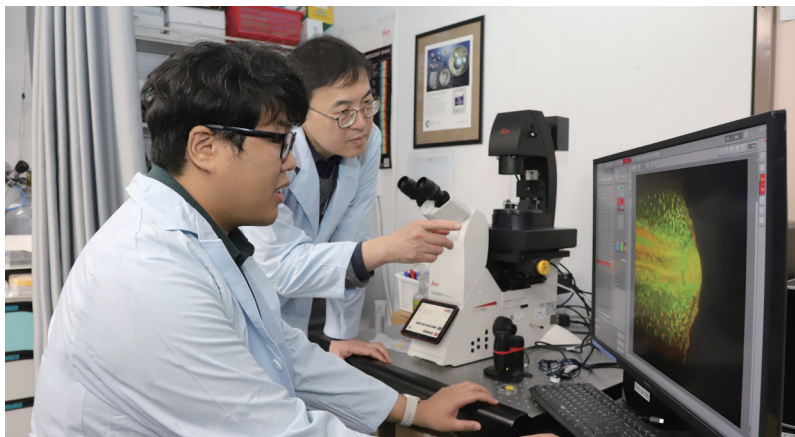
Cytochrome P450 enzymes are

known to catalyze oxidation reactions by introducing oxygen into organic compounds. In biological systems, they play essential roles in detoxification, steroid biosynthesis, and hormone metabolism. Notably, Dr. Ryu's team was also the first to report in 2019 that *Galleria mellonella* larvae can oxidize polyethylene independently, without the aid of gut microbiota.

"This study presents a new direction for plastic degradation using insect-derived enzymes," said Dr. Ryu. "Through AI-guided analysis, we were able to elucidate the catalytic mechanism and demonstrate

the platform's potential for practical application."

The research was published online in the October 23, 2023 edition of *Journal of Hazardous Materials* under the title "Enzymatic oxidation of polyethylene by *Galleria mellonella* intestinal cytochrome P450s." Dr. Choong-Min Ryu served as the corresponding author, while Dr. Jin-Soo Son and researcher Soohyun Lee were co-first authors. The project was supported by the Agricultural Microbiome Program of the Rural Development Administration and KRIBB's Major Research Program.



New Pathway for Tau Clearance Identified in Alzheimer's Disease Korea-U.S. Research Team Uncovers Key Mechanism for Future Therapeutics

A collaborative research team from Korea and the United States has identified a new biological pathway that facilitates the removal of tau proteins, one of the primary pathological features of Alzheimer's disease. The discovery is expected to offer crucial insight into the development of therapeutics for tauopathies, a group of neurodegenerative disorders associated with tau accumulation.

The research was conducted jointly by Dr. Jeong Soo Lee of the Microbiome Convergence Research Center at the Korea Research Institute of Bioscience and Biotechnology (KRIBB), Dr. Hoon Ryu of the Korea Institute of Science and Technology (KIST), and Professor Jeonghui Lee of Boston University School of Medicine. The team found that valosin-containing protein (VCP), a key factor in maintaining protein homeostasis, plays a central role in facilitating the degradation

of tau proteins.

Tau proteins are known to contribute to a range of neurodegenerative diseases, including Alzheimer's disease, frontotemporal dementia, and progressive supranuclear palsy. Among these, Alzheimer's remains one of the most challenging illnesses due to the absence of a definitive cure. According to Korea's Health Insurance Review and Assessment Service, the number of Alzheimer's patients in South Korea reached approximately 620,000 in 2023, marking a 25% increase from 2019. Associated long-term care expenditures in the same year were estimated at KRW 1.9 trillion.

Using a mouse model expressing human tau, the researchers observed that VCP expression levels changed in tandem with tau expression. When VCP levels were increased, tau aggregation was suppressed, leading to improvements in

related cognitive behaviors. Conversely, reduced VCP expression resulted in significant tau accumulation. These patterns were also observed in human brain tissue from Alzheimer's patients, where VCP and tau protein levels exhibited an inverse relationship.

Further analysis revealed that VCP contributes to tau clearance via the autophagy pathway. The team also demonstrated that combined administration of the VCP activator SMER-28 and the autophagy inducer rapamycin resulted in more pronounced clearance of tau proteins than either compound alone.

"This study proposes a new therapeutic approach for tau-related neurodegenerative diseases, for which no approved treatment currently exists," said Dr. Jeong Soo Lee. "It has significant implications not only for Alzheimer's disease but also for broader strategies in neurodegeneration research."

The study was published online in *Acta Neuropathologica* on September 24, 2023, under the title "Tau accumulation is cleared by the induced expression of VCP via autophagy."

Corresponding authors are Dr. Jeong Soo Lee and Dr. Hoon Ryu, and the first authors are Dr. Hoi-Khoanh Giong, Dr. Seung Jae Hyeon, and Dr. Jae-Geun Lee.

The research was supported by the Ministry of Science and ICT and the Ministry of Health and Welfare of Korea under national research programs for brain and dementia, as well as by core funding from KRIBB and KIST, and grants from the U.S. National Institutes of Health.



KRIBB to Host Annual Conference on Drug Innovation 2024 Event to Highlight Advances in Protein Design and Therapeutic Delivery Technologies

The Korea Research Institute of Bioscience and Biotechnology (KRIBB) announced that it will hold the 2024 KRIBB Annual Conference on December 5 at its headquarters in Daejeon. Themed "The Innovation Imperative: Drug Development," the event will focus on emerging strategies and platforms to address unmet medical needs through novel drug development and delivery technologies.

The conference will open with a keynote address by Celltrion Chairman Jung-Jin Seo, titled "The Present and Future of Targeted Therapy." Other dignitaries, including KRIBB President Dr. Jang-Seong Kim and NST Chairman Yeung Shik Kim,

along with leading researchers in the bioscience sector, are expected to attend.

Although low molecular weight compounds have long played a key role in disease treatment, their limitations have fueled a growing demand for next-generation therapies, including antibodies, peptides, gene and cell-based treatments. In parallel, AI-powered protein structure prediction and optimization of delivery platforms have become central to innovation in drug development.

The conference will feature two specialized sessions. The Protein Design session, chaired by Dr. Eui-Jeon Woo (Principal Researcher at KRIBB), will include presentations by Dr. Kwang Hyun Park

(Senior Researcher, KRIBB), Prof. Byung-Ha Oh (KAIST), Prof. Sangmin Lee (POSTECH), and Dr. Woo himself. The Therapeutic Delivery Technologies session, chaired by Dr. Hyunjoo Cha-Molstad (Director of the Nucleic Acid Therapeutics Center at KRIBB), will host speakers including Prof. Ji Ho Park (KAIST), Dr. Eun-Kyoung Bang (KIST), Dr. Jeongeun Shin (KRIBB), and Prof. Joonbum Bae (Korea University).

In addition to academic presentations, the event will showcase KRIBB's annual research outcomes through various programs. The KRIBB Poster Festival will display over 120 high-impact papers presented at domestic and international conferences. The Young Speaker Symposium will feature around 20 early-career scientists presenting major achievements from their 2024 research projects. An exhibition on the institute's monthly "KRIBB Person of the Month" awardees will also be held on-site.

In his congratulatory remarks, NST Chairman Yeung Shik Kim stated, "Advanced biotechnology offers new solutions to areas where conventional medicine has fallen short. We will actively support cross-institutional collaboration to drive technological innovation."

In his opening address, KRIBB President Jang-Seong Kim emphasized, "In this era of convergence between AI and digital bioscience, we aim to assess the current state of core technologies and explore future directions. KRIBB will work to dismantle barriers across academia, industry, research, and clinical practice to lead open innovation."



Asia-Pacific Countries Strengthen Regional Cooperation on Infectious Disease Preparedness

KRIBB to Host the 3rd APIS Forum in Seoul on November 8

An international forum aimed at enhancing Asia's infectious disease response capabilities will convene in Seoul. The Korea Research Institute of Bioscience and Biotechnology (KRIBB) announced that the 3rd Asia-Pacific Infectious Disease Shield (APIS) Forum will be held on November 8 at the Grand InterContinental Seoul Parnas Hotel.

Asia is considered a high-risk region for infectious disease outbreaks due to its temperate climate and high population density. Major international airports in Incheon, Beijing, and Singapore further increase the risk of rapid cross-border transmission. While Africa has established continent-wide preparedness systems

through collaboration with the European Centre for Disease Prevention and Control (ECDC), experts have noted that intergovernmental cooperation in Asia remains relatively limited.

In response, the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) launched a continental hub development strategy in 2021 and designated South Korea as the coordinating country for the Asia-Pacific region.

Based on this role, the APIS initiative has been established as a Korea-centered international research cooperation platform, with KRIBB serving as the project's implementing agency under the

support of the Ministry of Science and ICT.

The forum will bring together public health and infectious disease experts from seven countries, including Korea, Malaysia, Singapore, India, Indonesia, Thailand, the Philippines, and Australia. Participants will share updates on national research programs and discuss strategies for joint response in vulnerable areas.

Dr. Choong-Min Ryu, Director of KRIBB's Infectious Disease Research Center, who also serves as Korea's representative to GloPID-R and Chair of APIS, will present the initiative's progress and unveil the "APIS 2.0" roadmap, set to launch in 2025. He will also introduce national-level programs to support preclinical testing for emerging infectious diseases.

Key agenda items include breakout discussions on vector-borne diseases—expected to spread further due to climate change—and antimicrobial resistance, which experts warn may drive a "silent pandemic" if left unchecked.

"The forum will strengthen the foundation for cooperation among seven Asia-Pacific countries with relatively well-developed infectious disease infrastructures," said Dr. Ryu. "It is a step forward in building a safer, more resilient region."

KRIBB President Dr. Jang-Seong Kim added, "KRIBB will continue to expand international collaborations in infectious disease research and help bridge gaps between high- and lower-resourced countries in the region by supporting global scientific solidarity."



KRIBB and Harvard Team Develop Ultra-Sensitive Cancer Detection Platform

New CRISPR-based Liquid Biopsy Technology Enables Early Diagnosis with Minimal Blood Sample

A collaborative research team from Korea and the United States has developed a new gene-based diagnostic technology capable of detecting cancer from trace amounts of blood. The platform, which demonstrates higher sensitivity and greater simplicity than existing methods, holds strong potential for broader clinical applications in cancer monitoring and recurrence prediction.

The Korea Research Institute of Bioscience and Biotechnology (KRIBB) announced that Dr. Taejoon Kang's team at the BioNano Research Center has jointly developed a high-sensitivity diagnostic platform called SCOPE (Self-amplified and CRISPR-aided Operation to Profile Extracellular Vesicles) in collaboration with Massachusetts General Hospital (MGH), Harvard Medical School (HMS), and

Sungkyunkwan University.

SCOPE works by detecting mRNA within extracellular vesicles (EVs)—nanoscale particles secreted by tumor cells—through amplification using the CRISPR-Cas13a system. This approach enables precise identification of cancer-related gene mutations from even extremely small volumes of biofluids, overcoming the sensitivity limitations of traditional detection techniques.

In preclinical tests using animal models, the team successfully diagnosed early-stage lung cancer using just 40 microliters of EV-enriched plasma. In samples from colorectal cancer patients, the platform also demonstrated higher sensitivity and specificity than conventional PCR assays in detecting oncogenic mutations.

SCOPE is also optimized for clinical

settings. It can simultaneously process 16 samples and provides results in under 40 minutes. To further improve clinical usability, the research team partnered with Korean molecular diagnostics firm RevoSketch to miniaturize the platform, enabling deployment in field settings without the need for complex lab equipment.

"This system offers unprecedented sensitivity in detecting key cancer mutations that are difficult to identify with conventional methods," said Dr. Taejoon Kang. "With simplified procedures and rapid turnaround, SCOPE has high potential for real-time use in cancer diagnostics and treatment monitoring."

Prof. Hakho Lee of Harvard Medical School added, "SCOPE can detect molecular changes in tumors even before abnormalities appear in imaging scans, making it highly promising for clinical translation."

The study was published online in Nature Biotechnology on October 7, 2023, under the title "Amplifying mutational profiling of extracellular vesicle mRNA with SCOPE." Corresponding authors are Dr. Taejoon Kang (KRIBB), Prof. Cesar M. Castro (MGH), and Prof. Hakho Lee (HMS), with Prof. Jayeon Song (Sungkyunkwan University) as the first author.

The research was supported by the Ministry of Science and ICT of Korea through its Bio & Medical Technology Development Program, Nanomaterials Development Program, and Mid-career Researcher Support Program, as well as by KRIBB's Major Research Projects.



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