

PRC

Preclinical Research Center

Critical infrastructure in the field of national preclinical Research and animal experiment

03

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Key Achievements of K-MEDI hub PRC

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Daegu–Gyeongbuk Medical Cluster

Daegu–Gyeongbuk Medical Cluster

High-tech medical industry cluster created to strategically foster the new drug and advanced medical device industries at the national level

Cluster status

- ✓ Location : “Innovation City”, Dong-gu, Daegu
- ✓ Project period : 2009–2038 (construction: 2009–2013)
- ✓ Total project cost : KRW 4.6 trillion (KRW 1.1 trillion national, KRW 0.9 trillion local, and KRW 2.6 trillion private)
- ✓ Size : 1,030,000m² (Innovation City = 4,220,000m²)

Key Facilities

Category	Name	Site area (m ²)	Key features
Research support	New Drug Development Center	28,500	Evaluation of new drug candidates, joint R&D, etc.
	Medical Device Development Center	18,200	Product design and prototyping support/development, etc.
	Preclinical Research Center	13,700	Non-clinical evaluation of medical products, providing tailored animal experiment systems, etc.
	Drug Manufacturing Center	9,700	Production of clinical trial samples, technology transfer support, etc.
Clinical trials	High-tech Clinical Trial Center	15,713	Verification of clinical applicability, etc.
Amenities	Communication Center	10,112	Offices, meeting rooms, guesthouses, etc
	Joint Research Center	14,266	Space for corporate tenants, support facilities, etc.
	Dormitories	2,300	Accommodations and ancillary facilities
Research institution tenants	Private tenant area	320,647	Research institutions, venture center, etc.

Daegu-Gyeongbuk Medical Innovation Foundation (K-MEDI hub)

Purpose of establishment

To contribute to the development of the domestic medical industry and ensure that the Daegu-Gyeongbuk Medical Cluster becomes a global medical R&D hub, in accordance with the "Special Act on the Designation and Support of High-tech Medical Complexes"



Vision

Collaborate with the medical industry to promote the adoption of advanced technologies and provide a dynamic platform for its growth and development

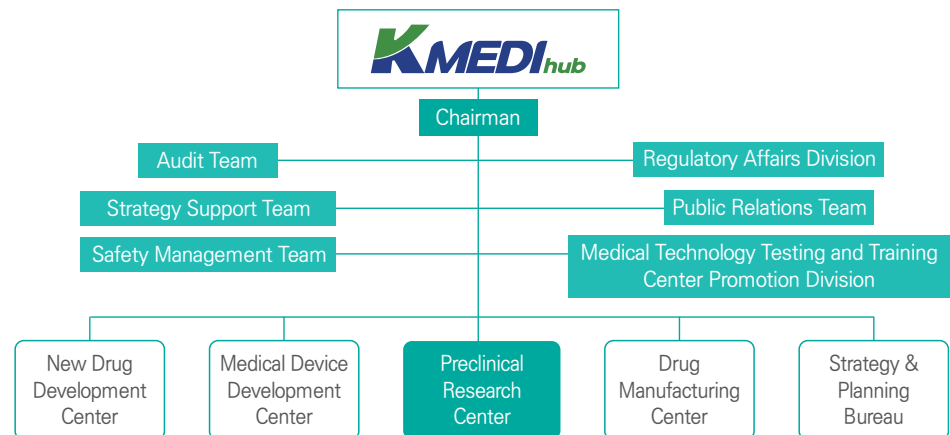
Mission

Bring R&D innovations to market to support the transfer of knowledge and technologies from the lab to the high-value-added medical industry

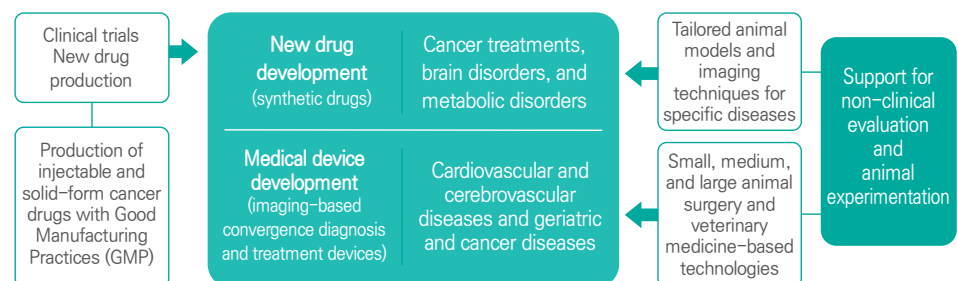
Goal

- ☑ Provide comprehensive research infrastructure at the global level
- ☑ Establish an R&D base for complex and advanced products

Organizational



Specialized areas





K-MEDI hub PRC



Director's Message

02 Preclinical Research Center (K-MEDI hub PRC)

Purpose of establishment

- ☑ To support the evaluation of the biological efficacy and safety of new drug candidates and medical devices in development as a specialized research facility in the field of experimental animals in the cluster
- ☑ To establish a world-class experimental animal facility that can contribute to the success of the medical cluster and the development of the medical and scientific fields in the region through the maintenance and management of experimental animals and creation and use of various animal disease models

Key functions

- ☑ Production, supply, and maintenance of experimental animals required by research institutions
- ☑ Support for non-clinical research and animal experiment
- ☑ Development, maintenance, collection, preservation, and supply of various animal disease models

Relevant government department

Ministry of Health and Welfare

Facilities

- ☑ Overview : site area of 13,700m², building floor area of 8,696m² (1 underground floor, 3 aboveground floors)
- ☑ Key facilities : small animal area, medium-sized animal area (dogs, pigs), primate area, medical device area, in vivo imaging area, ABSL2 area, surgical area, etc.
- ☑ Ancillary facilities : mini-pig research facility, bio-imaging agent research lab

Certifications

- '20 Accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC-I)
- '17 Participation in the International Council for Laboratory Animal Science - Performance Evaluation Program for Diagnostic Laboratories (ICLAS-PEP), the first in Korea
- '16 Certification as an Korea Excellent Laboratory Animal Facility (KELAF) by the Ministry of Food and Drug Safety
- '15 Designation as a Core Facility for Bio Research Resources by the Ministry of Food and Drug Safety

Greetings,

I am Kilsoo Kim, the director of the Preclinical Research Center at K-MEDI hub.

The Preclinical Research Center is a crucial infrastructure for developing advanced drugs and medical devices at the global level, providing important information on the efficacy and safety of cutting-edge drugs and medical devices before clinical trials.

We promise to provide differentiated animal experimentation support through our state-of-the-art facilities, such as advanced imaging and surgical equipment, excellent technical and human resources, and the network within the Daegu-Gyeongbuk Medical Cluster.

We are also committed to ethical animal experimentation by ensuring humane animal care and consistent ethical review of animal experiments, promoting awareness of research ethics and respect for life.

Thank you.



Director, Preclinical
Research Center,
K-MEDI hub

Kilsoo Kim

KMEDIhub

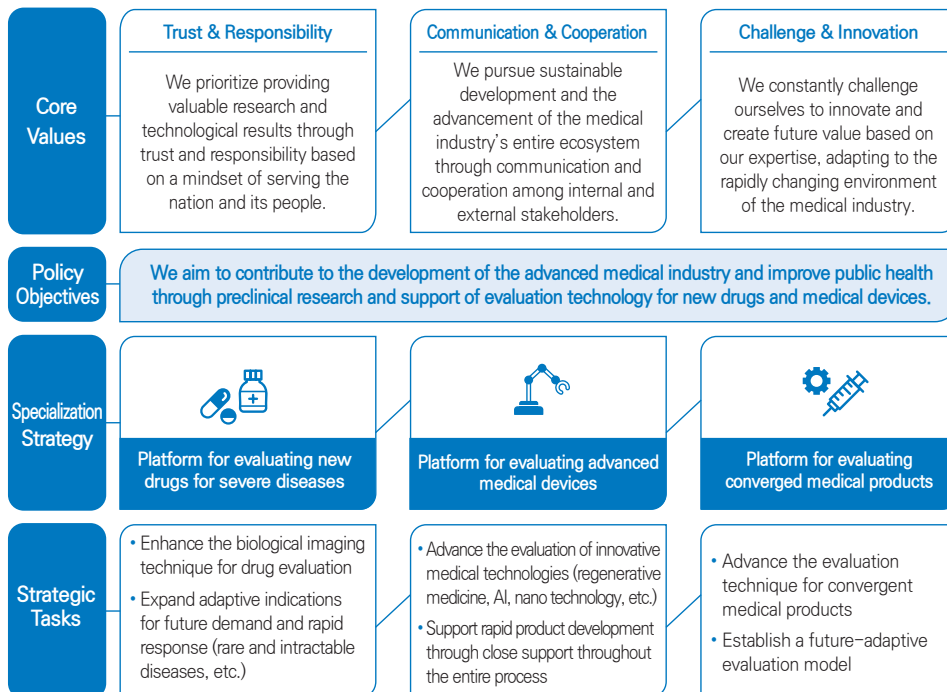


Vision of K-MEDI hub PRC

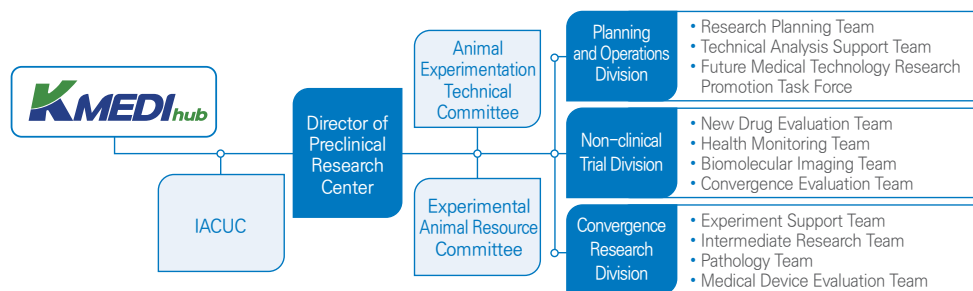
Vision

Passion for innovation
Responsibility for cooperation
Companion for global R&D!

PRC



Organizational chart of K-MEDI hub PRC

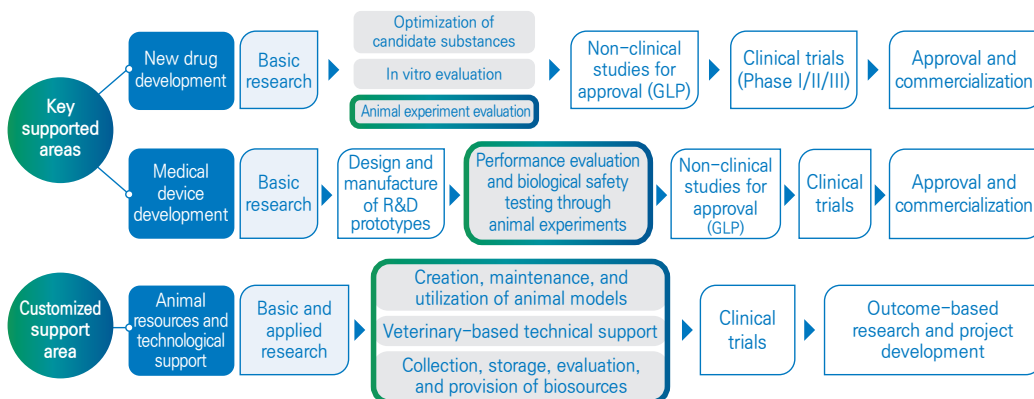


Division	Team	Major Responsibilities
Planning and Operations Division	Research Planning Team	Project planning and management, establishment of short- and long-term development plans for the center, performance management, promotion, and external cooperation
	Technical Analysis Support Team	General administration (purchasing, expenditure, etc.), research funding management, IACUC, and management of experiment coordination room
	Future Medical Technology Research Promotion Task Force	Facility operation management and promotion of future construction of medical technology research facilities
Non-clinical Trial Division	New Drug Evaluation Team	Efficacy evaluation of new drug candidates
	Health Monitoring Team	Quality control of experimental animals (health monitoring) and development of next-generation diagnostic methods and diagnostic kits
	Biomolecular Imaging Team	Evaluation of efficacy and preliminary safety of medical products using bio-imaging
	Convergence Evaluation Team	Efficacy evaluation of convergent medical products based on animal disease model production technology
Convergence Research Division	Experiment Support Team	Maintenance and management of animal resources and experiment support, production of animal models based on veterinary science technology, and evaluation of medical product efficacy
	Pathology Team	Collection, storage, evaluation, and provision of animal-derived biosources and clinical/tissue pathology and analysis
	Intermediate Research Team	Convergent medical product evaluation and intermediary research support
	Medical Device Evaluation Team	Evaluation of efficacy and preliminary safety of medical device prototypes

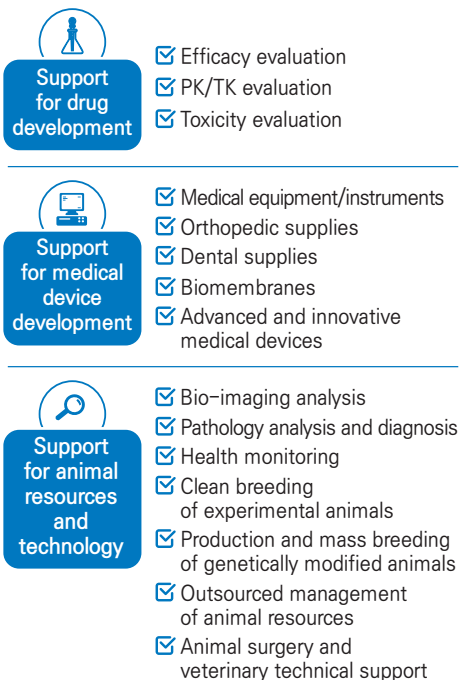


Support from K-MEDI hub PRC

Scope of support



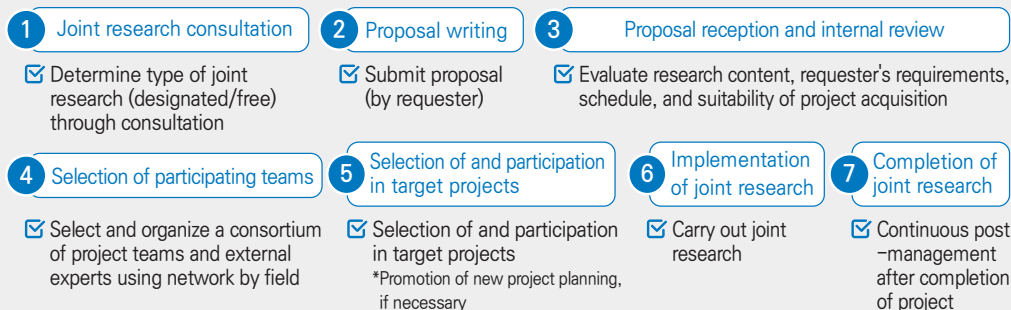
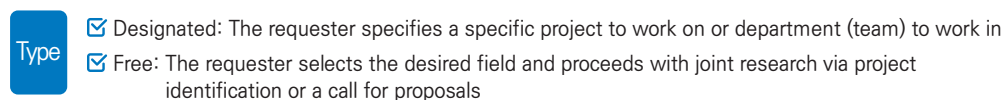
Content of main support



Technical services



Customized joint research



Contact information for Technical Services
Technical Analysis Support Team
Jungjoo Rhyu
Senior Researcher (DVM)
✉ rhyu@kmedihub.re.kr

Contact information for Customized Joint Research
Research Planning Team
Yunjeong Choe
Senior Researcher (Ph.D)
✉ yun0509@kmedihub.re.kr



Main Research Equipment of K-MEDI hub PRC

MRI
(Bruker 9.4T)



- Evaluation of tumors and brain diseases
- MRS
- Functional MRI
- Vascular imaging

OCT
(Abbott Medical)



- Evaluation of medical products for cardiovascular diseases
- Interventional procedures for cardiovascular diseases
- Evaluation of medical devices and drug candidates

IVIS Lumina K
(Perkin Elmer)



- Evaluation of new drug efficacy
- Biodistribution evaluation
- Stem cell tracking

IVIS spectrum-CT
(Perkin Elmer)



- Evaluation of new drug efficacy
- Phenotypic analysis of TG models
- Development of imaging probes
- Stem cell tracking

Micro-CT
(Quantum FX)



- Analysis of bone structure and density
- Evaluation of metabolic diseases
- Evaluation of pulmonary diseases

FMT4000MSIM
(Perkin Elmer)



- Evaluation of new drug efficacy
- Toxicity evaluation

Ultrasound
(Vevo 2100)



- Non-invasive imaging evaluation of cardiovascular and soft tissues

C-arm
(PROSTAR)



- Diagnosis and evaluation of vascular and orthopedic diseases through angiography

Fluorescence-guided imaging system (SPY)



- Support for fluorescence-guided surgery system
- Fluorescence imaging of large-animal blood vessels
- Visualization of lymph node images and tissue perfusion

DESI-Q-TOF
(Waters)



- Analysis of drug concentration in blood
- ADME research of drugs
- Measurement of distribution and concentration of drugs and metabolites in tissues

Utilization of Equipment from K-MEDI hub's Medical Device Development Center

Magnetom Skyra(3T)
(Siemens)



- Anatomical imaging
- Functional magnetic resonance imaging
- Diagnostic imaging techniques

Artis Zee Biplane System
(Siemens)



- Vascular imaging with contrast agent injection
- Interventional surgery with anti-cancer treatment
- High-resolution images of blood vessels
- Vascular surgery with use of catheter

PET/CT Scanner
(Siemens)



- Imaging of physiological and biochemical information in the body
- Anatomical imaging
- Evaluation of tumors, epilepsy, dementia, and other diseases



Support for Drug Development

Yonghyun Jeon

Principal Researcher (Ph.D)

✉ jeon9014@kmedihub.re.kr

⚙ Overall management of New Drug Evaluation Team

Tae-jun Kwon

Senior Researcher (Ph.D)

✉ tjkwon@kmedihub.re.kr

⚙ Overall management of Convergence Evaluation Team

Seonggon Kim

Senior Researcher (Ph.D)

✉ sgkim@kmedihub.re.kr

⚙ Overall management of Intermediate Research Team

Kwanghee Son

Researcher

✉ sonkh33@kmedihub.re.kr

⚙ Drug candidate efficacy evaluation and mediation research

Jae-eon Lee

Researcher

✉ koof12@kmedihub.re.kr

⚙ Drug candidate efficacy evaluation and mediation research

Bo-ra Lee

Researcher (Ph.D)

✉ damsmom68@kmedihub.re.kr

⚙ Drug candidate efficacy evaluation and mediation research

Sanghyun Kim

Senior Technician

✉ shkim@kmedihub.re.kr

⚙ Drug candidate pharmacokinetic experiments

Taeuk Park

Senior Technician

✉ tw3000@kmedihub.re.kr

⚙ Drug candidate pharmacokinetic experiments

So-young Jung

Technician

✉ jsy0126@kmedihub.re.kr

⚙ Drug candidate pharmacokinetic experiments

Evaluation of drug efficacy using animal models of human diseases

Disease	Indication	Evaluation model
Cancer	Breast cancer, Pancreatic cancer, Colorectal cancer, Liver cancer, Thyroid cancer, Kidney cancer, Prostate cancer, Brain cancer, Ovarian cancer, Blood cancer, etc.	Xenograft, Orthotopic transplantation, Angiogenesis, Metastasis
Inflammation/ metabolic	Inflammatory diseases, Osteoporosis, Arthritis, Obesity, Diabetes, etc.	Atopic dermatitis, Chemical-induced inflammation, CIA, OA, Diabetic obesity
Central nervous system/ cardiovascular system	Neurogenic pain, Stroke, Parkinson's disease, Dementia, etc.	Disease induction through chemical exposure and cell injection and gene transfer

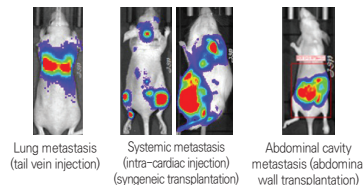
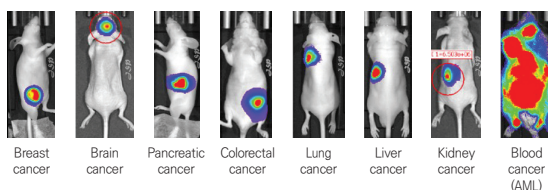
In vivo PK evaluation

- ✓ Support for drug pharmacokinetic testing and analysis (in mice, rats, dogs, etc.)
- ✓ Study of drug location and concentration within tissues using DESI-MSI

Preliminary non-GLP toxicity evaluation

- ✓ Drug toxicity evaluation (in mice, rats, etc.)
- ✓ Single-dose and two-week repeated-dose testing

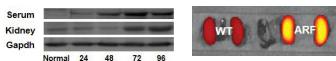
Construction of animal tumor models



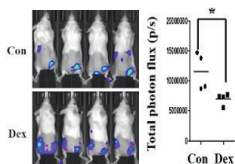
Orthotopic tumor model



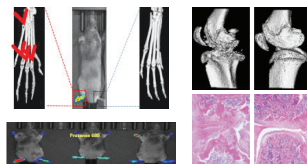
CSF drug concentration analysis



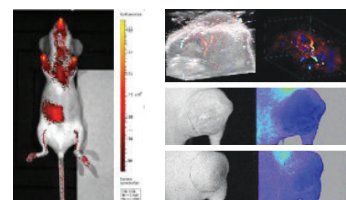
Drug kinetic studies (in small/medium animals)



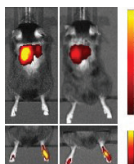
Toxicity evaluation using Kim-1 binding peptides



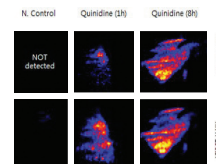
Metastasis model



PK evaluation with related jugular vein cannulation



Evaluation of vascular distribution and flow



Evaluation of anti-inflammatory and atopic dermatitis treatments

Evaluation of rheumatoid arthritis treatments

Evaluation of tissue cartilage injury models

Evaluation of inflammation treatments using immune cell tracking

Evaluation of drug and metabolite distribution within tissues



Support for medical device development

Sanghyun Ahn
Principal Researcher (Ph.D)
✉ ash4235@kmedihub.re.kr
⚙ Overall management of Medical Device Evaluation Team

Junsik Kim
Senior Researcher
✉ jskim@kmedihub.re.kr
⚙ Evaluation of medical device development and approval

Jongchul Kim
Senior Researcher (Ph.D)
✉ kjmjc7e@kmedihub.re.kr
⚙ Development and evaluation of medical devices for tissue engineering

Ryounghoon Jeon
Senior Researcher (DVM, Ph.D)
✉ rhjeon@kmedihub.re.kr
⚙ Development and evaluation of convergent/integrated medical devices

Mijin Jang
Researcher
✉ mijin22@kmedihub.re.kr
⚙ Development and evaluation of medical devices for skin diseases

Donghyun Lee
Researcher (Ph.D)
✉ donghyun@kmedihub.re.kr
⚙ Development and evaluation of medical devices for orthopedics and dentistry

Kyoungho Lee
Researcher
✉ leekh2211@kmedihub.re.kr
⚙ Development and evaluation of medical devices for 3D bioprinting

Yeon-seop Jung
Researcher (Ph.D)
✉ jys86170@kmedihub.re.kr
⚙ Molecular biology evaluation for medical device development

03 Support Field of K-MEDI hub PRC

Evaluation of medical device performance

- ☑ Performance evaluation of medical devices using experimental animals
- ☑ Performance evaluation of vascular access devices (stents, etc.)
- ☑ Development and evaluation of animal models
- ☑ Telemetry testing

Study Monitoring

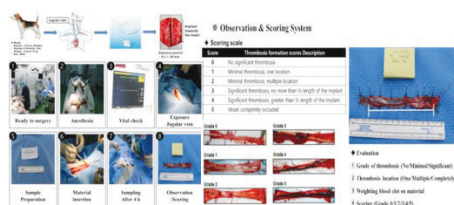
- ☑ Monitoring of approval testing evaluation
- ☑ Consulting on safety evaluation items
- ☑ Development and improvement of manuals/SOPs

Preclinical biological safety evaluation of medical devices

- ☑ Cell toxicity
- ☑ Hemocompatibility
- ☑ Irritation testing
- ☑ Leachables testing
- ☑ Sensitization testing
- ☑ Genotoxicity (chromosomal aberration, Ames test)
- ☑ Antimicrobial properties of materials
- ☑ Systemic toxicity (acute and sub-acute)
- ☑ Telemetry testing



Technical services and joint R&D support related to biomaterials and tissue engineering



Performance evaluation of IT-based medical devices (such as fat removal devices)

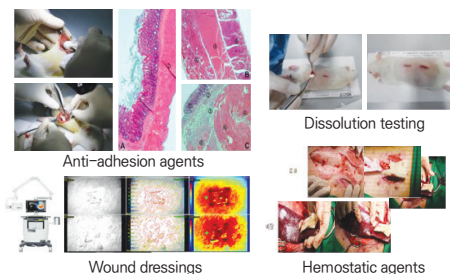


In-vivo hemocompatibility testing



Performance evaluation of coronary artery stents

Application and evaluation of medical devices in brain/neuroscience



Biomembrane performance evaluation



Support for evaluation and analysis based on bio-imaging

Hee-kyung Kim

Senior Researcher (Ph.D)

✉ hkkim@kmedihub.re.kr

- Overall management of Biomolecular Imaging Team and contrast agent synthesis

Hoesu Jung

Senior Researcher (Ph.D)

✉ junghs2000@kmedihub.re.kr

- Operation and analysis method development for 9.4T MRI and PET equipment

Dong-seon Kim

Researcher

✉ kds0433@kmedihub.re.kr

- Operation and analysis method development for 9.4T MRI and micro-CT equipment

Chang-hoon Shin

Researcher

✉ shinchoon@kmedihub.re.kr

- Evaluation of brain disease treatment and small animal behavioral experiments

Kyungrim Yi

Researcher

✉ lim2@kmedihub.re.kr

- Operation and analysis method development for micro-CT and IVIS equipment

Jun-young Choi

Researcher

✉ cjy4113@kmedihub.re.kr

- Efficacy evaluation of drug candidates and operation of IVIS equipment

Evaluation of efficacy and preliminary safety of medical products

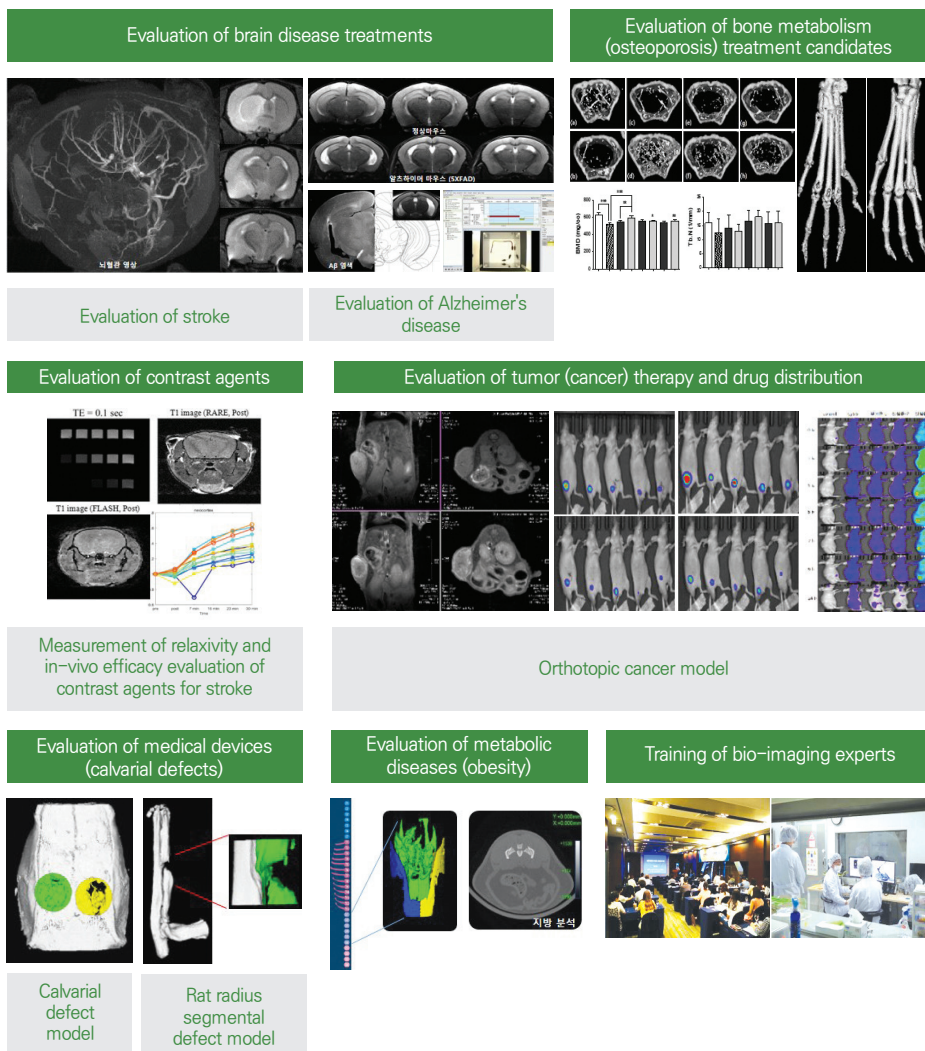
- ✓ Evaluation of brain disease treatments: utilization of 9.4T MRI and behavioral evaluation (object field, open field, avoidance, Y-maze) in animal models such as MCAO and 5XFAD
- ✓ Evaluation of metabolic disease treatments: creation of osteoporosis models in mice or rats and efficacy evaluation via micro-CT
- ✓ Evaluation of bone metabolism: creation of calvarial defect models and evaluation via micro-CT
- ✓ Support for imaging-based drug distribution evaluation
- ✓ Development and evaluation of imaging probes (contrast agents)

Construction of bio-imaging big data

- ✓ Construction of big data from MRI and CT images
- ✓ Development of reproductive toxicity assessment techniques based on big data

Training of bio-imaging experts

- ✓ Expansion of foundation for bio-imaging technology for domestic new drug development and cultivation of key personnel in the pharmaceutical industry
- ✓ Basic, advanced, and customized training





Support for surgical and veterinary technology

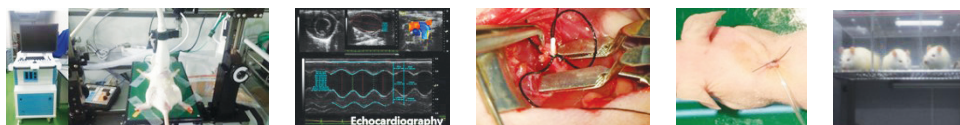
Provision of a platform for Efficacy Evaluation

- ✓ Creation and evaluation of animal models using surgical techniques
- ✓ Efficacy Evaluation of new drugs and medical devices using animal models
- ✓ Efficacy Evaluation of treatments for cardiovascular and cerebrovascular diseases (myocardial ischemia/reperfusion, limb ischemia, stroke, etc.)
- ✓ Efficacy Evaluation of treatments for specific diseases (osteoporosis, diabetic neuropathy, pain models, etc.)
- ✓ Efficacy Evaluation of stem cell therapies (rat myocardial ischemia/reperfusion, beagle bone defect animal models, etc.)

Veterinary management and support

- ✓ Enhancement of internal capacity for small animal surgical education
- ✓ Customized small animal surgical education for clients
- ✓ Clinical and nursing education and practical support utilizing experimental animals
- ✓ Programs related to veterinary medicine education and practical support

Cases of support



MCAO stroke model/vascular catheter insertion/DPN Von Frey test



Training and support for surgery education and practice

Facilities and equipment

- ✓ Surgical Rooms 1 and 2 (medium-sized animal/radiation-controlled areas): image transmission equipment, X-ray and C-arm, laparoscope (exploratory research equipment), SPY (fluorescence-based imaging equipment)
- ✓ Surgical Room 3 (small animals): microsurgery microscope (OPMI_PICO), high-frequency micro-imaging platform (Vevo2100)



Woori Jo
Senior Researcher (DVM, Ph.D)
✉ c2dar@kmedihub.re.kr
⚙ Overall management of Experiment Support Team and creation and evaluation of animal models using surgical techniques

Nahye Park
Researcher (Ph.D)
✉ pnh0211@kmedihub.re.kr
⚙ Creation and evaluation of animal models using surgical techniques

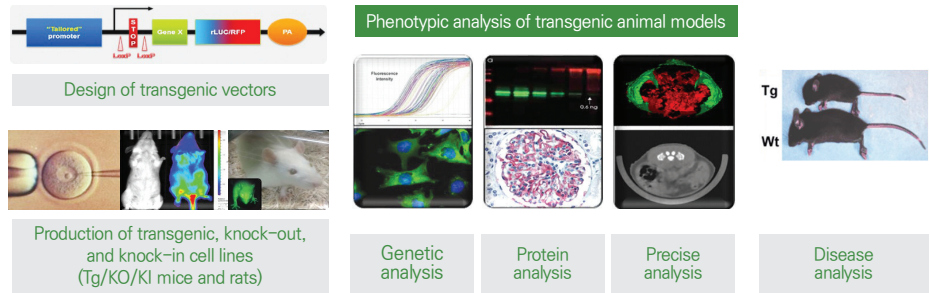
Yoonbum Lee
Technician
✉ lyb9009@kmedihub.re.kr
⚙ Creation and efficacy evaluation of disease models



Construction of customized animal models

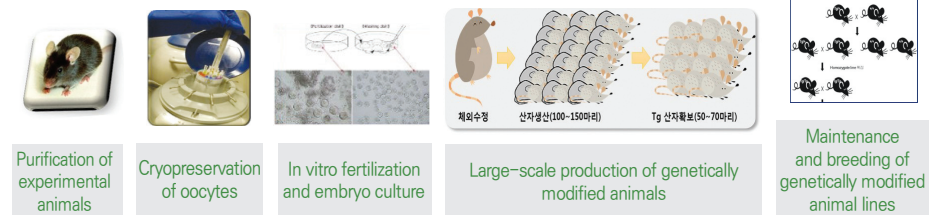
Transgenesis

- Utilization of gene editing techniques
- Design and validation of gene vectors
- Phenotypic analysis for disease modeling
- Production of transgenic/knock-out/knock-in cell lines, mice, and rats
- Large-scale production and efficacy analysis of transgenic animal models



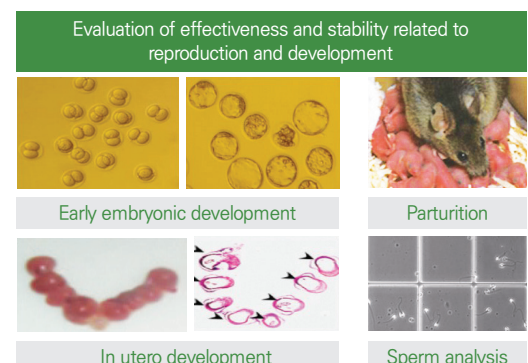
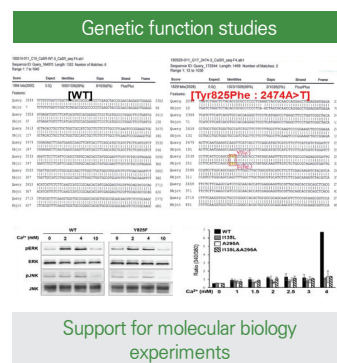
Quality control support for transgenic animal models

- Purification of imported animals and contaminated experimental animals
- Purification via embryo transfer
- In vitro fertilization for individual regeneration
- Cryopreservation of embryos and sperm
- Line breeding and management of transgenic animal models



Support for molecular biology experiments related to genetic studies

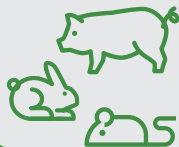
- Genetic analysis
- Performance of genetic function studies
- In vitro stability evaluation during embryonic development stages
- Evaluation of embryo development, implantation, and birth rates



Heeyoung Yang
Senior Researcher (Ph.D.)
✉ yhyang@kmedihub.re.kr
⚙ Support for animal model production and phenotype analysis

Yonghun Sung
Researcher (Ph.D.)
✉ yonghun20@kmedihub.re.kr
⚙ Support for animal model production and phenotype analysis

Dong-won Seol
Researcher (Ph.D.)
✉ seol@kmedihub.re.kr
⚙ Support for animal model production and phenotype analysis



Maintenance and management of experimental animal resources

Woori Jo

Senior Researcher (DVM, Ph.D)
✉ c2dar@kmedihub.re.kr
⚙ Center Manager, overall support for veterinary experiments

Gwanghoon Lee

Senior Researcher (DVM)
✉ ghl@kmedihub.re.kr
⚙ Attending veterinarian for preclinical center, monkey breeding and management, and experimental support

Taeku Kang

Technician
✉ tkang@kmedihub.re.kr
⚙ Breeding and experimental support for medium-sized animals

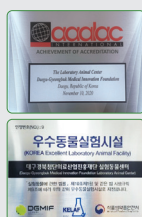
Hyeyoon Choi

Technician
✉ cromchy@kmedihub.re.kr
⚙ Breeding and experimental support for small animals

03 Support Field of K-MEDI hub PRC

Animal Resource Management and Support

- ☑ Management of experimental animals (small/medium-sized)
- ☑ Veterinary experimental support
 - Management of small sentinel animals
 - Inspection and health management of medium-sized animals
 - Health checkup for medium-sized animals twice a year
 - Support for monitoring (PAM) after IACUC approval twice a year
 - Support for environmental enrichment
 - Support for importation of experimental animals, access to animal facilities, and anesthesia training
- ☑ Monkey quarantine system
- ☑ Monkey breeding and experimental support



AAALAC-I accreditation since 2020

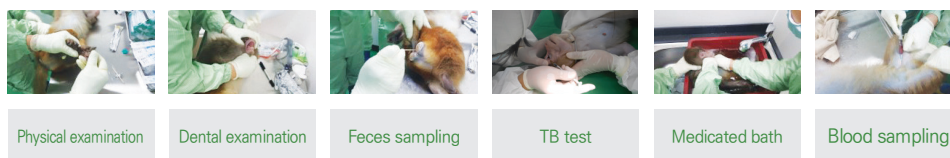
Designated as Korea Excellent Laboratory Animal Facility (KELAF) by MFDA since 2016

- ☑ Compliance with international guidelines for animal welfare and ethics in experimental animal management and use
- ☑ Ensuring reliability of experimental animal management
- ☑ Strengthening cooperation and support for industry-academia research
- ☑ Enhancing role as global partner in preclinical evaluation for medical product development

Animal breeding management

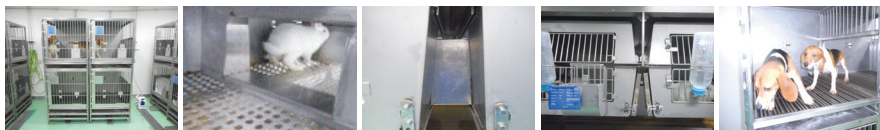


Monkey quarantine system



Support for veterinary experiments

- ☑ Behavioral and sociological management through group housing



- ☑ Support for environmental enrichment
- ☑ Playground for experimental animals

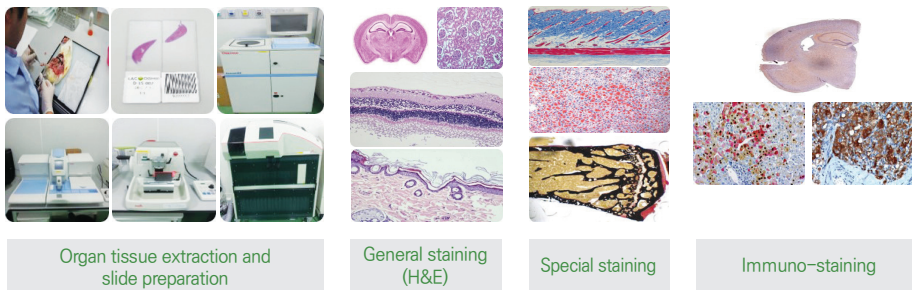




Pathological analysis and support for bioresources

Histopathology

- Autopsy
- Education
- Special staining
- Slide preparation
- Block preparation (paraffin, frozen)
- Immuno-staining
- General staining (H&E)
- Tissue fixation
- Interpretation



Organ tissue extraction and slide preparation

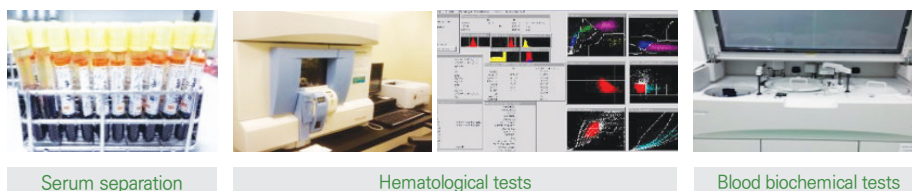
General staining (H&E)

Special staining

Immuno-staining

Clinical pathology

- Serum separation
- Blood biochemical tests (AST, ALT, and 22 others)
- Hematological tests (WBC, RBC, and 13 others)
- Urinalysis (10 types)



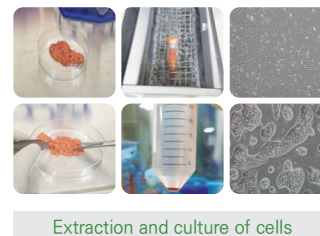
Serum separation

Hematological tests

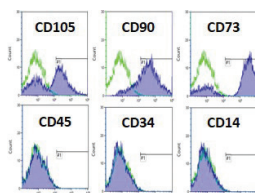
Blood biochemical tests

Bioresources (stem cells, etc.)

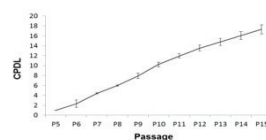
- Stem cell extraction and culture
- Extraction and culture of second-generation cells
- Analysis of cell surface antigen expression
- Evaluation of stem cell differentiation ability
- Efficacy evaluation and testing using sub-cultured cells



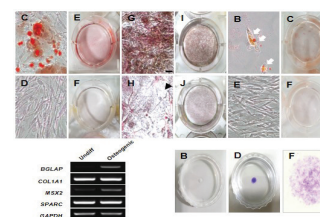
Extraction and culture of cells



Analysis of cell surface antigens



Confirmation of cell growth



Verification of cell differentiation ability

Kyung-ku Kang

Senior Researcher, DKSTP, DKVD (DVM)
✉ kangkk@kmedihub.re.kr
⚙ Overall management of Pathology Team

Soo-eun Sung

Researcher
✉ sesung@kmedihub.re.kr
⚙ Development and evaluation of bioresources (stem cells, extracellular vesicles)

Joo-hee Choi

Researcher (Ph.D)
✉ cjh522@kmedihub.re.kr
⚙ Development and evaluation of practical uses for bioresources (probiotics, exosomes)

Sijoon Lee

Researcher, DKSTP, DKVD (DVM, Ph.D)
✉ sjlee1013@kmedihub.re.kr
⚙ Histopathology and Clinical Pathology analysis

Minkyung Sung

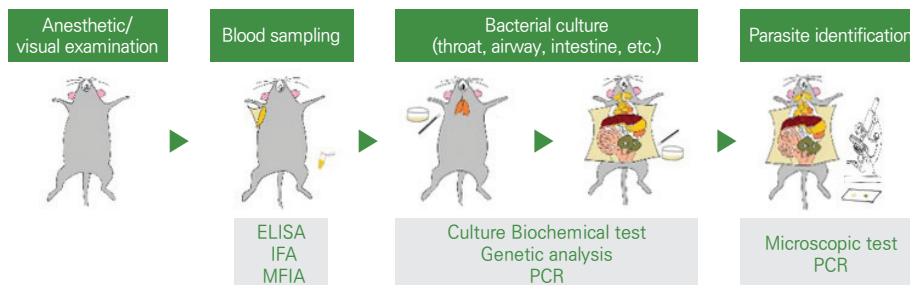
Technician
✉ tjdsrud27@kmedihub.re.kr
⚙ Histopathology and Clinical Pathology analysis



Health Monitoring

Health monitoring system(for mice, rats, rabbits, NHP, etc.)

- ☑ Serological tests: ELISA, IFA, MFI
- ☑ Molecular biological tests: PCR, qPCR
- ☑ Bacteriological tests: culture, biochemical pattern analysis, genetic sequence analysis
- ☑ Parasitological tests: naked-eye and microscopic examination
- ☑ Histopathological tests: H&E, special staining for lesion analysis



Consultation on health monitoring

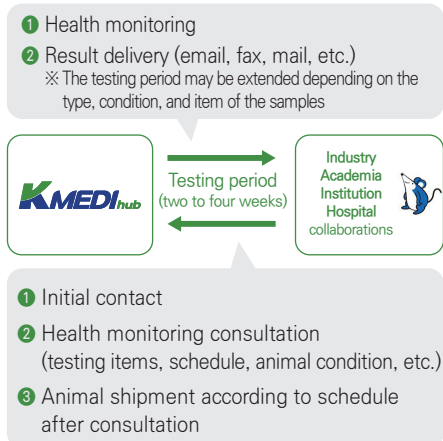
- ☑ Microbiological monitoring
- ☑ Quality control consulting and education
- ☑ Provision of disease information

Infrastructure for microbiological quality testing

- ☑ Facilities: Health Monitoring Rooms 1 and 2, Quarantine Room, Autopsy Room, and Biochemical Experiment Room



Health monitoring support process



Global-level cooperation network

- ☑ Participation in ICLAS, LAQN-PEP
 - International Council for Laboratory Animal Science (ICLAS)
 - Laboratory Animal Quality Network (LAQN)
 - Performance Evaluation Program for Diagnostic Laboratories (PEP)



ICLAS Certificate

- ☑ Accreditation of experimental animals health monitoring through improved technology and quality control

Eui-suk Jeong

Senior Researcher (Ph.D)
✉ jes9539@kmedihub.re.kr
⚙ Overall management of Health Monitoring Team

Se-kyung Oh

Researcher (Ph.D)
✉ osek1204@kmedihub.re.kr
⚙ Experimental animals quality control (health/environmental monitoring)

Minji Seong

Researcher
✉ minji19s@kmedihub.re.kr
⚙ Experimental animals quality control (health/environmental monitoring)

Hyejin Kim

Researcher
✉ khj428@kmedihub.re.kr
⚙ Experimental animals quality control (health/environmental monitoring)

Geumi Park

Researcher
✉ pg0929@kmedihub.re.kr
⚙ Experimental animals quality control (health/environmental monitoring)



Key Achievements of K-MEDI hub PRC

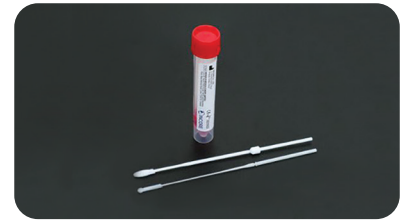


Preclinical Research Center

04 Key Achievements of K-MEDI hub PRC

Supported commercialization of Company I's COVID-19 sample collection kits

- ☑ Obtained CE certification in Europe, FDA certification in the United States, and NHS certification in the United Kingdom
- ☑ Provided first domestic support for overseas distribution
- ☑ Supported exports to 10 countries, including Canada and the United Kingdom



Supported commercialization of Company I's hemostatic surgical instruments

- ☑ Led localization of 100% imported products
- ☑ Obtained CE certification in Europe
- ☑ Increased sales and direct/indirect employment effects



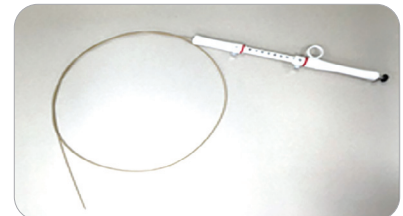
Supported Company D's periodontal tissue regeneration inducer

- ☑ Supported commercial launch
- ☑ Helped achieve superior performance verification compared to existing products
- ☑ Anticipated increase in demand due to aging population



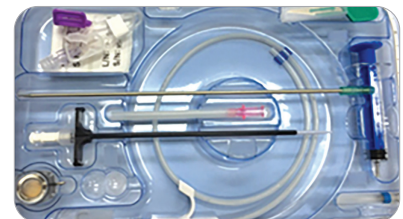
Supported domestic production of Company F's ultrasound-guided biopsy system

- ☑ Led localization of 100% imported product (approx. KRW 26 billion in global market)
- ☑ Obtained CE certification in Europe



Supported launch of Company I's chemotherapy port

- ☑ Domestic market size of approx. KRW 10 billion
- ☑ Import replacement effect
- ☑ Selected as representative achievement of R&D project by Daegu-Gyeongbuk Medical Innovation Foundation under Ministry of Health and Welfare



Supported commercialization of Company E's hemostatic gauze

- ☑ New sales revenue of KRW 4 billion
- ☑ Domestic market share of 50%
- ☑ Increased sales and direct/indirect employment effects

