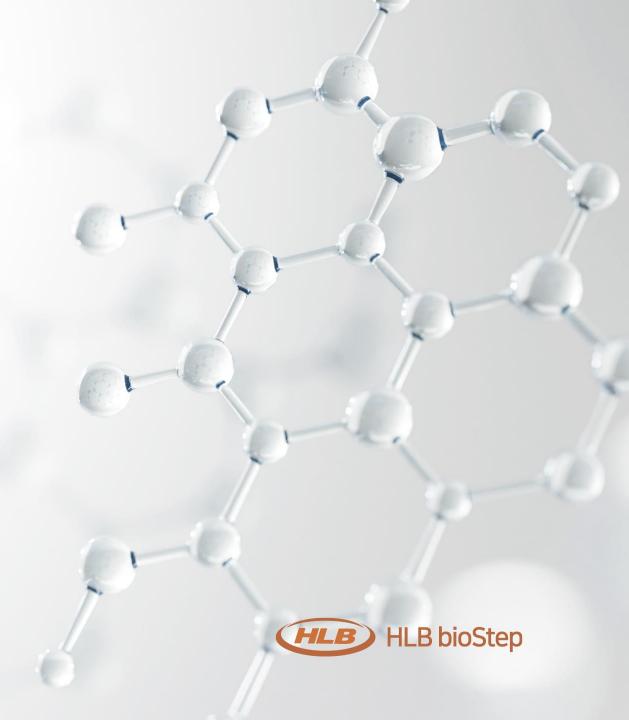
First Step to Success

HLB bioStep

Korea's No.1 Non-clinical CRO for Efficacy Studies





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O1. About Us



HLB bioStep

A leading Korean Non-clinical CRO in Efficacy Studies with a Veterinary Speciality

We offer services that cater to our clients' needs, utilizing our extensive experience in non-clinical testing and cutting-edge medical imaging equipment.

Since our inception in 2012, fueled by relentless research and a spirit of challenge, we have firmly positioned ourselves as the leading non-clinical CRO in efficacy testing, making significant contributions to the advancement of the bio industry in Korea.

Name	HLB bioStep Co., Ltd.
CEO	MOON Jeong Hwan
Founded	May 1, 2012
Capital	KRW 7.8 billion
Business	Non-clinical Service, LAB Consulting
Employees	170+
Location	38, Academy-ro 79beon-gil, Yeonsu-gu, Incheon, Korea



Division of Non-clinical Service (Headquarters)

Address	38, Academy-ro 79beon-gil, Yeonsu-gu, Incheon, Korea
Space	11,048.69m²
Facility	Rodent Room, Rabbit Room, Non-Rodent Room, Other Animal Room, Pharmacy, Biopsies & Pathology Room, Clinical Pathology Room, Stem Cell Incubation Room, Operation & Preparation Room, Air Conditioning Room, Feed Storehouse, Office Space, Conference Hall

Division of Bio-Infrastructure

Address	189, Donggureung-ro, Guri-si, Gyeonggi-do, Korea	
Space	4,481m²	
Facility	Office Space	





Growing into Korea's best non-clinical CRO specializing in efficacy studies



2016

Dec. 2016

May 2016 Created Lab

May 2016

Changed company name (KAMSI → KNOTUS)



2020 -2021

KOSDAQ

코스닥상장법인

Listed on KOSDAQ

2019

Nov. 2019

Mar. 2019

Songdo

Opened Lab in

Dec. 2021 Designated as an institution for clinical trials of animal drugs

Oct. 2021 Opened Medical Training Center

Sep. 2020 Designated as an institution for non-clinical trials of animal drugs



2023

2022

June 2022

Training

Mar. 2022

Acquired by

HLB Group

Medical Device

Center by Govn't

KKIDI

한국보건산업진흥원

Mar. 2023 Changed company name (KNOTUS → HLB bioStep)



Mar. 2023 Permitted Non-human Primate Facility

식품의약품안전처

2012

Apr. 2012 Registered lab animal facility

Apr. 2012 Founded

교육과학기술부

2015

May 2015.

Certified R&D center

2013

Feb. 2013 Licensed for LMO research facility

Acquired Saeron Bio and VS Pharm

Consulting Dept.

6



First Step to Success Korea's No.1 Non-clinical CRO HLB bioStep

Step 01



START
Leading clients to start
a new business

Step 02



STANDARD

The standard of

Non-clinical tests

Step 03



SECURITYThoroughly keeping the security of clients

Step 04



SUCCESS

Contributing to the success of clients

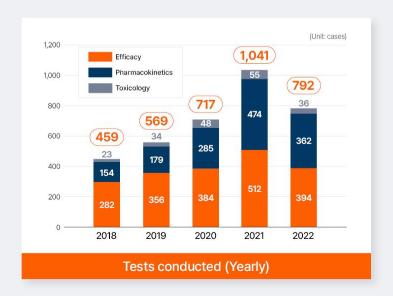
02. Non-clinical Services





Korea's No. 1 **Non-clinical CRO** in Efficacy testing

Maintaining a solid competitive edge by securing experience, professionals and high-tech equipment





Vast Experience

Most extensive experience in efficacy evaluation

Core competitiveness for Non-clinical CRO



Veterinarians

Responsible for implementation of the best test methods

Specializing in ophthalmology, surgery, veterinary pathology etc.



State-of-the-art Facility

Innovative laboratory and medical imaging equipment

Accurate analysis and diagnosis utilizing MRI, CT, X-ray etc.



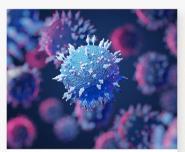
Large Animal Studies

High-level study with large animals

200+ per year

HLB bioStep

Securing accuracy and reliability of test results by using top-quality medical imaging equipment



Ability to produce disease animals



Veterinary care of disease animals



Differentiated services based on imaging equipment



Possessing diverse experimental capabilities, ranging from small to large animals

Boasting a Significant Number of Professionalsin Efficacy Evaluation

- Capable of conducting high-complexity efficacy evaluations that are challenging for other competitors
- 16% of research staff consists of veterinarians







Non-clinical Services

Efficacy Study

Cancer	XenograftSyngeneicOrthotopic
Bone Disease	 Monosodium Iodoacetate-induced OA (Osteoarthritis) Collagen-induced OA ACLT (Anterior cruciate ligament transection) + meniscectomy OA OVX (Ovariectomy)-induced osteoporosis Apolipoprotein E knockout (ApoE^{-/-} KO) mice
Neurologic Disorder	MCAO (Middle cerebral artery occlusion) modelThromboembolic infarctionAPP/PS1 TG mouse, 3xTg mouse
Endocrine & Metabolic Disease	 Ovariectomy (OVX)-induced climacterium db/db mouse (DM type II), STZ (Streptozotocin) model (DM type I) HF (High fat diet)/HCD (High cholesterol diet) induced hyperlipidemia
Ocular Disease	Dry AMD (Sodium iodate induced AMD)Wet AMD (Laser-induced choroidal neovascularization)Benzalkonium-induced dry eye

Liver Disease	 CCl₄-induced liver fibrosis model MCD diet-induced NAFLD model MDR2 knockout mouse liver disease model (Fibrosis, NAFLD)
Cardiovascula Disease	 Carrageenan-induced paw edema Hepatectomy or splenectomy induced hemorrhage model TAC (Transverse aortic constriction) model
Other Disease & Disorder	 Dentistry (Periodontitis) Gastrointestinal (Constipation, IBD colitis) Alopecia (Dexamethasone, DHT, Stress, Testosterone inducement) Kidney (Renal failure, Renal fibrosis) Skin (Atopic dermatitis, Burn wound, Lacerated wound)
In vitro	 Oncology Immunology Research Metabolic Health Skin care Neurology Customized in vitro experiment service



Non-clinical Services

Pharmacokinetics / Toxicology

Pharmacokinetics Studies

- In-vivo ADME studies of clinical candidates
- Various in-vivo ADME studies
 (Dog, Rat, Mouse, Rabbit, Miniature pig, etc.)
- · Customized study design as per client's needs
- Providing analysis service of substances and metabolite in plasma, urine, feces
- Providing analysis service of Biological sample analysis including method development and validation

Non-GLP Toxicology Studies

- Single-Dose General Toxicity Studies: Various species (Dog, Miniature pig, Rabbit, Rat, Mouse and etc.)
- Repeat-Dose General Toxicity Studies: General Toxicity Studies including DRF, MTD, etc.
- Local Tolerance Studies: Skin Irritation, Irritation of ocular mucous Membrane, etc.
- Other Toxicity Studies: Antigenicity, Skin Sensitization, Phototoxicity Studies

Pathology

Pathology

- · Tissue collection, Necropsy tissue fixation, Decalcification, Trimming
- Paraffin embedding, Sectioning, Cryosectioning, Serial Sectioning, Staining
- Interpreted by pathologist, Peer review
- Evaluated and interpreted by pathologist; provide a peer review

Clinical Pahtology

- Hematology and differential counts (Measure CBC, WBC, PLT and Reticulocyte count, etc.)
- · Coagulation tests (PT, APTT, Fibrinogen)
- Blood chemistry test (General List: TP, AL, B, AST, ALT and other parameters related to efficacy (e.g., HbA1c))
- Urinalysis Statistical analysis services
- Hormone tests









Non-clinical Services

Biological Analysis

Bioanalytical Mass Spectrometry Services

- Small molecules
- Biotherapeutics
- Peptide
- Fusion peptide
- Biomarkers

Bioanalysis Service

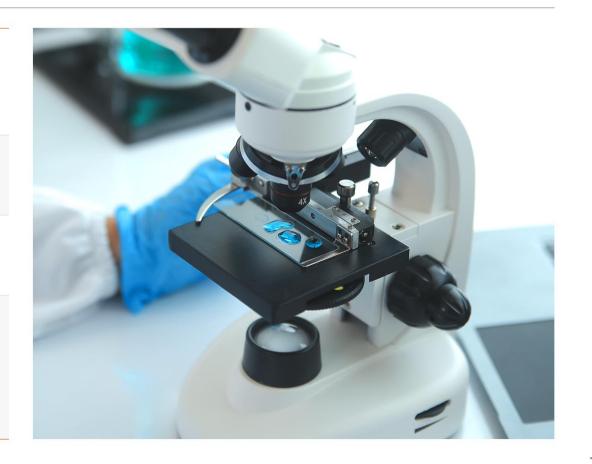
- DMPK ADME Studies
- Non-GLP TK (Toxicokinetics) Studies
- Analytical Method Development and Validation Studies

Bioanalytical Molecular analysis Service

- Protein : Western Blotting, ELISA, ELISPOT
- Gene : PCR, Real-Time RT-PCR

Bioanalytical Flow cytometry analysis Service

- Cell phenotyping and immunophenotyping analysis
- Immune Cell activation and response analysis
- Cell Cycle Analysis
- Cell proliferation
- Cell analysis assay
- ROS assay
- Cytometric Bead Array



03. LAB Consulting



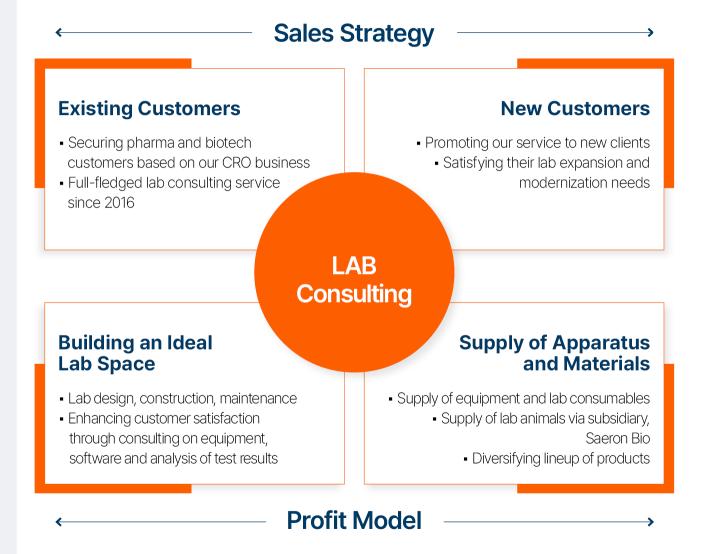


Service Expansion from Non-clinical to Lab Consulting

Expanding business with accumulated experience and know-how of building lab facilities

Expertise in designing optimized layouts for each lab

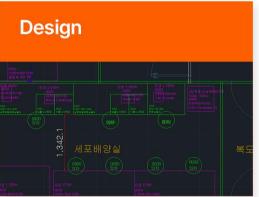
Providing equipment solutions tailored to the customer's needs





One Stop Service - Optimized Laboratory Design, Maintenance, and Equipment Supply









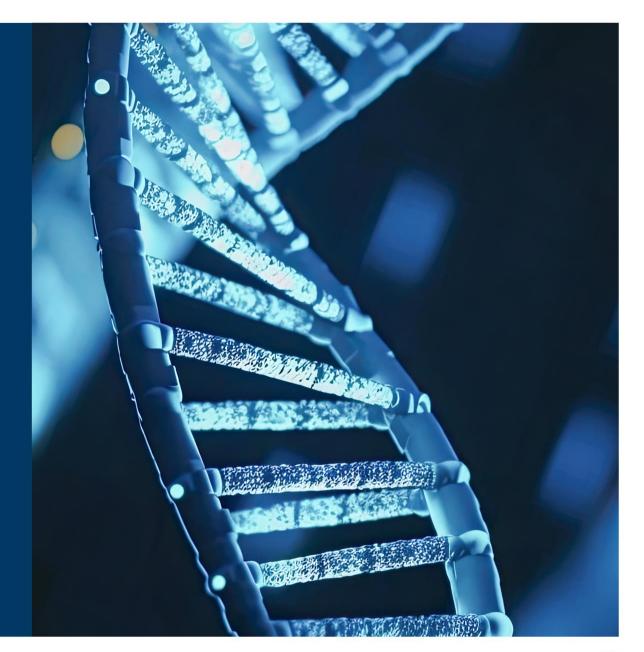








04. New Growth Engine





Business Structure that Evolves Alongside the Growth of Our Clients

Investment in bio firms developing medicines, vaccines, diagnostic instrument, veterinary drugs etc.











Veterinary Drug Development Cooperation

HLB Life Science - Medicine for mammary tumor in dogs

→ KFDA Approval(2022). Clinical trial in progress

Inventage Lab – Long-Acting Injection

- ✓ Collaborative development of dog heartworm medicine (Lasting for 3 months)
 - → Product Launched in 2022

NEXT BIOMEDICAL - Endoscopic Hemostat (Nexpower)

- ✓ Provided non-clinical services
 - → FDA Approval in 2022

3D MediVision - Educational Surgery 2DHD/3D Videos

- ✓ Cooperation in the production of surgical training videos for vets
 - → Utilizing our advanced medical equipment, facilities, and expertise



Bioanalysis Services

- Newly opended Bioanalysis Center (Nov. 2023)
- Supporting DMPK/ADME studies, Non-GLP TK(Toxicokinetics) studies, Analytical Method Development and Validation studies etc.
- Strengthening sales performance, attracting new customers, and enhancing customer trust

mRNA Evaluation Model

- Rapid growth of mRNA vaccines and therapeutics market post Covid-19
- Has a method to verify the effectiveness of gene therapy in the body
- Preemptive development of efficacy evaluation technology in line with the latest drug development trends

Alternative Assessment

- Development of human cell-based organoid evaluation system (Under joint research with HLB Cell Co.,Ltd)
- Expansion to artificial tissues/organs, cell processing, organ-on-a-chip, etc.
- Finding ways to produce the best results while minimizing animal testing

Non-human Primates

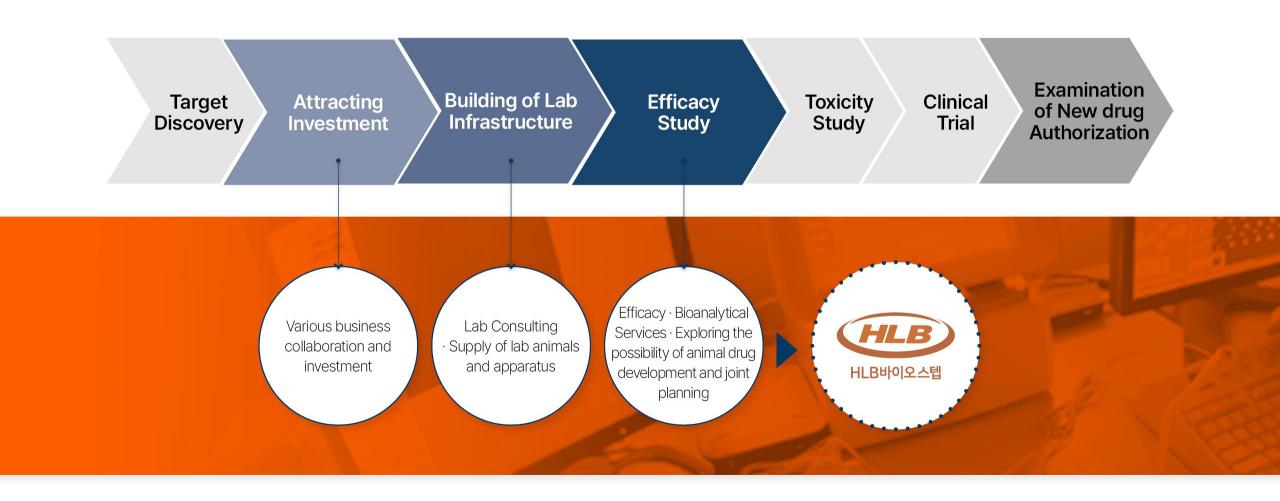
- Non-human Primate research facility approved by Ministry of Environment (Mar. 2023)
- Full portfolio of efficacy test covering from small animals to non-human primates

Expansion of Overseas Customers

- Conducted efficacy studies for Covid-19 for companies in the US and France
- Started a project for Eleva Therapeutics(US) in 2023
- Increasing sales and entering global markets through the expansion of overseas clients

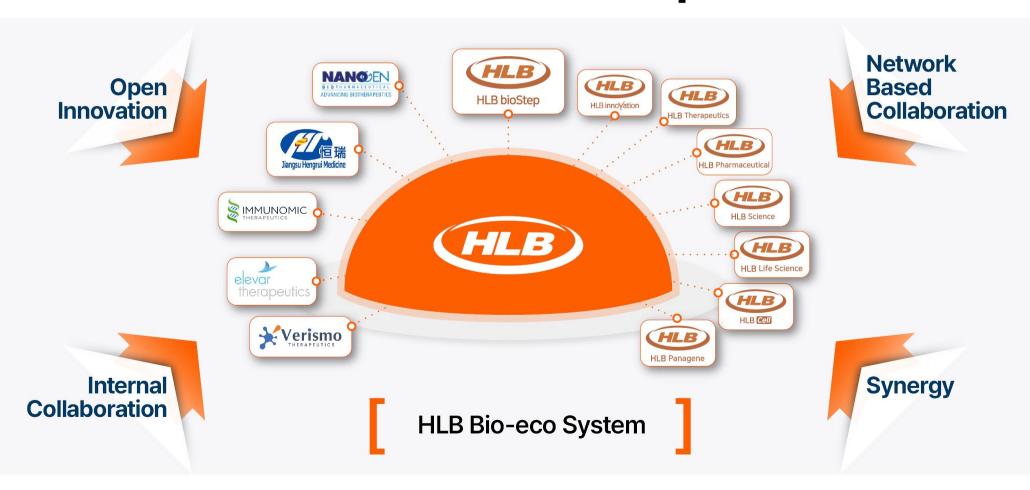


Business Expansion Platform





Expanding Business Synergy through Collaboration with HLB Affiliate Companies





Our Clients



"First Step to Success"



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