Dynamic and Innovative Growth
Biomedical Regulation-Free Zone Operating System

In vivo diagnostic devices

Difficulty in obtaining specimens (AS-Is)

Difficulty in obtaining specimens

- Idea conceived and product designed by an enterprise
- Take advantage of a central or local government project
- Joint research by the enterprise and a government-funded R&D institute

Need diverse types of specimens

1. Individual researchers
2. Joint research with hospitals
3. Utilization of the Korea BioBank (for research purposes only)

- Use for internal research purposes
- Specimens requested by enterprise (x)
- High-quality specimens (x)
- Time-consuming

Difficulty in pioneering sales channels

New health technology evaluation

1. Entry first, evaluation later
2. Complex evaluation
3. Pilot project on infectious diseases

- Time-consuming
- Clinical research paper necessary
- Cooperation with hospital not possible
- Difficulty in sales
- Recognition of pilot project on infectious diseases (X)
- Law on expanded application to in vivo diagnostic devices (X)

Idea and product design	Clinical performance verification and prototype production	Clinical efficacy verification	Clinical trial	MFDS approval	New health technology certification	Utility verification	Marketing
Basic research	Research for commercialization		Approval			Sales & Marketing	

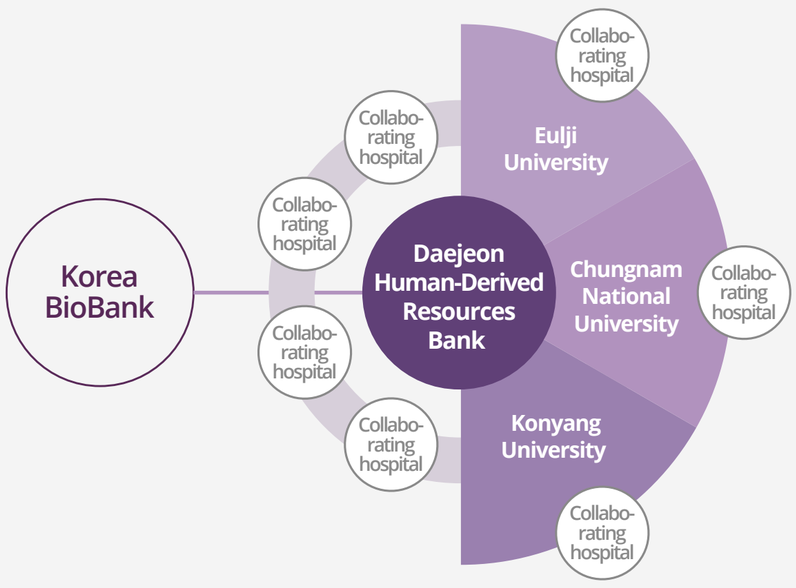
Platform for quickly obtaining specimens (To-Be1)

R&D consulting · Fast provision of specimens · Approval and clinical coordination · Verification of utility for the target disease by the hospital · Utilization in RWD evaluation · Market engry

Development and demonstration of in vivo diagnostic device based on the platform for quickly obtaining specimens

Special Case on Joint Operation of the Korea BioBank (articles 41 and 43 of the Bioethics and Safety Act)

- Secure necessary (target) specimen
- Boost the development of new technology
- Swift clinical trial process
- Enhance cooperation with hospitals



Fast track development and verification of in vivo diagnostic devices

Article 3 of the Rule on New Health Technology Evaluation

1. Fast confirmation of utility
2. Fast verification of market entry
3. Relaxation of regulations

New drugs, vaccines, etc.

Difficulty in utilizing pathogens (As-is)

Lack of research facilities that utilize pathogens

Hospitals

Lack of opportunities to gain R&D capacity related to pathogen treatment agents

Enterprises

Difficulties in developing new drugs due to the lack of research facilities that utilize pathogens

Difficulty in buying pathogens

Lack of opportunities for joint new drug development

1. Difficulties in buying and utilizing pathogen resources
2. Difficulties in carrying out related basic research and pre-clinical trials

Lack of environment for early commercialization based on preemptive R&D

Discovery and optimization of drug candidates	Inquiries on efficacy and safety	Checking efficacy and safety	Apply for MFDS approval / NHIS registration and approval	Safety monitoring and prescription
Basic research	Preclinical trial	Phase 1 to 3 clinical trials	MFDS review and approval for sale	Sales and post-marketing surveillance

Preemptive R&D (To-Be2)

Early commercialization of treatment agents using research facilities for shared use of pathogen resources

Research facilities for shared use of pathogen resources

Clean animal lab		Pathogen resources storage
Breeding lab	Negative-pressure room	
BL-3 lab	BL-3 lab	BL-3 lab / ABL-3 lab

BL-3 Lab

- **Articles 22 and 23 of the Infectious Disease Control and Prevention Act**
- **Article 14 of the Act on the Promotion of Collection, Management, and Utilization of Pathogen Resources**
- **Article 22 of the Transboundary Movement, etc. of Living Modified Organisms Act**

1. Installation of shared research facilities at a pathogen resources bank
2. Approval of sales of pathogen resources and high-risk pathogens to enterprises
3. Approval for enterprises to bring in pathogens
4. Approval of development of and experiments on genetically modified organisms
5. Faster approval of genetically modified organisms