Korea's Strategy for NAMs Adoption:

Harmonizing Regulatory Science and Innovation

In-Sook Park
Korea Regulatory Science Center
Republic of Korea

insook.park@k-rsc.or.kr

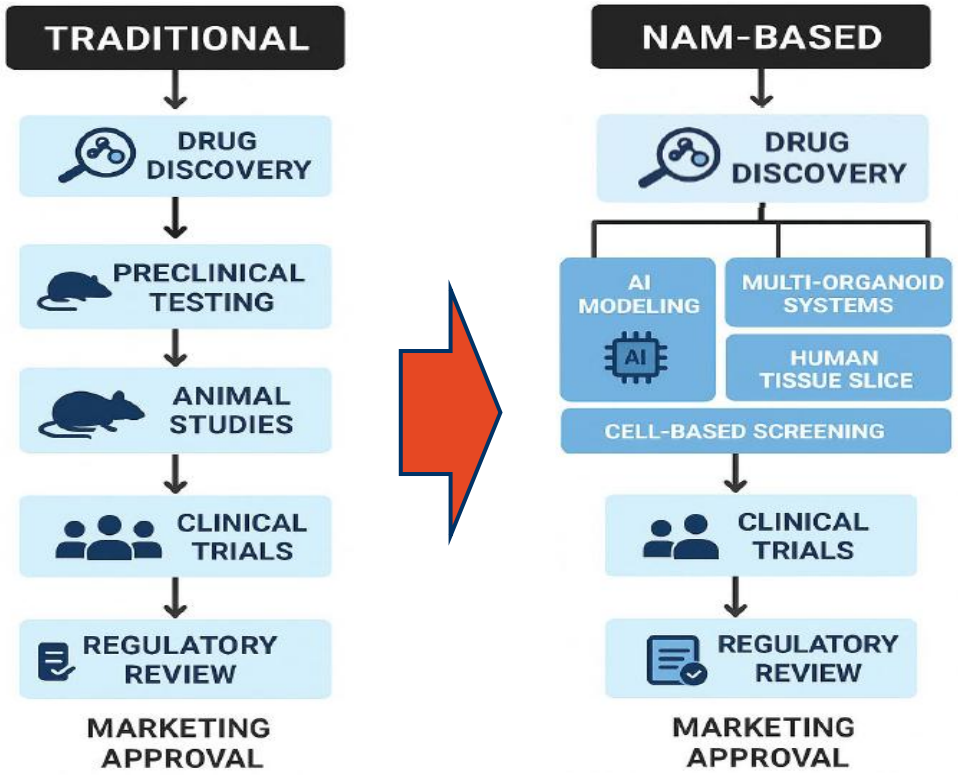
NAMs: A Paradigm Shift in Regulatory Science

Core Shift: From 3Rs to High-Tech Predictive Models	
Traditional Approach (3Rs)	✓ Focused on minimizing or refining animal use
New Approach Methodologies (NAMs)	✓ Focused on maximizing **human relevance, predictive accuracy, and efficiency**
Global Goal	✓ Establishing a new safety assessment system that is **ethical, faster, and more scientifically robust** than traditional animal testing

Korea's Strategic Focus

To leverage our strength in biotechnology to drive this regulatory transformation and secure global competitiveness in the biopharmaceutical industry

Restructuring the Non-Clinical Ecosystem



Why a Systemic Restructuring?

- ✓ Limitation of Traditional Models
- ✓ NAMs Imperative
- ✓ Goal: A predictive, human-centric ecosystem

Key Enablers in Korea: Advanced Research & Collaboration

- **Advanced Technology**

  Focus on developing and standardizing **Organoids / Organ-on-a-Chip** models for superior, human-relevant toxicity assessment.

- **K-Consortium Model**

  Establishing a robust **Public-Private-Academic-Research partnership** to build **standardized NAMs infrastructure and protocols**, ensuring research quickly translates to industrial application.

- **Regulatory Acceptance**

  Ensuring NAMs data is accepted for regulatory decisions

Success Story 1:
Driving Change Through Policy and Legislation (1)

➢ Mandatory NAMs Use: The Cosmetics Act

- ✓ **Policy Success:** South Korea banned the use and sale of cosmetics and ingredients tested on animals (effective 2017).
- ✓ **Impact:** This legal mandate successfully pushed the cosmetics industry to fully transition to **OECD Test Guidelines (TGs)**-listed alternative methods (e.g., for skin irritation, eye irritation).
- ✓ **Significance:** Demonstrates a **strong regulatory commitment** to ethical science through legal enforcement.

Success Story 1:
Driving Change Through Policy and Legislation (2)

➢ **The Legal Framework for Future NAMs**

: The "Alternative Test Methods Promotion Act (Draft)"

✓ **Status:** Currently under legislative review.

✓ **Goal:** To provide the **legal definition and framework** for the development, validation, and acceptance of NAMs across **all regulatory sectors** (MFDS, chemical safety, etc.)

✓ **Significance:** Secures a **powerful, government-led implementation foundation** and ensures **legal stability** for NAMs adoption.

Success Story 2: Regulator-Driven Infrastructure

➢ Validation Infrastructure: KoCVAM

: Korean Center for the Validation of Alternative Methods (KoCVAM)

- ✓ **Role:** The national expert body responsible for the **scientific validation and standardization** of all alternative test methods.
- ✓ **Global Link:** Ensures Korean-developed NAMs are aligned with international standards (OECD TG, ICATM) for global acceptance

Success Story 3: Core Drivers
Advanced Technology and Collaboration Models

➢ Innovation

- ✓ Investing in next-generation NAMs (Organoids, AI) through collaborative models

➢ Focus on Cultivating Technological Strengths

- ✓ Organoids and Organ-on-a-Chip (OOC): Utilize human-derived cell bases and mimic the in vivo environment to provide high predictive accuracy.
- ✓ AI-based Toxicity Prediction: Leverage Big Data and Machine Learning to increase the efficiency of toxicity evaluation in the early stages of drug development.

➢ K-Consortium Model (Industry-Academia-Research-Government Cooperation)

- ✓ Goal: To establish a standard NAMs infrastructure to ensure that research results can be rapidly applied by the industry.
- ✓ Effect: Minimizing the gap between technology development and regulatory approval to secure NAMs industrial competitiveness.

Innovation : Korea National Program for Standardizing Organoid-Based Non-Animal Testing Methods (1)

➢ Purpose of the program

- ✓ Develop and standardize organoid- and microphysiological system (MPS)-based non-animal testing methods for regulatory use in drug safety assessment.
- ✓ Strengthen scientific reliability, reduce animal use, and align with global NAMs (New Approach Methodologies) trends

➢ Program Overview

- ✓ 5-year national R&D program developing organoid/MPS-based non-animal test methods
- ✓ 8 integrated projects: 7 organ-specific + 1 AI-based
- ✓ Coordination system ensuring governance, quality control, and regulatory alignment

Innovation : Korea National Program for Standardizing Organoid-Based Non-Animal Testing Methods (2)

➢ Key Activities

- ✓ Development and optimization of organoid/MPS-based toxicity test models across major organs.
- ✓ Establishment of standardized SOPs, reference materials, data quality criteria, and reproducibility frameworks.
- ✓ AI-driven prediction model development using organoid-based toxicology datasets.

➢ International Collaboration & Standardization

- ✓ Collaboration with OECD, ISO, and global research/regulatory bodies to prepare future Test Guideline (TG) and Detailed Review Process(DRP) submissions.
- ✓ Hosting international conferences and technical seminars to strengthen Korea's global NAMs presence.

➢ National Impact

- ✓ Builds a unified ecosystem linking academia, industry, and regulators.
- ✓ Enhances Korea's competitiveness in next-generation safety testing and positions the country as a global NAMs hub.

Success Story 4: Regulator-driven Transformation

- Animal Free Routine QC Testing in Biologics
- Regulator-driven initiatives to update core national standards

Total project budget

- ✓ 8.59M USD MFDS funding in cash
- ✓ This project has received funding for 5 years (‘25~’29) from MFDS under grant agreement

Participants

- ✓ Academia, Public institutions, Bio-pharmaceutical associations
- ✓ Botulinum and DTaP Vaccine manufacturers performing quality control of lot release
- ✓ Foreign national control laboratories

Objectives

- ✓ Provide sound evidence on which alternatives for animal testing for routine lot release testing of approved Botulinum and DTaP vaccine products can be based.

Expected results

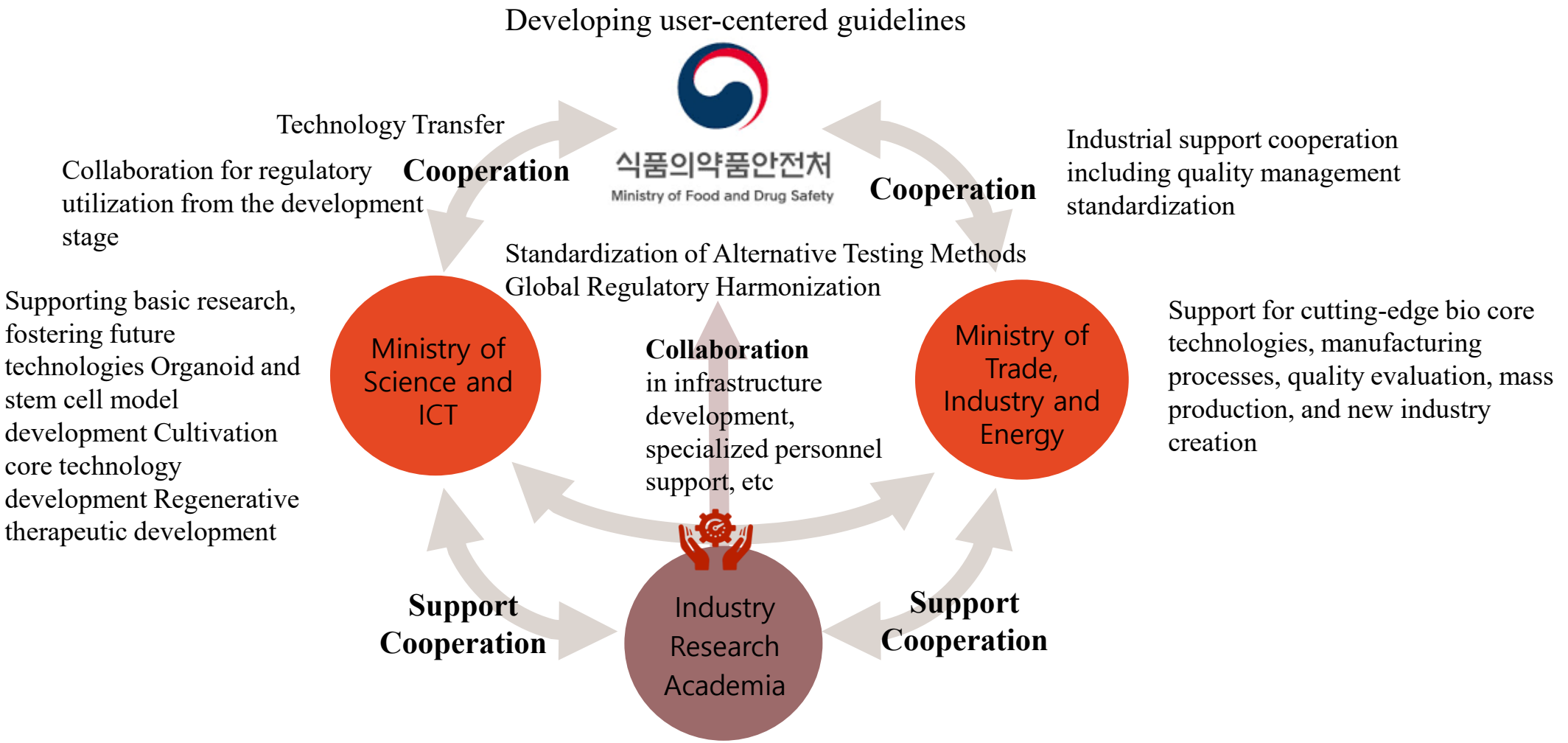
- ✓ Revise Specifications and Test Methods for Biologicals
- ✓ Change animal potency testing into in vitro testing for manufacturers’ batch release and MFDS’ national lot release of Botulinum and DTaP Vaccine products

MFDS's Project Direction for Promoting Alternative Animal Testing Methods for Regulatory Application

➢ Introduction of a New Approach Method (NAMs) Eligibility Assessment System Utilizing Advanced Technologies

<table>
<tr><td rowspan="2">Bio Advanced Technology Utilization Toxicity Testing International Standardization Leadership</td><td colspan="2">Promoting the Development and Practical Application of Internationally Harmonized Toxicity Tests</td></tr>
<tr><td colspan="2">Pursuing listing in internationally recognized test methods such as those of the OECD and ISO</td></tr>
<tr><td></td><td colspan="2">Establishing a Collaborative Framework for Standardization Research to Promote the Practical Application of Advanced Toxicity Testing in Korea</td></tr>
<tr><td rowspan="4">AI-based toxicity, efficacy, quality assessment and prediction technology acquisition</td><td>Biomarkers</td><td>Organoids, biochips, etc</td></tr>
<tr><td>Clinical Evaluation</td><td>Development of AI-Based Immunogenicity and Toxicity Prediction Technology</td></tr>
<tr><td>In Silico Evaluation</td><td>Development and Validation of Biological Mechanism Models Using In Silico Models (PBPK, QSP)</td></tr>
<tr><td>Disease Animal Verification</td><td>Toxicity Effect Verification</td></tr>
</table>

Domestic Cooperation Model in Korea



Conclusion;

Accelerating Innovation and Global Standard-Setting

◆ Key Takeaways from the Korean Strategy

- ✓ **Policy:** Creating a mandatory legal environment for NAMs acceptance (Cosmetics Act / NAMs Act).
- ✓ **Infrastructure:** Operating a credible, centralized validation body (KoCVAM).
- ✓ **Innovation:** Investing in next-generation NAMs (Organoids, AI) through collaborative models (K-Consortium).
- ✓ **Transformation:** Regulator-driven initiatives to update core national standards (Botulinum Toxin CBA).

◆ The Future Outlook

- ✓ South Korea is committed to leveraging NAMs to achieve global standards, secure public trust, and **lead the harmonization of ethical, efficient regulatory science** worldwide.

Thank You