

FOR IMMEDIATE RELEASE

CMIC Partners with the Japanese Society for Inherited Metabolic Diseases to Address “Drug Loss” in Japan

Collaboration aims to accelerate development and availability of therapies not yet approved in Japan

TOKYO, Japan — October 8, 2025 — CMIC Co., Ltd. (Headquarters: Minato-ku, Tokyo; President: **Shunji Katayama**), a group company of **CMIC Holdings Co., Ltd.** (Headquarters: Minato-ku, Tokyo; President & CEO: **Kazuo Nakamura**), today announced a service agreement with the **Japanese Society for Inherited Metabolic Diseases** (Headquarters: Chuo-ku, Tokyo; President: **Kimitoshi Nakamura**). Through this collaboration, CMIC and the Society will encourage emerging—primarily overseas—biopharmaceutical companies to pursue drug development in Japan, helping to resolve the growing problem of “**drug loss**” (therapies approved abroad that remain unavailable domestically).

The Need: Tackling “Drug Loss” and “Drug Lag”

Japan faces two persistent access challenges:

- **Drug loss**—medicines receive approval in other countries but are not developed or filed in Japan.
- **Drug lag**—the timing of Japanese approvals significantly trails those abroad.

A major driver is that many innovative medicines are now advanced by smaller, overseas biopharma companies without a base in Japan. Limited familiarity with Japan’s regulatory pathways, perceived complexity, and costs often deter inclusion of Japan in global development plans. These hurdles are **especially acute in rare and intractable diseases**, where unmet need is high and, once drug loss occurs, it becomes difficult to reverse.

What the Partnership Will Do

Under the agreement, CMIC and the Society will establish a practical, clinician-informed framework to close these gaps:

- **Identify & Prioritize Needs:** With the Society’s cooperation, CMIC will **investigate therapies already affected by drug loss and pipeline candidates at risk**, focusing on rare and inherited metabolic diseases.
- **Surface Japanese Clinical Insights:** CMIC will **synthesize scientific, clinical, and care-delivery perspectives** from Japan’s medical community—insights that may be under-recognized by overseas developers due to the rarity of these conditions and the limited number of domestic specialists.
- **Engage Global Innovators:** Based on these findings, CMIC will **proactively approach overseas biopharmaceutical companies**, sharing Japan-specific evidence and guidance to support



feasibility planning, trial inclusion, regulatory strategy, and ultimately **Japan market entry**.

This initiative reflects CMIC's ongoing commitment to **bridging global innovation and Japan's healthcare needs**. By leveraging CMIC's deep expertise in clinical development and the Society's network of medical specialists, the partnership seeks to make Japan a more accessible and attractive market for innovative therapies—particularly for patients with rare and inherited metabolic diseases.

■ About the CMIC Group

CMIC launched Japan's first CRO (contract research organization) business in 1992, and now provides comprehensive pharmaceutical-related support services, covering the entire process from drug development and manufacturing to sales and marketing. CMIC also assists overseas companies in entering the Japanese market in fields such as pharmaceuticals, biotechnology, and medical devices, and supports the implementation of clinical trials in Asia as well as drug development and manufacturing in both Japan and the United States. In addition, CMIC offers new healthcare solutions that support individuals and local governments. Building on its extensive experience and track record in providing comprehensive support for the entire pharmaceutical value chain, CMIC aims to expand its PHVC (Personal Health Value Creator) business model, which seeks to "maximize the health value of each individual." The CMIC Group comprises more than 7,500 employees and 27 group companies worldwide. For more information, please visit our website: <https://www.cmicgroup.com>

■ About the Japanese Society for Inherited Metabolic Diseases

For more information, please visit the Society's website: <https://jsimd.net/>

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