

## Press Release

**CMIC Introduces UltraIntake, a New Tool to Streamline Drug Safety Information Management**

CMIC Co., Ltd. (headquarters: Minato-ku, Tokyo; President and CEO: Akihisa Mitake; hereafter, CMIC) announces the introduction of UltraIntake, a new automation tool designed to enhance the efficiency of drug safety information management, or pharmacovigilance (PV). Services using UltraIntake for pharmaceutical companies are scheduled to begin in March 2025.

UltraIntake was developed by an Indian IT systems consulting company, Ultragenic, and has been jointly designed by CMIC and Ultragenic as a system that complies with Japanese pharmaceutical development regulations and domestic specifications. This collaboration with Ultragenic marks the first such initiative by a domestic contract research organization.

**Background**

PV operations have seen a yearly increase in workload due to the extensive manual processing required for reports received from diverse information sources and in various formats, including PDF, Excel, and text files. Additionally, amid growing interest in IT and robotic process automation solutions that automate operations, there is a demand for business transformation, improved efficiency, and cost reduction.

To address these challenges, CMIC will provide services using UltraIntake, a tool that automates portions of the workflow from report reception to regulatory submissions in pharmaceutical companies' PV departments. UltraIntake can be flexibly customized according to companies' needs and operational scale. The system supports not only pharmaceutical clinical trials but also regenerative medicine products and medical device trials.

Through the implementation of UltraIntake, CMIC aims to reduce work hours and costs in PV operations while maintaining quality standards, addressing a wide range of challenges faced by pharmaceutical companies.

**Key Features of UltraIntake**

- **Diverse information sources:** Automatically imports information from different systems such as medical representatives, call centers, and social media in a variety of formats, including PDF, XML, Excel, and text files.
- **Reduction in work hours and manual labor:** Converts and automatically imports information from various sources and formats into databases.
- **Various automation solutions:** Enables automatic PDF import of CIOMS forms (the domestic and international standard format for sharing adverse event information), web-based input reception from doctors and medical representatives, and creation of XML files for regulatory reporting.
- **Support for regenerative medicine product trials:** Complies with Japan-specific regulations and automates reporting for regenerative medicine product clinical trials.



### CMIC PV e-Solutions

- **Full-package service provision:** CMIC partners with Oracle Corporation's comprehensive PV platform, Oracle Argus Safety. This enables us to provide full-package support—including data management, line listing creation, and generation of CIOMS and XML files for overseas regulatory reporting—for pharmaceutical companies that do not have their own databases or wish to use their PV resources more strategically.
- **Flexible service structure:** We provide all PV-related services, including partial system provision based on cost and needs, for domestic and international biotech ventures and other companies that cannot allocate sufficient resources to PV operations.

To learn more about CMIC's PV e-Solutions, please contact us:

<https://en.cmicgroup.com/contact/>

### ■ About CMIC Group

CMIC pioneered Japan's first contract research organization business in 1992, and now provides comprehensive support services for pharmaceuticals, from development to manufacturing, sales, and marketing. The company supports foreign pharmaceutical, biotechnology, and medical device companies entering the Japanese market, conducts clinical trials in Asia, and provides pharmaceutical development and manufacturing support in both the United States and Japan. Additionally, CMIC provides new healthcare solutions supporting individuals and local governments, and aims to develop its "Personal Health Value Creator" business model to maximize individual health value, building on its extensive experience and track record in comprehensively supporting the pharmaceutical company value chain. The CMIC Group has over 7,500 employees and 28 group companies worldwide. For more information, please visit our website:

<https://www.cmicgroup.com/>