

Your Trusted Service Partner for the U.S., Japan, and Asia

Better Medicine Sooner



Leading CRO in Asia-Pacific Offering Broader Services Globally

Founded in 1992, CMIC pioneered Japan's first contract research organization (CRO) and later became the country's first site management organization (SMO). We also extended our footprint across Asia as the first CRO to operate in South Korea.

To enable pharmaceutical companies to develop better medicine sooner, we expanded our solutions to include contract development and manufacturing (CDMO), consulting, and market solutions, supporting global companies to bring highly desired treatments to the Japanese market.

Leveraging our vast experience and expertise in the medical industry, CMIC also offer solutions using a new ecosystem of healthcare to support individuals and local governments.

We strive to be a **Personal Health Value Creator (PHVC)** to meet our global customers' needs in the U.S., Japan, and broader Asia.

80% of new drug development in JAPAN

One of the Largest CROs in JAPAN with leading ICCC studies

Top 3
largest CDMOs in JAPAN

Connected with 4,000+ clinical sites in ASIA-PACIFIC

The Only
end-to-end
JAPAN
MARKET ENTRY
solution
provider

70% of new ONCOLOGY drug development in JAPAN

17+ Years
of continuous
commercial
manufacturing
and drug
development
services in
the U.S.

Completed

400+
oligonucleotide
assays in
the U.S.

Largest regulatory consulting and medical writing team in JAPAN with 180+ Experts

The Only
CRO in JAPAN
with CMC,
bioanalysis,
and nonclinical
services

The First CRO in SOUTH KOREA with experience in 700+ Studies

2nd Largest CSO in JAPAN with 750+ sales reps, nurses, and MSLs



Our Specialized Solutions

CMIC offers solutions for pharmaceutical companies, medical device manufacturers, academia, bio-ventures, and medical institutions. Using our collective strengths, we offer a broad range of services from pre-clinical research to practical applications.



Japanese Market Entry

Providing full pharmaceutical capabilities for overseas business partners to enter the Japanese market.

- In-country clinical caretaker (ICCC)
- Marketing authorization holder (MAH) services



Asia Clinical Trials

Supporting our clients' clinical trials in 13 countries in the Asia-Pacific region.

- Consulting services
- Regulatory affairs

- Project management
- · Clinical operations



Oncology Drug Development

Highly specialized oncology experts support your drug development.

- · Consulting services
 - Strategic development planning
 - Study design optimization
- Regulatory affairs

- · Clinical trials
- Site and patient support
- CSO services



Orphan Drugs

- · Regulatory affairs
- Manufacturing, packaging/labeling
- · Quality management
- Safety management

- Medical affairs
- Marketing
- · Supply chain management
- · Sales and distribution



Medical Device & In Vitro Diagnostics

- QMS organization setup
- · Design and development
- Nonclinical studies
- Clinical trials

- · Approval/certification support
- Reimbursement support
- Post-marketing surveillance



Cell & Gene Therapy

Established systems ready to implement and form development strategies and support every stage of the regenerative medicine life cycle.

- Consulting services
- · Regulatory affairs

- Nonclinical studies
- · Clinical trials

The Only End-to-End Pharmaceutical Solution Partner in Japan

Pre-Clinical

Clinical

Consulting

- Drug development consulting
- Japan/foreign market entry

- Out-licensing to other pharma
- Out-needsing to other pharms

Medical devices consulting

• Interview/research with physicians, paramedical, patients and families

Regulatory Affairs

· Regulatory submissions and correspondence

Laboratory

- Chemistry manufacturing and control (CMC) and GMP analytical services
- GLP bioanalysis and analytical services
- Nonclinical studies (toxicity, safety, and efficacy)

Formulation Design

• Formulation, process, and analytical development

Clinical Trials

- ICCC/local country agent
- Project management
- Clinical operations
- Data management
- Pharmacovigilance
- Quality assurance and control
- Statistical analysis
- Medical writing
- Patient recruitment and retention
- Decentralized Clinical Trials

Investigational Product Manufacturing

- Formulation, process, and analytical development
- Early-to-late-phase manufacturing
- Packaging and labeling
- Release and stability tests
- Technology transfer
- Antibody active pharmaceutical ingredients manufacturing

Laboratory

- CMC and GMP analytical services
- GLP bioanalysis and analytical services

Site and Patient Support

- Patient call center and help desk
- Clinical research coordinator (CRC) services
- Clinical site administration support

Medical Affairs

- Evidence generation
- QOL study
- Medical affairs consulting
- Medical science liaison (MSL) talent solutions
- MSL training and assessment
- Patient support program



CMIC Group can take your product from pre-clinical, to clinical, to commercialization and through post-marketing studies seamlessly.

Whether in the U.S., Japan, or elsewhere in Asia, we are your dedicated, customer-centric, full-service provider across the full drug development continuum.

Filing/Approval

Post-Approval

- · In vitro diagnostics consulting
- CMC Consulting

- Regenerative medicine consulting
- Product life cycle management

Consulting

- MAH related services
- National health insurance (NHI) pricing

Medical Writing

Commercial Supply

- Commercial manufacturing
- Packaging and labeling
- Release and stability tests
- Antibody active pharmaceutical ingredients manufacturing

Medical Affairs

- Evidence generation
- Medical affairs consulting
- Medical science liaison (MSL) talent solutions
- MSL training and assessment
- Materials review

Site and Patient Support

- Call center
- Patient support program

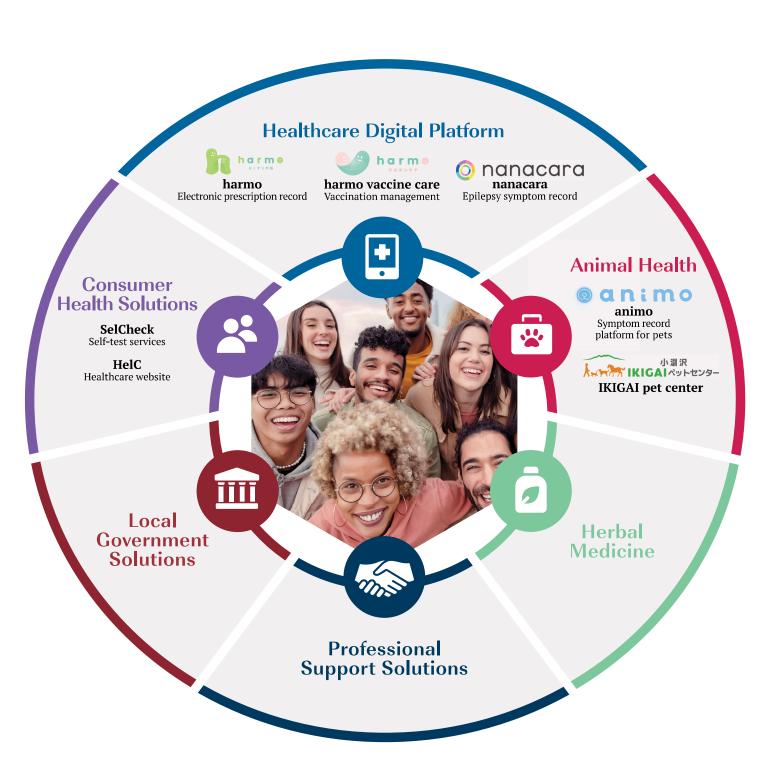
Post-Marketing Surveillance and Clinical Research

Sales and Marketing

- Sales/medical representative solutions
- Remote detailing services
- Sales support
- Customer service representatives
- Clinical/nurse educator

Innovative Healthcare Solutions

CMIC is committed to providing patient-centered healthcare solutions that meet the evolving needs of various diseases through advanced technology, including digital/IoT and contact center services.





Agile Access to the World's Major Pharmaceutical Markets

CMIC supports clinical trials in Asia-Pacific, Japan market entry, and bridging non-clinical and manufacturing needs between the U.S. and Japan.









Contract Research Organization

Comprehensive support for research and development of disease prevention and treatment

Site Support Solutions

Comprehensive support of medical institutes and medical staff

Personal Health Value Creator

Contract Development & Manufacturing Organization

Development and manufacturing support for pharmaceutical products and biopharmaceutical API from clinical to commercial

Healthcare Revolution

Support individuals, local governments, etc. with solutions using a new ecosystem of healthcare

Market Solutions

Medical, sales and marketing support for pharmaceuticals, and orphan drugs development to commercialization

CMIC Group

Email: information@cmic.co.jp Website: en.cmicgroup.com

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