



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

Better Medicine Sooner



# The First and Largest CRO in Japan Offers You Services Globally

CMIC was founded in 1992 as the first contract research organization (CRO) in Japan. To enable pharmaceutical companies to develop better medicine sooner, we expanded our solutions to include contract development and manufacturing (CDMO), site support, 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.

Involved in nearly  
**80%**  
of new drug  
development  
in **JAPAN**

**Largest  
CRO**  
in **JAPAN** with  
leading  
ICCC studies

Among  
**Top 3**  
largest CDMOs  
in **JAPAN**

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

Experienced in  
**5,000+**  
**Protocols**

Involved in nearly  
**70%**  
of new  
**ONCOLOGY**  
drug development  
in **JAPAN**

Completed  
**400+**  
oligonucleotide  
assays in  
the **U.S.**

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

Largest regulatory  
consulting and  
medical writing  
team in **JAPAN** with  
**140+**  
**Experts**

Connected with  
**3,000+**  
clinical sites in  
**ASIA-PACIFIC**

The First CRO in  
**SOUTH KOREA**  
with experience in  
**300+**  
**Studies**

2nd Largest  
CSO in **JAPAN**  
with over  
**700+**  
sales reps,  
nurses, and MSLS

# Our Tailored Solutions

CMIC offers tailored 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

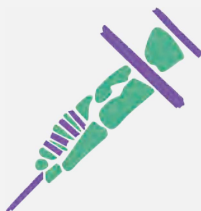
Supporting our clients' clinical trials in 13 countries in the Asia-Pacific region.

- Consulting services
- Regulatory affairs
- Project management
- Clinical operations



## Medical Device & In Vitro Diagnostics

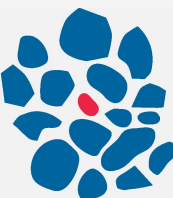
- QMS organization setup
- Design and development
- Nonclinical studies
- Clinical trials
- Approval/certification support
- Reimbursement support
- Post-marketing surveillance



## 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



## Regenerative Medicine

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 Solution Partner in Japan

## Pre-Clinical

### Consulting

- Drug development consulting
- Japan/foreign market entry
- Medical devices consulting
- Out-licensing to other pharma

### 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

### 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

### 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

## Other Services and Products

- Orphan drugs



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

- In vitro diagnostics consulting
- CMC Consulting

## Post-Approval

- Regenerative medicine consulting
- Product life cycle management

### Consulting

- MAH related services
- National health insurance (NHI) pricing
- Health technology assessment (HTA) related consulting

### Medical Writing

### Commercial Supply

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

### Health Economics and Outcomes Research

### Medical Affairs

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

### Patient and Healthcare Services

- Call center
- Patient support program
- Digital healthcare channel service: harmo
- Prescription drug database services
- Healthcare website: HelC+
- Self-test kit: SelCheck

### Post-Marketing Surveillance and Clinical Research

### Sales and Marketing

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

# Agile Access to the World's Major Pharmaceutical Markets

A variety of services can be provided, worldwide, with CMIC facilities or modern technology.



Services		U.S.	Japan	Korea	Singapore	China	Taiwan	Malaysia	Hong Kong	Philippines	Vietnam	Thailand	Indonesia	Australia	New Zealand
Pre-Clinical	Consulting	✓	✓												
	Laboratory	✓	✓												
	Formulation Design	✓	✓												
Clinical	Clinical Trials		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Investigational Product Manufacturing	✓	✓	✓											
	Laboratory	✓	✓												
	Medical Affairs		✓												
	Regulatory Affairs		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Site and Patient Support		✓												
Filing/Approval	Consulting		✓												
Post-Approval	Commercial Supply	✓	✓	✓											
	Medical Affairs		✓												
	Patient and Healthcare Services		✓												
	Post-Marketing Surveillance and Clinical Research		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Sales and Marketing		✓												

\*Full range of services for development stage may not be available for some locations.



# CMIC's Mission

CMIC is an innovative and unique provider of high-quality solutions for the healthcare industry. We create value by accelerating the access to therapies that improve patients' lives.

# CMIC's Vision

To advance the innovation of products and solutions that will empower people worldwide to achieve greater health and wellbeing.

# CMIC's Values

## W & 3C

**WELLBEING:** Fully Live Every Moment

**Challenge:** Liberate opportunity by changing our vantage point

**Change:** Transform without seeking refuge in conventional wisdom

**Communication:** Proactively reach out to people and society





**CMIC Group**

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