

# Your Strategic Partner for Japanese Market Entry

# The Japanese market is growing and changing

# 2nd largest market

in the world for prescription medications and per capita drug spending

## Faster drug approval

by PMDA than the FDA and EMA from 2014 to 2016\*

### New options for drug pricing premiums

reward innovative medicine

# Favorable regulations

for regenerative medicine through conditional/ term-limited authorization

## more than 25% / of its population

now over the age of 65; Central Nervous System and Oncology therapies are growing

Although quality and innovation standards in Japan are comparable to that of the U.S. and European markets, the Japanese market can hold many regulatory and lingual obstacles for the first-timer. As Japan's first CRO, CMIC is your most experienced partner in Japan. Let our experts guide you in navigating the market.

\*Bujar M, McAuslane N, Liberti L. 2017. R&D Briefing 62: New drug approvals in ICH countries 2007-2016. Centre for Innovation in Regulatory Science.

# Tailor our services to meet your Japanese market entry needs

CMIC provides end-to-end solutions for market entry into Japan. Our 50+ experienced consultants will help you determine the best strategy in accordance with Japan-specific changing regulations and unique environment, working flexibly with your company's plans for market entry. We provide options for entry at any stage in drug development: before clinical trials have started abroad, after approval abroad or after commercializing in a different country. As a Pharmaceutical Value Creator, CMIC strives to provide value by spanning our services across the entire drug development value chain.

## Featured services for Japanese market entry



#### **Consultation services for market entry**

**Establish a company in Japan:** Solutions for establishing a presence in Japan. **Out-Licensing to other pharma:** Partnering services as an add-on option.

#### Laboratory

 Pre-clinical data gap analysis

#### **Regulatory Affairs**

 PMDA consultations & Clinical Trial Notification (CTN) submissions

#### Investigational Product Manufacturing

 Investigational Product visual inspections, packaging & labeling per Japanese regulations

#### **Medical Affairs**

• Medical affairs organization setup, consultation & resources for Japan

#### **Regulatory Affairs**

- CTD preparation, submission & correspondence
- correspondenceInspection support &
- interpreter services
  National Health Insurance (NHI) reimbursement pricing and consultation

#### Post Marketing Surveillance & Clinical Research

 Post Marketing Surveillance services

#### **Commercial Supply**

 Visual inspections, packaging & labeling per Japanese standards

#### Sales and Marketing

• Commercial planning, setup and resources for Japan



### Contract Research Organization

Experienced non-clinical, clinical and regulatory research & development solutions

### Innovative Pharma Model

A flexible service platform providing full pharmaceutical capabilities for overseas business partners to enter Japan

## Pharmaceutical Value Creator

A business model of comprehensive services creating added value from preclinical to commercialization

### Contract Development & Manufacturing Organization

Quality solutions for formulation development, analytical testing, manufacturing and packaging

### Healthcare Business

Patient and consumer support programs, and clinical site management for hospitals and medical institutions

### Contract Sales Organization

Broad medical affairs, sales and marketing solutions

### **CMIC Group**

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