

# Your Strategic Partner for Japanese Market Entry



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# Growing and Changing Japanese Market



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 first-time entrants. As Japan's first CRO, CMIC is your most experienced partner in Japan. Let our experts guide you in navigating the market.

Source:

<sup>\*1</sup>: Centre for Innovation in Regulatory Science (2024) R&D Briefing 93: New drug approvals in six major authorities 2014–2023: Changing regulatory landscape and facilitated regulatory pathways. Centre for Innovation in Regulatory Science (CIRS), London, UK.

<sup>\*2</sup>: The Global Use of Medicines 2023: Outlook to 2027; IQVIA Institute, Jan 2023

<sup>\*3</sup>: Ministry of Health, Labour and Welfare website (<https://www.mhlw.go.jp/content/12404000/001120014.pdf>)

<sup>\*4</sup>: Population Estimates, May 2025; Statistics Bureau, Ministry of Internal Affairs and Communications

# PMDA's Regulatory Updates: Bridging Global and Local Development

The PMDA's recent updates offer a flexible and pragmatic approach to drug development for both rare and common diseases, ensuring alignment with global development strategies.

## Key Provisions



### Global Data Acceptance

- › Clinical trial data from non-Japanese populations can serve as the primary basis for regulatory approval if efficacy and safety are robustly demonstrated.
- › This reduces the need for extensive local trials and expedites market entry.



### Streamlined Requirements for Local Data

- › Small-scale bridging studies or ethnically stratified analyses within multinational clinical trials may suffice for specific cases.
- › In some instances, Japanese data requirements may be waived entirely.



### Ethnic Sensitivity

- › The PMDA emphasizes targeted analyses to confirm pharmacokinetics and efficacy differences, ensuring applicability to Japanese patients.



### Proactive Consultations

- › Sponsors are encouraged to engage in early consultations with the PMDA to clarify data requirements, optimizing trial design and reducing uncertainties.

## Implications for Global Biotech

The PMDA's updates are transformative for global Biotech, offering



Reduced local trial requirements lower development expenses.



Acceptance of global data ensures faster regulatory approvals.

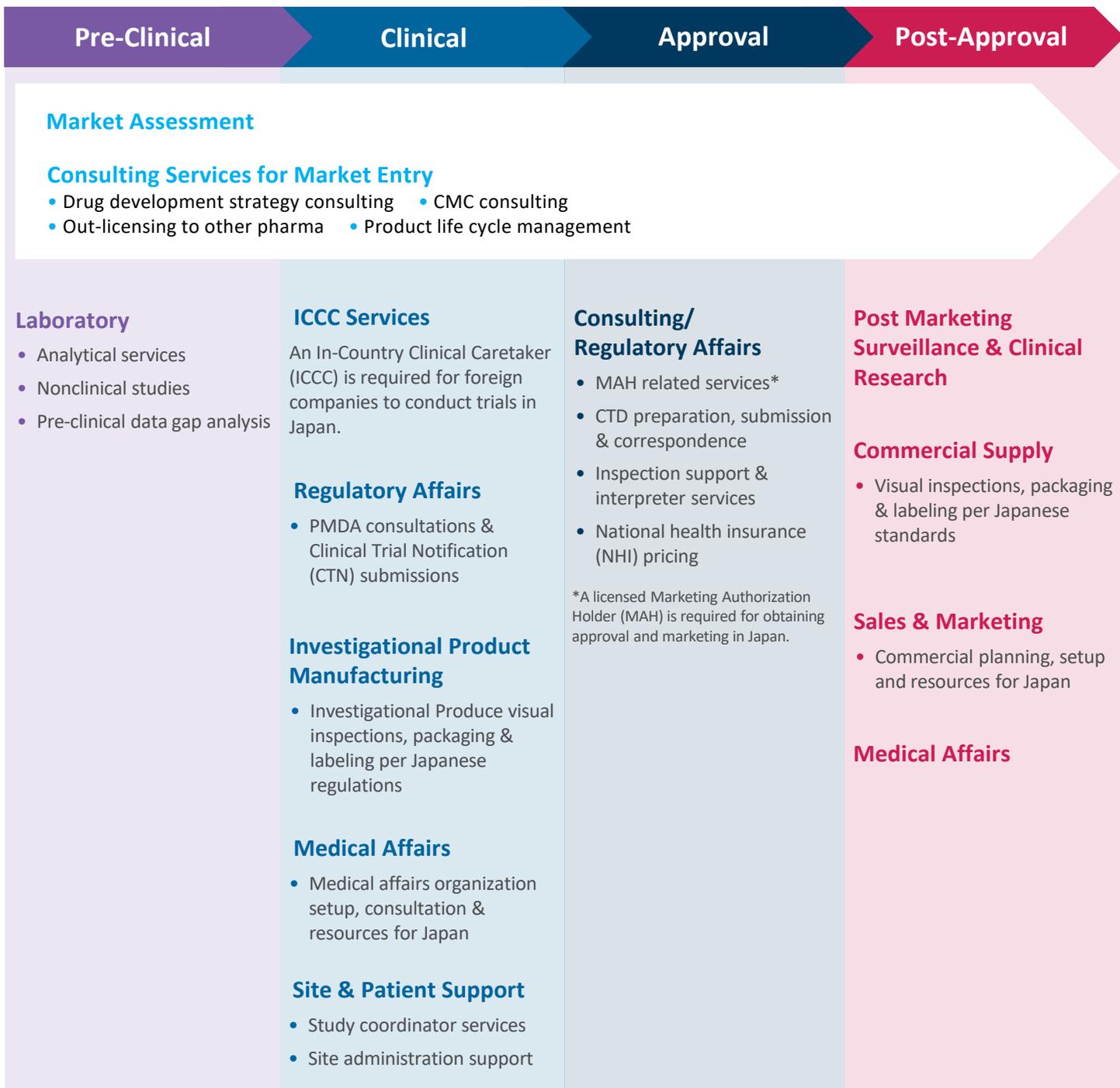


Clear guidelines allow sponsors to seamlessly integrate Japanese-specific considerations into global programs.

# Tailor Our Services to Meet Your Japanese Market Entry Needs

CMIC provides end-to-end solutions for market entry into Japan, and our Japan Market Entry framework is specifically designed to tackle the complexities of accessing market value, regulatory, pre-clinical, clinical, and market penetration strategies across diverse therapeutic indications.

## CMIC's Services



## Key Success Factors

Adopt CMIC's Japan Market Entry Framework

Utilize KOL Networks

Engage with PMDA Early and leverage the latest guidelines

Optimize MRCT\* Designs

\*MRCT: Multi-Regional Clinical Trial