



Early Phase Clinical Trial Solutions

CMIC Group is the largest CRO in Japan with clinical operations in Asia-Pacific. With our vast expertise and experience, CMIC Group is your trusted partner for your early phase clinical development.

Why Japan?

The regulatory authority requires Pharmacokinetics and/or safety data of healthy volunteer data in Japan.

Why Australia?

- ✓ No IND required
- ✓ Diverse population
- ✓ Fast start-up
- ✓ Data accepted by FDA, EMA, CFDA & PMDA



Tailor our solutions to meet your development needs

Strategic Consulting Services

- Drug development
- Medical Device
- Regenerative Medicine
- In-Vitro Diagnostics

Regulatory Affairs

- Regulatory document preparation
- Regulatory authority consultation
- Regulatory submission and correspondence

e-Clinical solutions

- e-Source, eCRF, ePRO

Phase I Clinical Site Networks

- Patient recruitment and retention

Clinical Trials

- ICCC / local country agent
- Project management
- Clinical operations
- Data management
- Pharmacovigilance
- Quality assurance
- Statistical analysis
- Medical writing

Laboratory

- Bioanalysis

Investigational Product Management

- Early to late phase manufacturing
- Packaging and labelling
- Logistics management



Our Solution Provides Quality and Speed

1. Extensive expertise and experience



Quality and process optimization

- e-Clinical Solutions (e-Source, eCRF, ePRO, etc.)
- Remote / Off-site SDVs
- Online meetings with clinical sites



Vast experience as the first CRO in Japan

- Utilize our past experiences /procedures for your clinical study



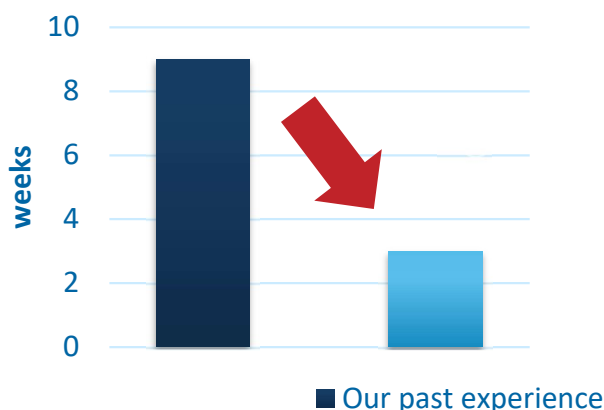
Strong network with Phase I clinical sites

- Collaborate with Phase I clinical sites in Japan and Australia
- Developed early phase specific operational process with clinical sites.
- e-Source can be utilized at our partnered sites
- Data from diverse population can be obtained in Australia

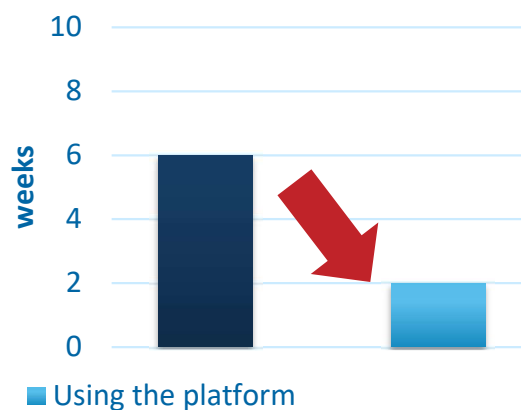
2. Accelerate timeline

Our platform can accelerate your study timeline at any phase of the drug development.

[Case 1] Feasibility + Qualification + Site Initiation + PI agreement



[Case 2] eCRF system set-up + SDV/Data cleaning + Database Lock



CMIC Group

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