The Changing Face of Global Clinical Trials:

Asia-Pacific as an Ideal Destination for Specialty Biopharma

FROST & SULLIVAN

CMIC

Pharmaceutical Market Trends

4.5% ▼ 4.2%

Slowdown expected in pharma industry growth rate to 4.2% (2016-2020) from 4.5% (2012-2015)

Expansion to emerging countries for access to new markets

Regulatory & pricing pressures

Patent cliff of blockbusters and personalized medicine trend shifting R&D focus to orphan drugs and biologics

Areas to Watch: Global Biologics and Orphan Drugs Market Revenue Growth*

USD375 billion

forecast market for Biologics drugs by 2022

USD220 billion

forecast market for Orphan drugs by 2022

20% of orphan drugs expected to capture prescription drug sales by 2020.

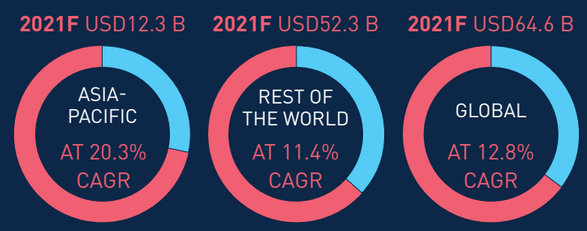
50% of the top 20 Orphan pipeline drugs will be from mid to small biotech companies based on net present value in 2015

**Source: The Economic Intelligence Unit; BMI Research; Frost & Sullivan, Global Orphan Drug Market, Nov 2016*

Clinical Trials Outsourcing: Key Drivers for small and mid-sized companies in the US

- Lengthy trial time due to differences in US Federal, State and Institutional policies
- Rising cost of drug discovery & development, and lack of extensive in-house R&D talent and infrastructure
- Long and challenging recruitment of desired patients due to high penetration of clinical trials in the US
- Laborious task to hire most sought-after investigators for small and mid-size pharmaceutical companies

Asia-Pacific is fast becoming the preferred destination for clinical trials



Fast-growing pharma market

Strong IP protection and low legal barriers

Regulatory harmonization with international guidelines (i.e., ICH E17; AFTA) with fast-track options

High resource availability and access to state-of-the-art facilities	Large treatment-naïve patient pool across many disease profiles

5 KEY PARAMETERS TO SELECTING THE RIGHT CRO PARTNER

1. Global support and scalability
2. Significant presence in Asia with deep local market knowledge
3. Strong relationship with local regulators, investigators and KOLs
4. Exemplary regulatory track record
5. Therapeutic expertise aligned to specialty pharma

CMIC: THE LARGEST JAPANESE INTEGRATED SERVICE PROVIDER PROVIDING FULL RANGE OF SERVICES

Extensive presence in Japan, US, and Asia (33 bases in Japan, 12 overseas bases, 16 Asian affiliates)

1000 clinical research associates, 600 medical representatives, and 50 regulatory consultants

Vast expertise in legal, IP, manufacturing, and commercialization

Excellent Regulatory Track Record

Supported >80% of drug approvals in Japan

Strong relationship with PMDA and Ministry of Health, Labour and Welfare (MHLW) and other regulatory bodies

Deep understanding of cross-border pre-clinical bioanalysis in US and Europe (FDA+EMEA), Japan, and Asia-Pacific

Vast Therapeutic Area Expertise

Focus on Oncology, Neurology, and Rare Diseases

CMIC's regenerative medicine group has executed 50 projects from >20 companies since 2015

"Pharmaceutical Value Creator" model to support full-range services

CRO: Supporting drug development

CDMO: Supporting both drug development-stage and commercial-stage manufacturing

CSO: Supporting pharmaceutical sales

Healthcare: Supporting medical institutions (SMO) and elevating the health of individuals

IPM: Innovative pharma model, including OrphanPacific, a dedicated subsidiary on rare diseases

To learn more about Asia as a preferred destination for CRO, its advantages and how CMIC can support small and mid-sized pharmaceutical companies in their innovation journey download the white paper here.

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