

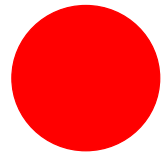


Far Horizons & Close Contact – Managing the Change of demand for outsourced clinical studies in Japan

- Rob Aitchison, Head of Outsourcing & Contracts, Ono Pharmaceutical UK
- Dan Feldman, VP, Asia Pacific, Medpace
- Eunhee Chung, PhD, Director, Global Clinical Development, SOUSEIKAI Global Clinical Research Center
- Brendan Ellis, Global Project Manager, Asahi Kasei Pharma Corporation

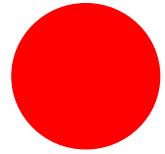
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Japan FACTS



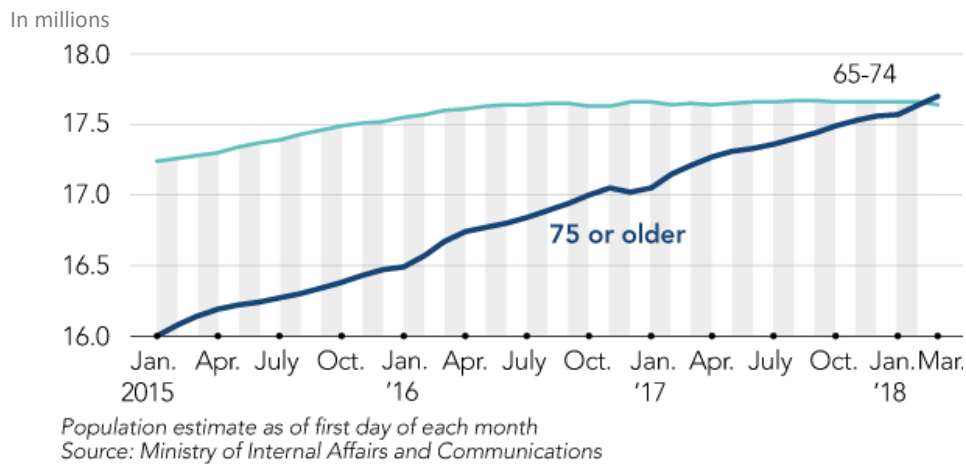
- Population of Japan : **126,885,150** as of May 28, 2019
- The world 3rd largest economy
- The world 2nd largest Pharmaceutical market
- Universal health insurance and no restriction on access
- One of the original ICH-GCP member countries

Japan FACTS

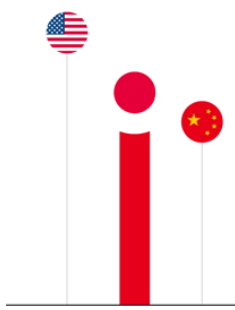


- Healthcare expenditures as a share of GDP: 10.9% (2016)
- Japan Pharma's prescription pharmaceutical product revenue; forecast to grow to \$69.5bn by 2027 at a CAGR of 1.0%.
- Facilitating Generic Growth; Generic domestic market share from 26% in 2012 to goal of 80 % by 2020
- 310 Pharmaceutical companies
- Less than 10 full service local CROs

Aged to Super-aged Society



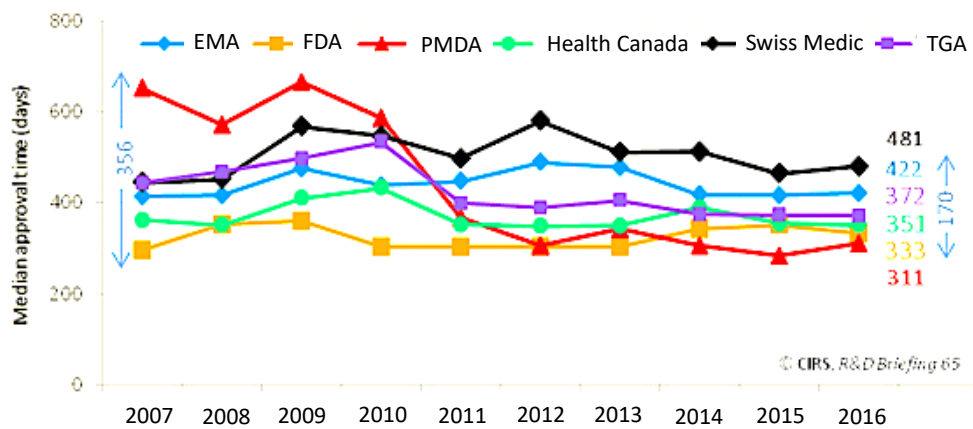
Huge Pharmaceutical market



2nd

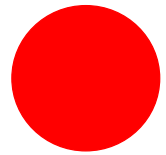
Largest Pharmaceutical Market
in the World

FAST Approval Time



So, Why Japan?

- Ever growing pharmaceutical market
- Favorable and harmonized regulatory environment
- Minimum legal hassle in recruiting patients for clinical trials
- Strong Intellectual property protection
- Large scale advanced clinical trial centers and specialized disease centers
- Internationally renowned KOLs
- Skilled clinical trial specialists
- Pristine quality data
- Now competitive clinical trial costs



Back Up Slides

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ICH GCP vs Japanese GCP

	ICH GCP	J-GCP
Site Head Responsibilities	Not mentioned	Many specific roles and responsibilities
Sign Contracts	Investigator and Site	Site Head
Ensure Compliance with SOPs and Confidentiality Laws	Not mentioned	Site Head
Provision of IMP	Investigator	Site Head
Record Keeping	Investigator	Site Head
Establishment of IRB	Not mentioned	Each site must have its own IRB
Obtain IRB approval and follow guidance	Investigator	Site Head