



Conducting Clinical Trials in China

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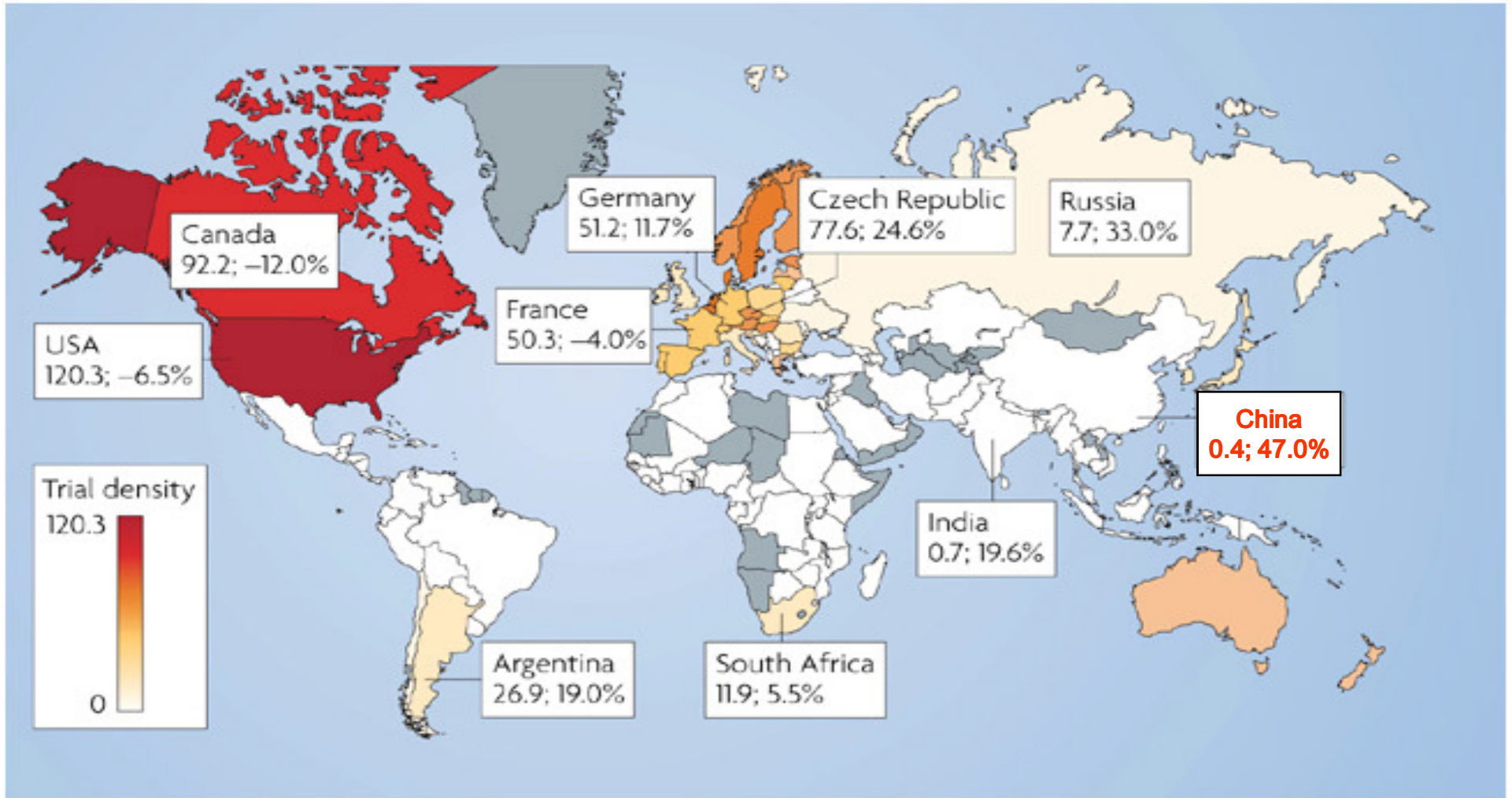
1-3 December 2009

Intercontinental Hotel, Singapore

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Globalization of Clinical Trial



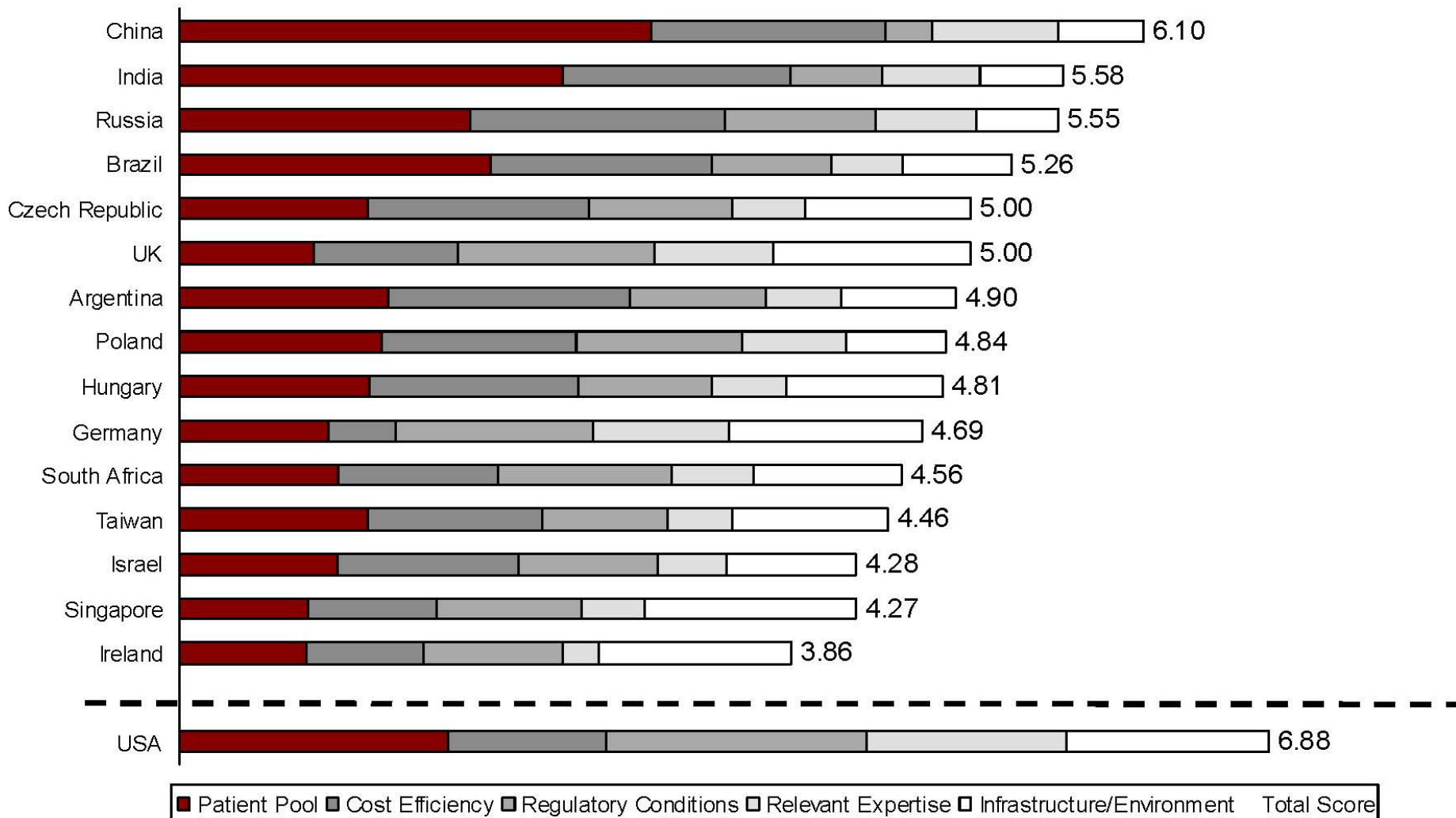
Source: trends in the Globalization of Clinical Trial, Nature Reviews Drug Discovery 7, 13-14 (January 2008)

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Why Conduct Studies in China?

Overall Country Attractiveness Index¹



Resource: Kearney Nov 2006

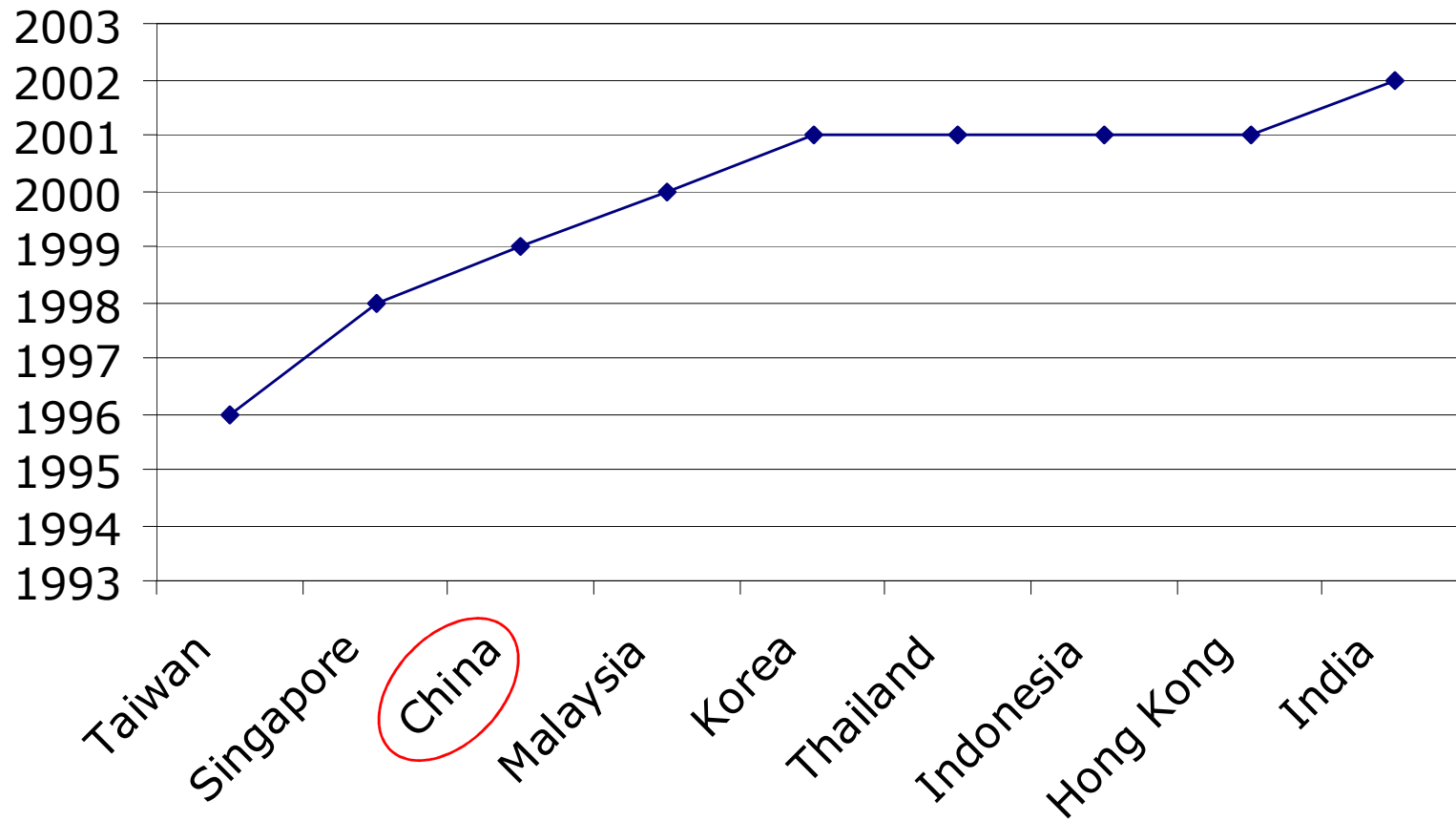
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Challenges and Strategies

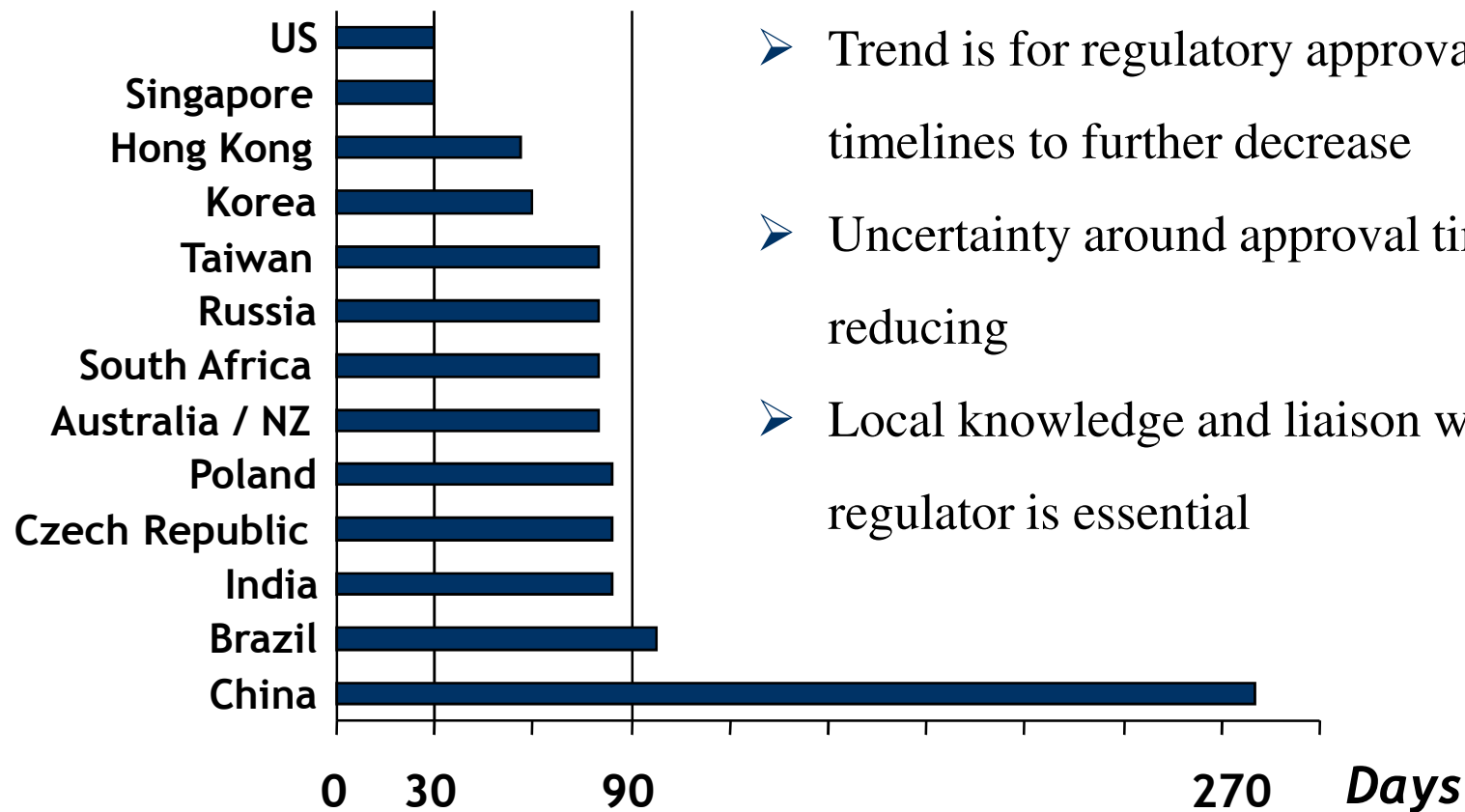
- **Regulatory**
- **Investigator & site**
- **People and Training**
- **Communication**
- **Infrastructure**

1. Regulatory: Overview



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Regulatory: Challenges



- Trend is for regulatory approval timelines to further decrease
- Uncertainty around approval times is reducing
- Local knowledge and liaison with regulator is essential

Regulatory: Strategy

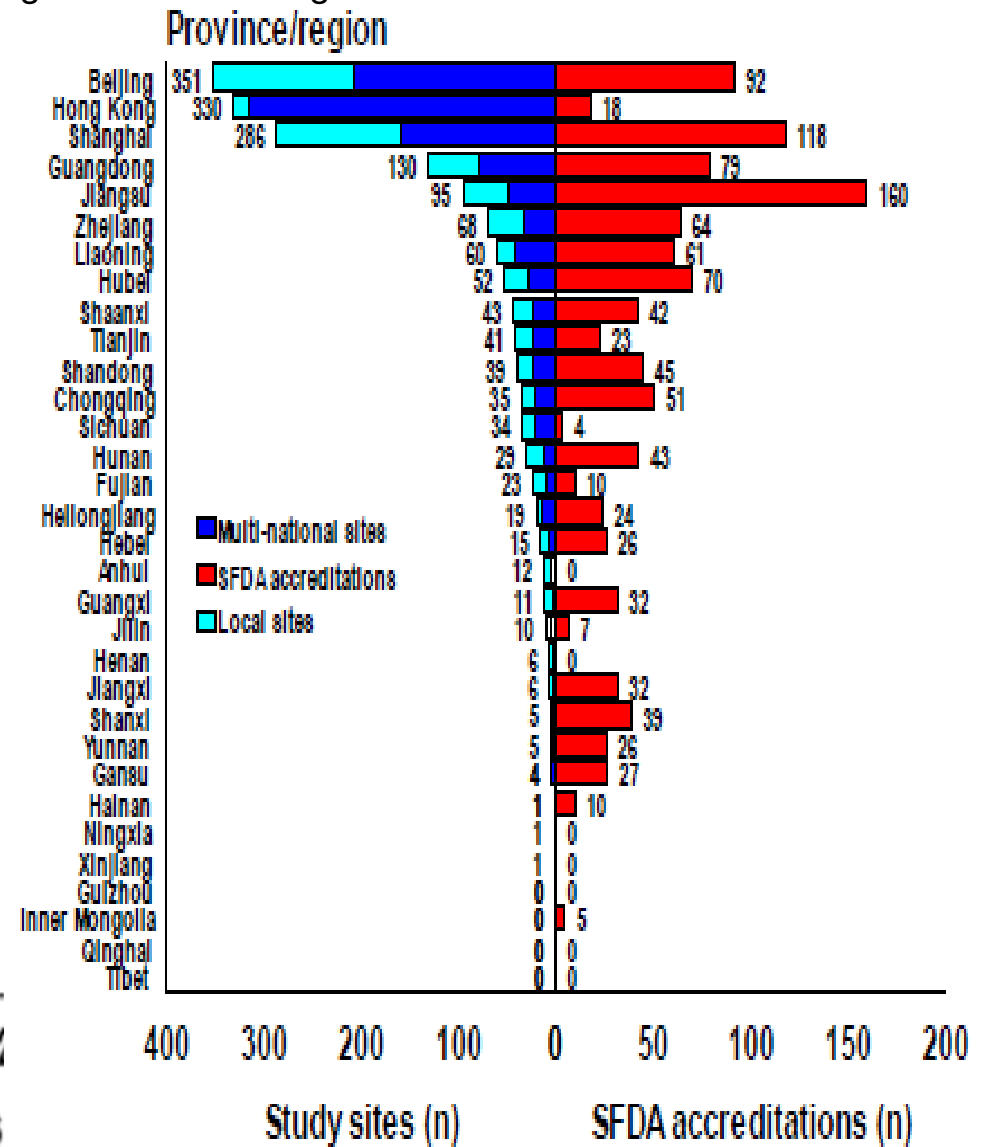
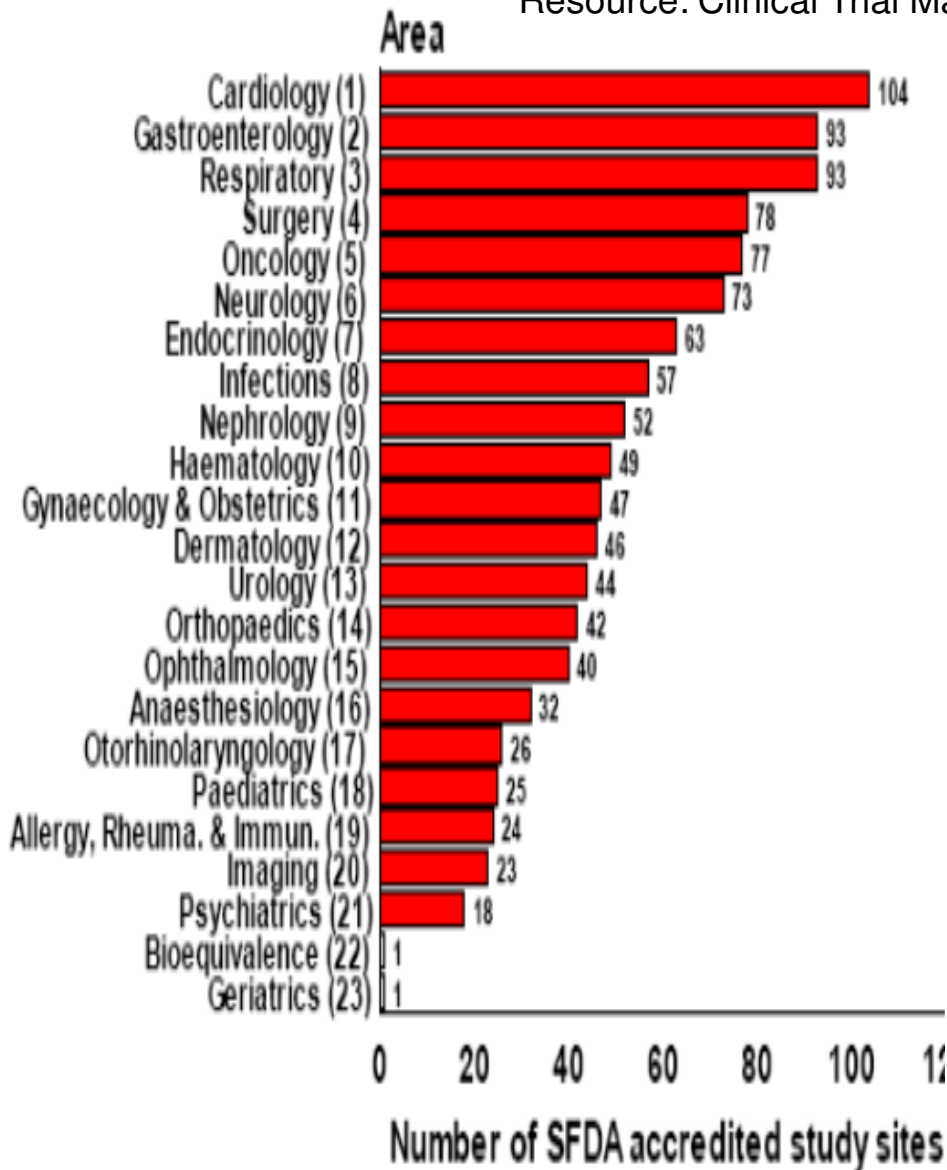
- **Understand the regulatory direction**
- **Synchronize China Development and Launch Timelines with Global Development**
- **Submit a high quality complete application**
- **Build up a local regulatory capacities**

2. Site Selection: Overview

- Clinical Trial to be conducted at SFDA certificated hospitals
- SFDA certificated sites rapid increasing:
125 in 2001, 251 in 2007 and 335 in 2009
- All sites have the clinical trial administration office
- Construction of Platform for Clinical Research in Drug Development: 23-30 platforms

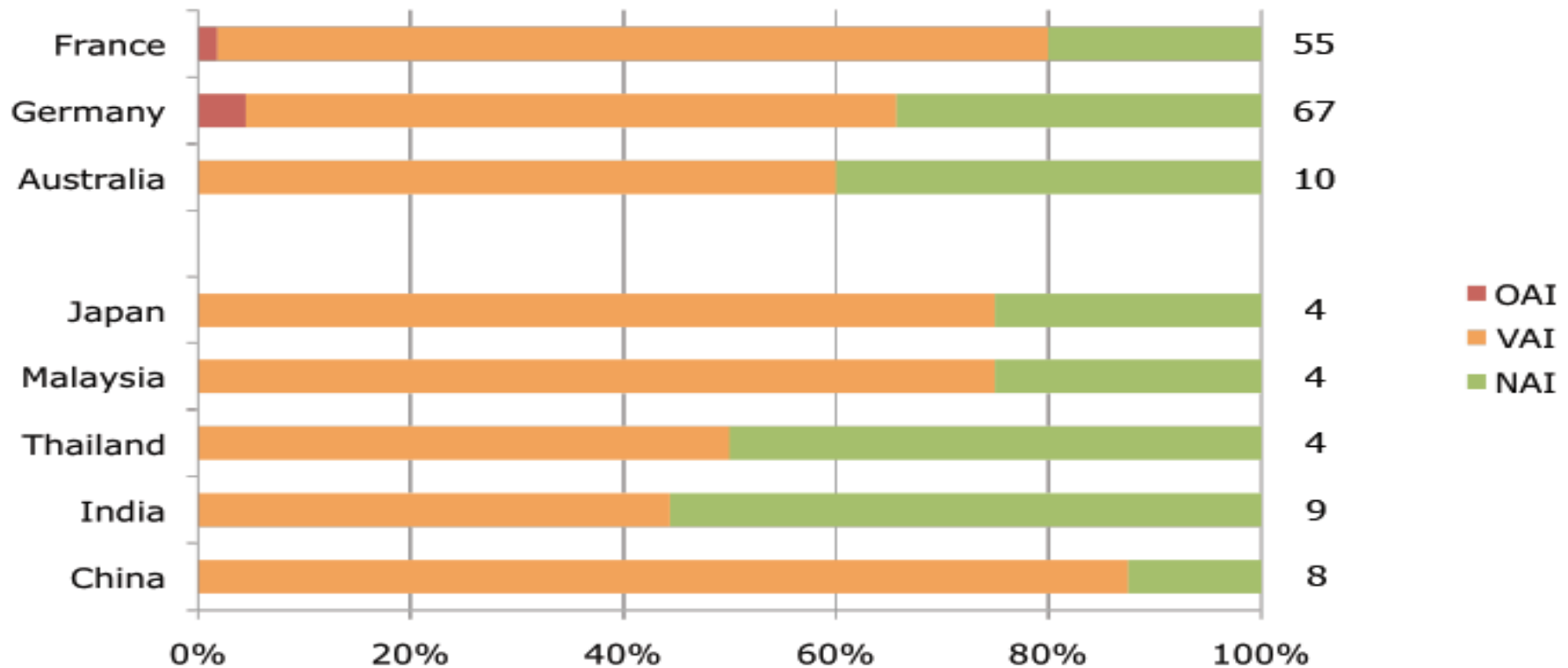
Site Selection: Overview

Resource: Clinical Trial Magnifier: Vol 1:8 Aug 2008



Sites Qualification in China

FDA inspections suggest a maturing quality outlook in China



Site Selection: Challenges

- Increasing competition running clinical trials at sites
- Not very rewarding conducting clinical trials in China (for some hospitals/institutes)!
- Investigator may have no enough access to hospital resource
- Insufficient training to investigators
- Investigator limited time and insufficient local coordinator support!

Site Selection: Strategy

- Liaison with Platform / Network / Association

Anti-Cancer Association, China CDC, Liver Disease

platform

- Big name: Check the hidden
- Select a leading PI: KOLs
- Providing CRC support

3. People Development: Overview

- Rapid growth has resulted in a shortage of qualified staffs

CRAs, Study Coordinators, Junior PIs, registration staffs

- Staffs turnover

- Training: from University, from SFDA

3. People Development: Strategy

- Set up a complete (virtual) structure for project in-source and out-source
- Invest on training
- Training elements include:
 - Good Clinical Practice Guidelines
 - Ethics and Consent
 - Patient Recruitment and Retention
 - Investigator Relations
 - Communication & Other Soft Skills

4. Communication: Overview

- Personal Connections (*Guanxi*):

Earning respect and trust should be considered first step

- English communication

- Communication between CROs and MNCs

- Communication with HQ

4. Communication: Strategy

➤ With HQ:

Fully Discuss with HQ at the early stage for the science /regulatory issue

Close communication through out the process

➤ With CRO:

To develop a CRO oversee plan

To establish an appropriate performance matrix

Project management tools

5. Infrastructure: Overview

- Government Initiation of supporting innovation
- CROU development
- EDC
- Central Lab

5. Infrastructure: Strategies

- Work together with government initiation: SFDA, MOH, MoST
- CROU:
- Local partner: EDC and Central Lab

Key Factors to Successful Clinical Research in China

- Clear understanding of China & Foreign regulations.
- Qualified PI and sites
- Relationship with Sites and PIs
- Continuous training and support to project team
- Communication

Recipe: Partnership

- Key Outsourcing Partner Requirements Include:
 - Clear understanding of China & Foreign regulations.
 - Experience on the therapy area
 - A highly trained, skilled, responsive and creative team
 - A performance driven culture
 - Frequent and consistent communication
 - Flexibility to work under multiple types of requirements
 - Transparency and trust

Contact

- Thank you for your attention and participation!
- Best wishes for successful registration of your Products in China!
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