



# Outsourcing to Asia Pacific

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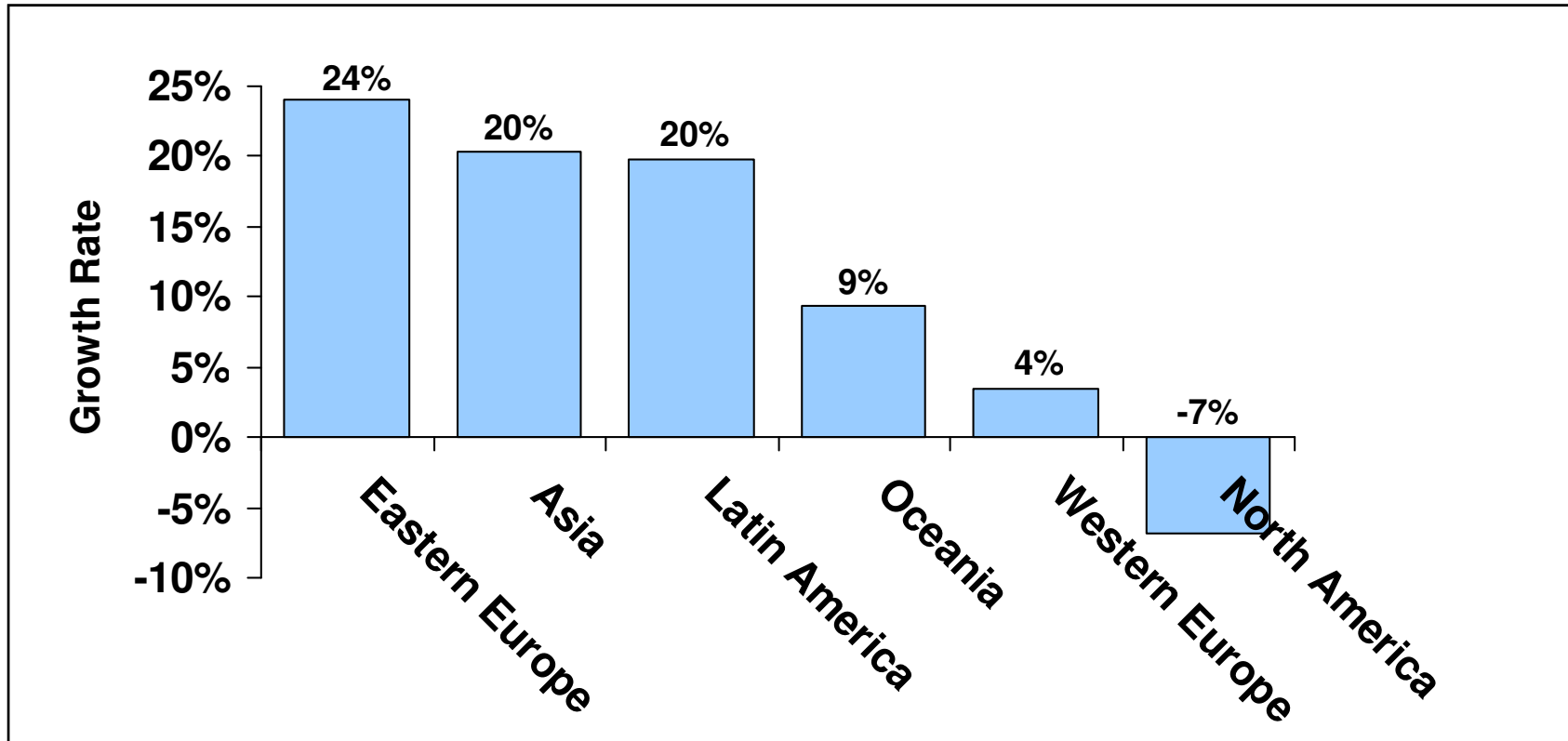
# Outsourcing to Asia Pacific

## Agenda

- Growth region
- Regulatory challenges
- Other challenges
- Benefits of outsourcing
- Case study

# Emerging Markets are Playing an Increasingly Important Role in Clinical Trials

## Average Relative Annual Growth Rate of Clinical Trials in Major Regions



Source:

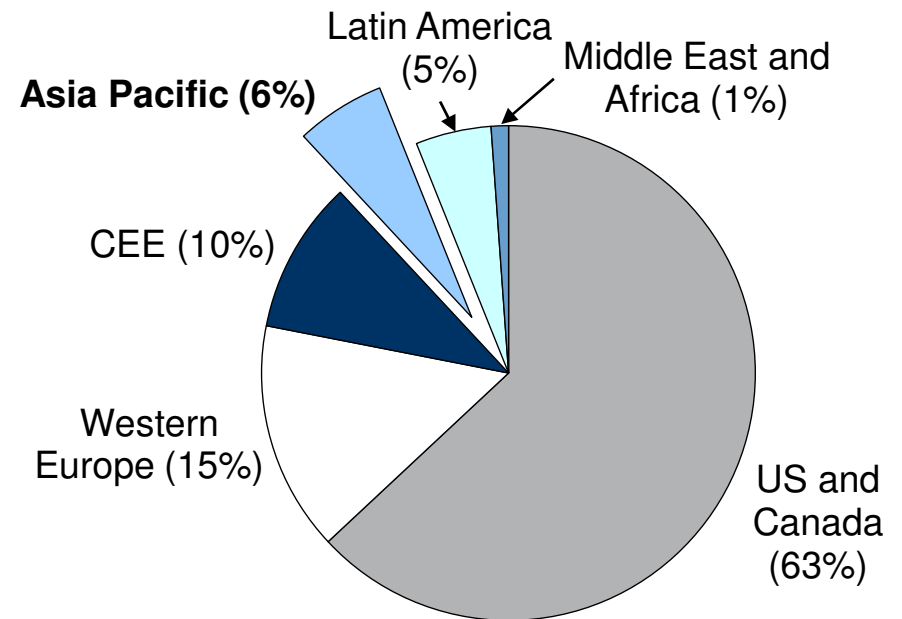
- Analysis by Thiers et al. based on data from [www.clinicaltrials.gov](http://www.clinicaltrials.gov) ("Trends in the globalization of clinical trials," *Nature Reviews Drug Discovery*, Jan. 2008)
- Growth Rate is based on share of total trials (2002-2006)

# Comparing Asia Pacific to Other Regions

**Regional Population and Percent Urban Estimates**

	<b>Total Population (millions)</b>	<b>Percent Urban</b>
<b>Asia Pacific</b>	3,960	41%
<b>Latin America and the Caribbean</b>	590	79%
<b>Central and Eastern Europe (CEE)</b>	400	68%
<b>Western Europe</b>	390	77%
<b>U.S. and Canada</b>	350	82%

**Investigators Completing 1572 Forms in 2008 by Region\***

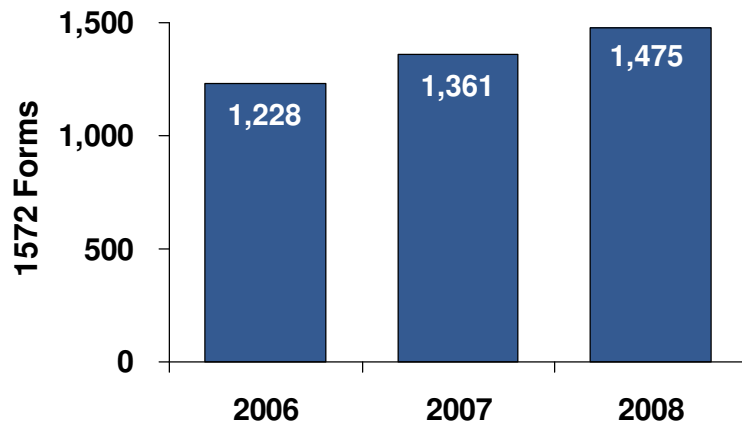


\*Number of investigators who filed forms to participate in FDA-regulated trials in 2008

Sources: Company websites; UN World Urbanization Prospects: The 2007 Revision Population Database; Parexel's Bio/Pharmaceutical R&D Statistical Sourcebook 2009/2010

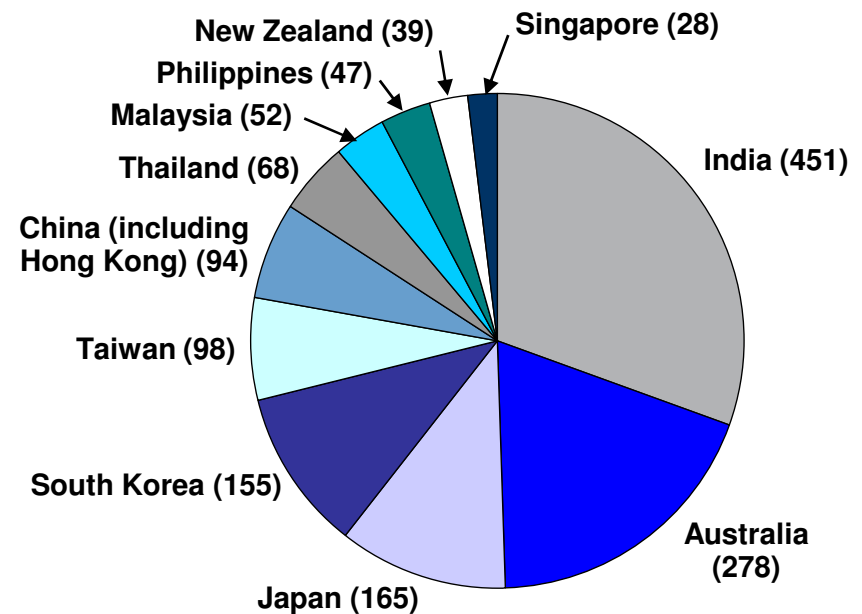
# Trials In Asia Pacific

Investigators Participating in FDA-Regulated Trials\*



- Trial activity in Asia Pacific increased by ~20% between 2006 and 2008 (as measured by 1572 forms)
- India and Australia have the greatest number of trials

Investigators Participating in FDA-Regulated Trials\* in 2008 by Country

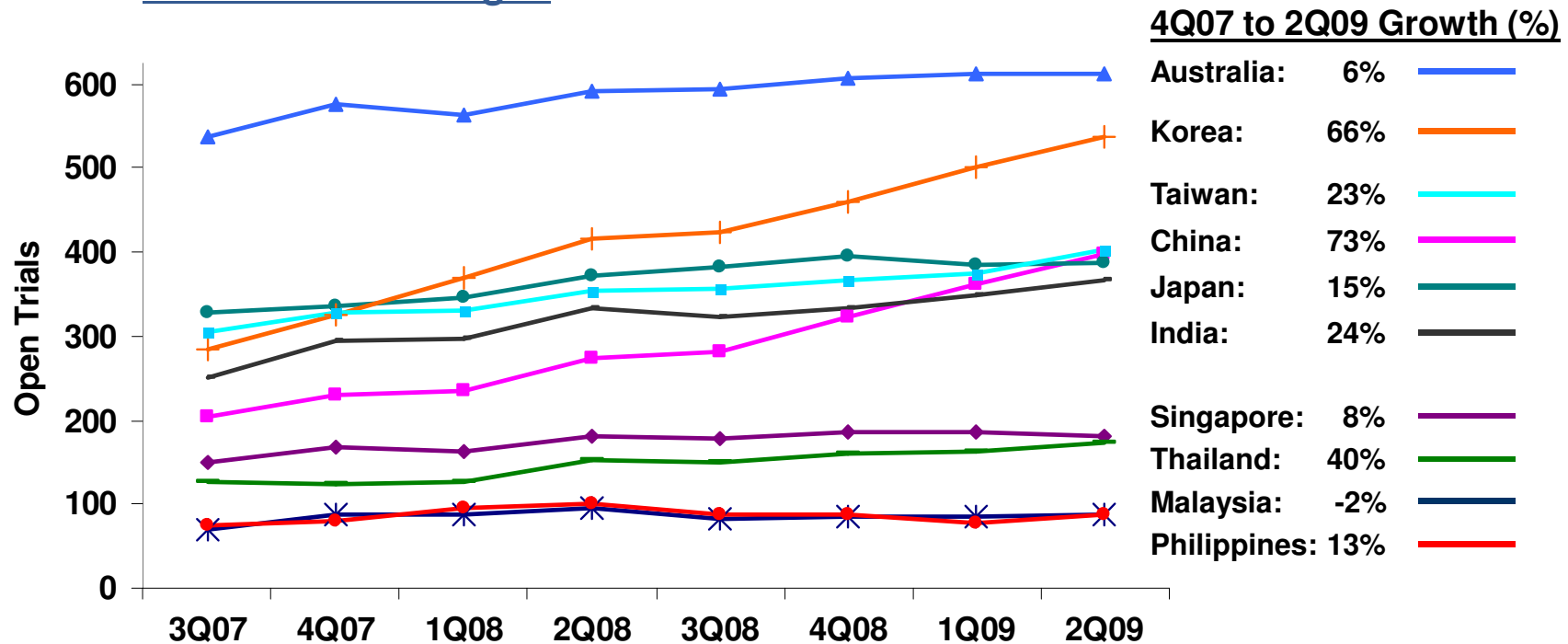


\*Measured by number of completed 1572 forms from each country

Source: Parexel's Bio/Pharmaceutical R&D Statistical Sourcebook 2008/2009

# Trial Growth by Country

Number of Open Phase I-IV Trials in [www.clinicaltrials.gov](http://www.clinicaltrials.gov) at the End of Each Quarter



- Between the end of 2007 and mid-2009, China and South Korea experienced the most significant growth in open trials

Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

# Population, Health Infrastructure

## Key Countries (ordered by population)

	China	India	Indonesia	Japan	Philippines	Vietnam	Thailand
<b>Population</b>							
<b>Pop. (millions)</b>	1,339	1,166	240	127	98	87	66
<b>Percent Urban</b>	45%	30%	54%	67%	66%	29%	34%
<b>Healthcare Workforce (per 1,000 people)</b>							
<b>Physicians</b>	1.4	0.6	0.1	2.1	1.2	0.6	0.4
<b>Nurses</b>	1.0	1.3	0.8	9.5	6.1	0.8	2.8

Sources: Company websites; CIA World Factbook, <https://www.cia.gov/library/publications/the-world-factbook/>; UN World Urbanization Prospects: The 2007 Revision Population Database; World Health Statistics 2007, WHO

# Population, Health Infrastructure

## Key Countries (ordered by population)

	South Korea	Malaysia	Taiwan	Australia	Hong Kong	Singapore	New Zealand
<b>Population</b>							
<b>Pop. (millions)</b>	49	26	23	21	7	5	4
<b>Percent Urban</b>	82%	72%	Not available	89%	100%	100%	87%
<b>Healthcare Workforce (per 1,000 people)</b>							
<b>Physicians</b>	1.6	0.7	Not available	2.5	Not available	1.5	2.1
<b>Nurses</b>	1.9	1.8	Not available	9.7	Not available	4.4	8.9

Sources: Company websites; CIA World Factbook, <https://www.cia.gov/library/publications/the-world-factbook/>; UN World Urbanization Prospects: The 2007 Revision Population Database; World Health Statistics 2007, WHO

# Rapidly Changing Market

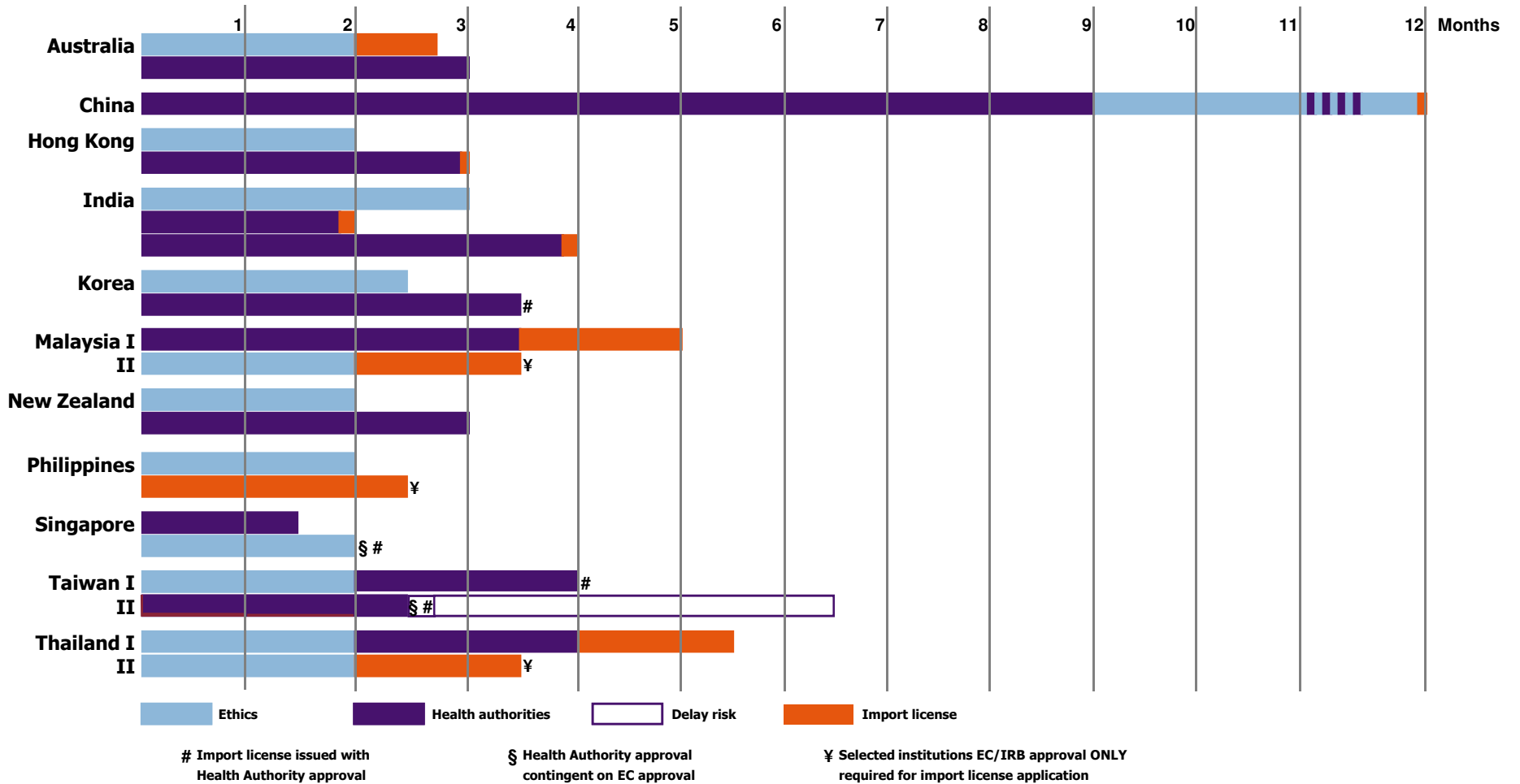
- Huge commercialisation potential
  - Quick recovery post-economic crisis
- Changing legislation around medicine research & marketing
- Rapidly expanding economies
  - Since 1997 the economy in Shanghai has expanded by 5X
- China's poverty rate fell from 85% to less than 16% (this is equivalent to 600 million people)
- Issues include soaring manufacturing and staffing costs



# Regulatory Challenges in Asia Pacific

- Regulatory approval – protracted in some countries
- CTA/CTX application processes
- Country-specific translation requirements
  - e.g., IB, protocol synopsis, patient informed consent

# Regulatory Approval Timelines



# Other Challenges in Asia Pacific

- Regulations and adherence to GCP vary among countries in Asia Pacific
- Increased competition for GCP-trained investigators
- Importing drug samples and clinical supplies
- Infrastructure for EDC varies by country
- Additional treatment costs
- Insurance and indemnification language
- Low literacy rates complicates obtaining Informed Consent

# Advantages of Outsourcing in Asia Pacific

- Resources already available in key locations
  - Knowledge of local and global standards
  - Local language, often bilingual, facilitating communication with investigators and sponsors
  - Knowledge of unique cultural requirements
  - Improves site oversight, adherence to protocols
- Expertise in identifying optimum locations for specific study needs
  - Make appropriate financial allocations and decisions

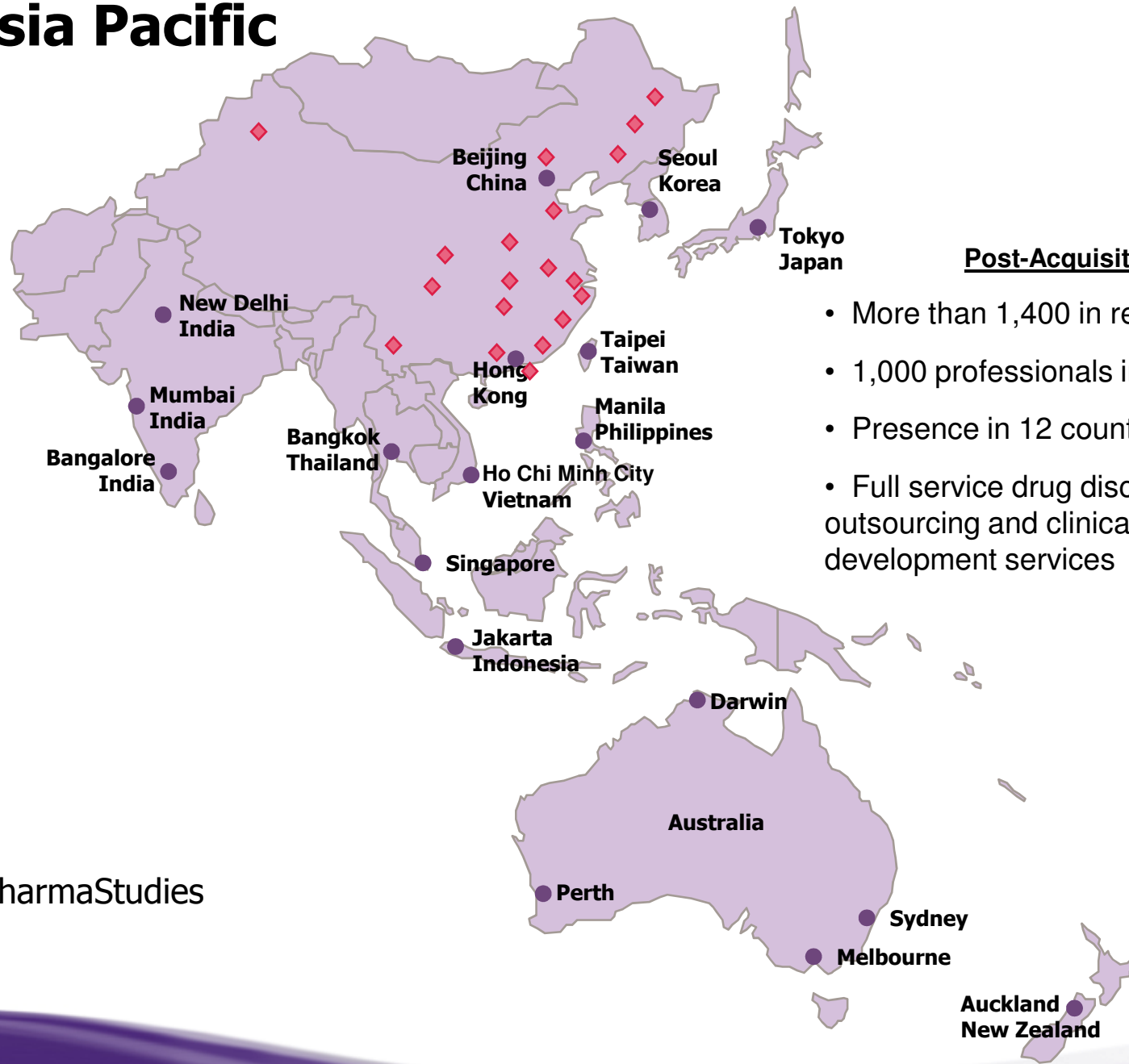
# Advantages of Outsourcing in Asia Pacific con't

- Local expertise in navigating country-specific regulatory challenges
  - Prepare regulatory documents
  - Arrange translations, increasing efficiency
  - Quality data acceptable for global registration

# With PPD's Acquisition of China's Excel PharmaStudies, Inc. and BioDuro LLC

- Increased local resources to conduct drug discovery and clinical trials
- Local services speed study timelines and lower costs
  - Central lab services provide results more quickly and lower export costs
  - Added full-service capabilities help streamline communication and minimize project delays
- Excel's experience with the State FDA (SFDA) provides insights to improve submission and approval process in China

# PPD Asia Pacific



## Post-Acquisition

- More than 1,400 in region
- 1,000 professionals in China
- Presence in 12 countries
- Full service drug discovery outsourcing and clinical development services

- PPD
- ◆ Excel PharmaStudies

# PPD in Asia Pacific — Services

- Conducting clinical trials since 1997
- Now providing a range of drug discovery outsourcing and clinical development services affairs
  - Drug discovery outsourcing
  - Site selection, evaluation and initiation
  - Clinical monitoring
  - Vaccines clinical study center
  - Project management
  - Patient recruitment
  - Regulatory affairs
  - Pharmacovigilance
  - Data management
  - Biometrics center
  - Quality assurance
- Comprehensive laboratory services
  - Global central lab (China and Singapore)