

Clinical Trial in Asia-Pacific New Challenges and Opportunities

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Speakers & Panelists

- Focus Strategy and Opportunity
 - RuiPing Dong, MD & PhD
Bristol Myers Squibb
- Focus Operational Challenge
 - Sven Ohlman, MD
Astrazeneca
- Focus Measurement
 - Larry Fiori,
Boehringer Ingelheim

Strategies & Opportunities

RuiPing Dong, MD & PhD
VP, Global Development & Medical Affairs
Bristol Myers Squibb

Japan/ASIA-PACIFIC: A DIVERSE REGION

- Uneven spread of 50% of world population
- Broad range of growth rates and age distribution
- Extremes of wealth and poverty
- Wide spectrum of medical practice, price, payor systems



Rationale For Study In Asia

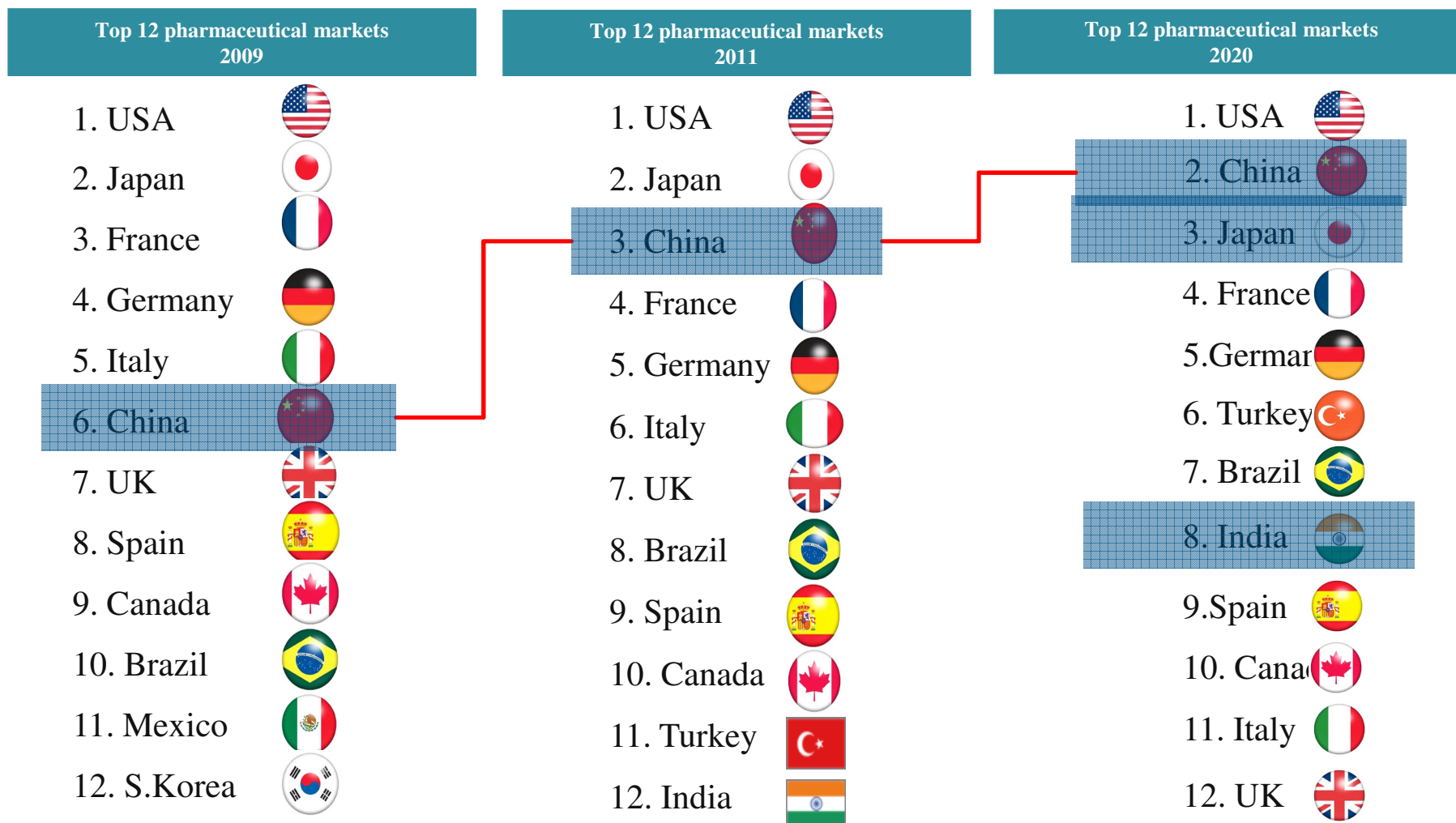
PUSH

- Increasing recruitment challenges
- High R&D costs
- Regional opportunity

PULL

- Large patient population
 - ↑ lifestyle diseases
 - ↑ demand for ‘western’ medicine
 - ↑ awareness of clinical trial participation benefits
- Favorable R&D profile
 - Trial experienced investigators
 - World-class research facilities
 - ↑ need for Asian data for registration
 - Lower R&D costs
- Growing pharmaceutical market

Growth in China has made it a strategic focus for all global Pharmaceutical companies



Source: IMS China Market Prognosis 2009, IMS Health Global Market Prognosis 2009

Note: Estimated China pharma market size for ethical and OTC drugs at ex-factory level excluding TCM (US\$ BN)

Re-defining Development Strategy to Focus on Global/Regional Studies



▶ Country alone
clinical studies

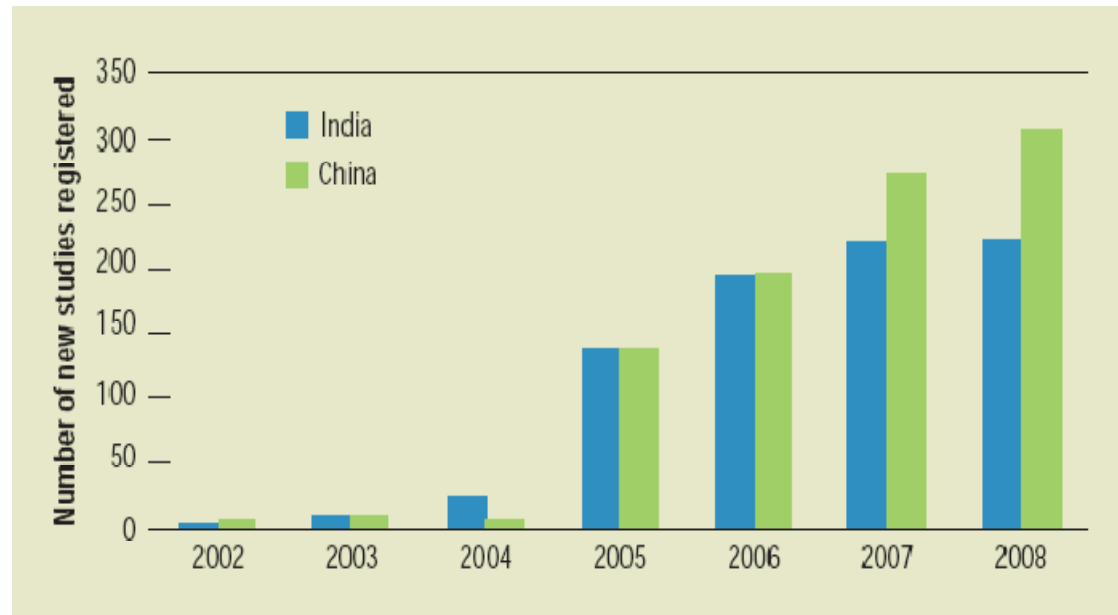


▶ Extrapolate foreign
clinical data to Local

▶ Global studies
▶ Asian studies



Overall Global Clinical Trials Environment in Asia



- Increased number of clinical trials in emerging countries
 - Study site contribution: Eastern Europe 8.9%, Asia 5.9% (**based on 10,000 clinical trials registered between October 2005 – October 2007**)
 - Increase in global trials from 2002-2008: 30-fold in China, 20-fold in India (**based on registered trials at ClinicaTrials.gov**)
 - 21.3% average annual growth rate in the share of active clinical sites in Asia vs. -2.9% in North America & EU (**between 2002-2006**)

(Source: www.clinicaltrials.gov)

Types of Trial by Region

Nature of Trial	North America	Western Europe	Oceania	Eastern Europe	Latin America	Asia	Middle East	Africa
Early (Phases I, I/II, & II)	23.9	18.1	24.6	21.4	15.8	12.2	17.3	18.9
Confirmatory (Phases II/III & III)	61.0	59.9	65.0	67.5	70.8	72.3	65.4	67.3
Post-Marketing (Phase IV)	15.2	21.7	10.3	11.2	13.4	15.5	17.4	14.9
Small (< 20 sites)	14.3	12.8	25.1	9.5	9.9	24.0	14.3	13.7
Large (≥ 20 sites)	85.7	87.2	74.9	90.5	90.1	76.0	85.7	86.3
Regional (1 region)	54.7	27.0	53.9	4.4	3.1	19.2	2.4	8.8
Global (> 1 region)	45.3	73.0	46.1	95.6	96.9	80.8	97.6	91.2

► Large, untapped opportunity for early trials in Asia

Nature Reviews: Drug Discovery 2008

Different Disease Pattern between China & USA

Non Oncology disease areas	China Morbidity (000s)	US Morbidity (000s)
Hepatitis (B & C)	166,000	5,100
Diabetes	30,000	12,000
Atherosclerosis	27,000	18,400
Affective and psychiatric disorders	20,000	19,700
Obesity	20,000	63,000
Alzheimer's Disease	5,000	4,500
RA & SLE	4,000	1,500
Oncology (Breast Cancer)	2,100	2,200
HIV	840	850
Solid organ transplantation	25	116

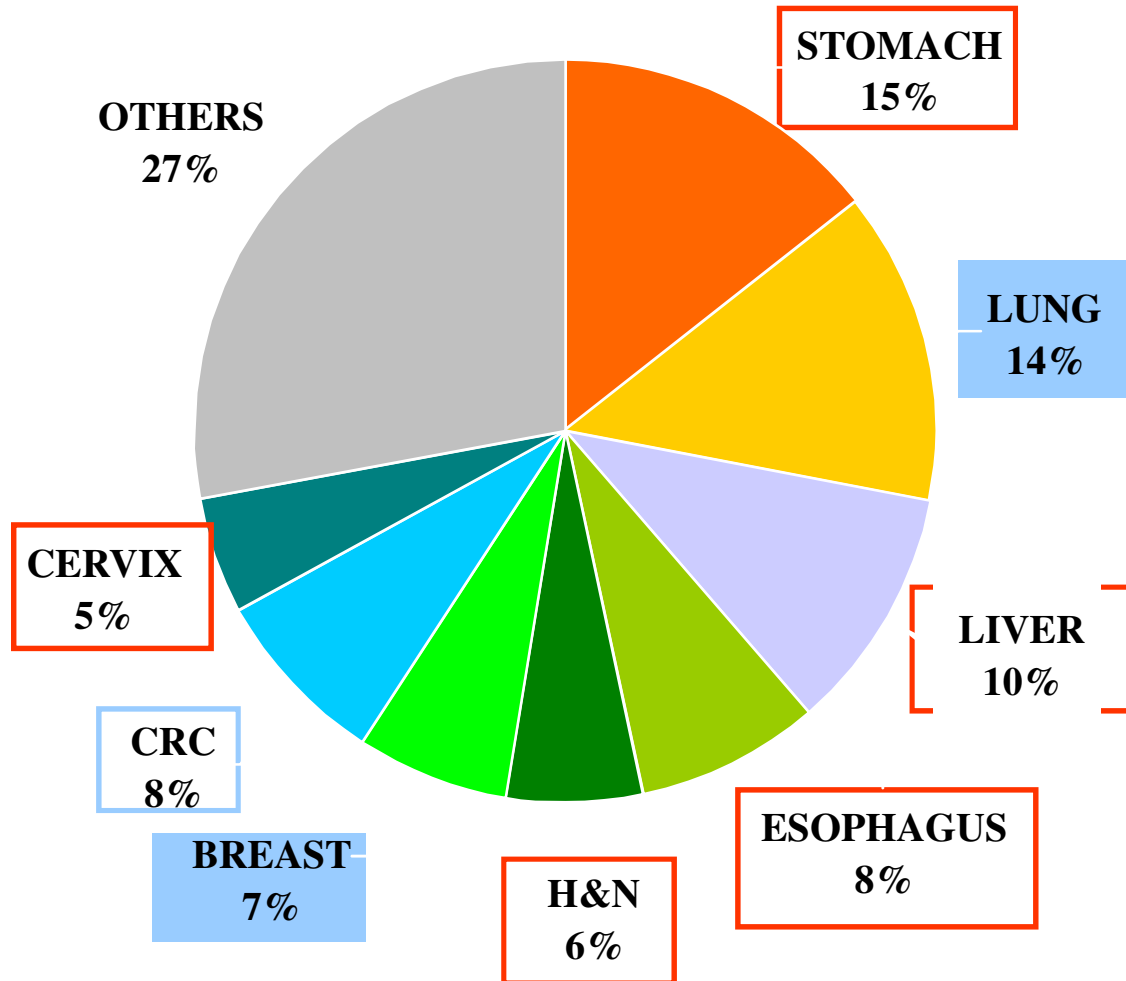
Yearly New Patients (000), Oncology	China Incidence	US Incidence
Breast Cancer	188	180
Lung cancer (including NSCLC and SCLC)	500	213
Hepacellular Carcinoma (HCC)	384	19
Gastric Cancer	376	21
Ovarian cancer	97	191

New Cancer Cases in Four Key Countries

GLOBOCAN 2002, IARC

CHINA	KOREA	INDIA	JAPAN
N = 2,190,623	N = 108,684	N = 851,901	N = 570,598
Lung	Stomach	H&N	Stomach
396,368 (18%)	23,649 (22%)	160,030 (19%)	106,760 (19%)
Stomach	Lung	Cervix	Colorectal
392,938 (18%)	15,490 (14%)	132,082 (16%)	105,195 (18%)
Liver	Liver	Breast	Lung
345,844 (16%)	14,425 (13%)	82,951 (10%)	73,635 (13%)
Esophagus	Colorectal	Esophagus	Breast
253,752 (12%)	10,211 (9%)	50,457 (6%)	41,960 (7%)
Colorectal	Breast	Lung	Liver
150,656 (7%)	5,511 (5%)	35,495 (4%)	40,604 (7%)
Breast	Cervix	Stomach	Prostate
126,227 (6%)	4,949 (4%)	34,393 (4%)	29,345 (5%)
H&N	H&N	Colorectal	Pancreas
64,053 (3%)	3,536 (3%)	33,063 (4%)	21,386 (4%)
Leukemia	Esophagus	Leukemia	Gall / Bile duct
64,053 (3%)	1,985 (2%)	24,840 (3%)	17,876 (3%)

New Cancer Cases in Four Key Countries



Rationale For North Asia Development

- Scientific rationale
 - *Similar genetic and disease patterns*
- Regulatory rationale
 - *Response to changing environment*
- Operational rationale
 - *Improve efficiency/productivity*
- For Patients
 - *Let patient access innovative drug early*

