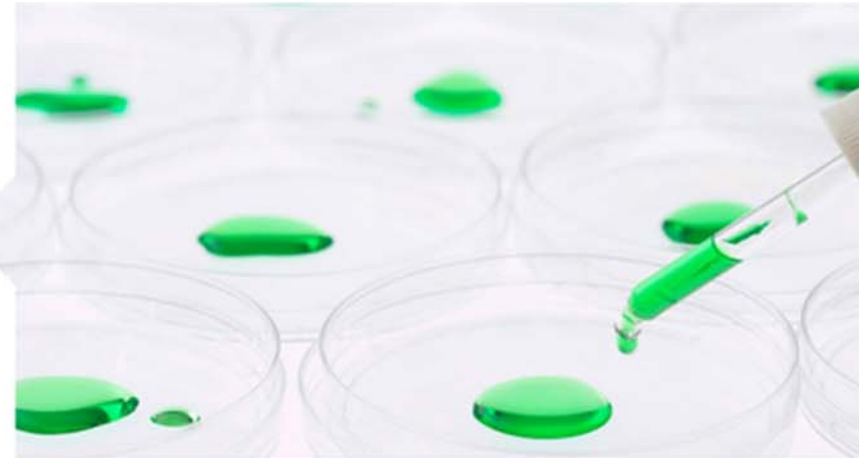




Clinical Trials in Asia: The Context

*Mini Summit II: Asia Pacific Compliance
Issues*

*Asia Pacific Pharma Congress
Shanghai, 12th September 2012*



*Dr. Amar Kureishi
Chief Medical Officer & Head
Drug Development Asia
Quintiles*



clinical | commercial | consulting | capital

Global Biopharma in Distress



Evolution of Bio-Pharma in Asia

Globalization of Asian healthcare solutions

Asian disease trends & medical need to guide R&D

Entry into Asian markets with localized products

Entry into Asian markets for global products

Access to patients for clinical trials

2020+

2015

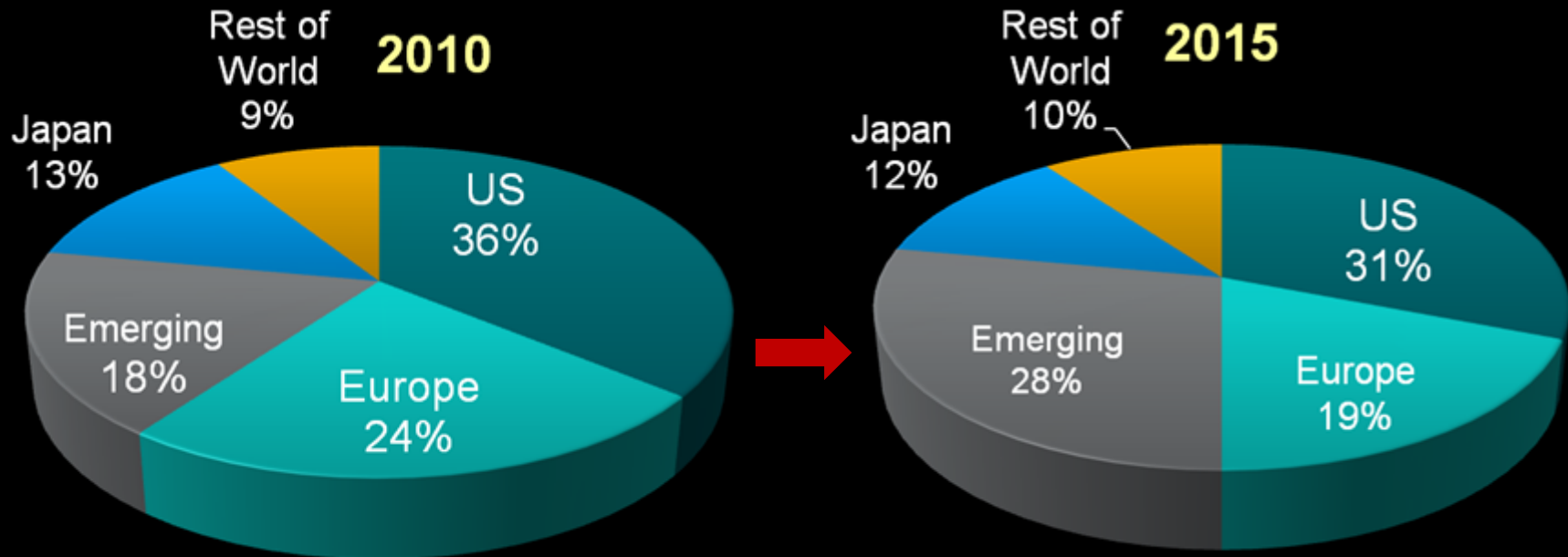
2011

2005

1998



Changing Pharma Landscape – World Pharma Market



2010 market: \$865 Billion

2015 market: \$1.1 Trillion

	2010	2015
US	311 bn	341 bn
EU	208 bn	209 bn
Emerging	156 bn	308 bn

Breast cancer nearly doubles in urban India in 24 years

Kounteya Sinha | TNN

Yamini Panchal

Breast cancer cases are spiralling world over, and urban India is no exception. A recent landmark analysis of cancer cases among women in Delhi, Mumbai, Chennai and Bangalore from 1982 to 2005, conducted by the Indian Council of Medical Research (ICMR) shows that the incidence of breast cancer has nearly doubled in metropolitan cities. (See box for rise in incidence). On the other hand, cases of cervical cancer, which is the most common form of cancer among Indian women, is dipping—in some cities by almost 50%.

India's National Health Profile 2010 predicts that by 2020, breast cancer will overtake cervical cancer as the most common type of cancer among women in India.

According to Dr Rajni Mutneja, head of preventive oncology at Rajiv Gandhi Cancer Institute, Delhi, almost one in 20 women in metropolitan cities are suffering from breast cancer. "Cases have almost doubled in the last decade, and nearly half of the patients come to us at the final stage when curing it is difficult," he said.

A health ministry official said: "Till a decade ago, breast cancer was diagnosed in around 10 per one lakh women every year.

Let's Pink
October is Breast Cancer Awareness Month. Let's Pink is a movement to raise awareness on the disease and its prevention

Now, it has more than doubled to 23 per one lakh women. In cities like Chennai, the figures are troubling with the breast cancer ratio as high as 1:33."

TOI also looked at the 10 leading types of cancer that women in urban cities suffered from between 2006 and 2008, and found that breast cancer accounted for a high percentage in each city. In Mumbai, 30% of cancer cases among women were that of the breast; in Delhi and Bangalore it was almost 26.9% while the incidence in Chennai was marginally lower at 26.5%. In Kolkata, it accounted for 27.2% of cancer cases among women and in Pune it was 28.9%.

ICMR has also come out with the "possibility of one in 'n' number of people developing cancer of any site" score. The calculation is age specific—0-64 and 0-74 years. In Mumbai and Kolkata, one in 14 women runs the risk of developing cancer before she reaches 64 years (See Risk Factor). Director general of ICMR Dr V M Katoch said that certain anatomical sites of cancer have shown a significantly steady increase across all registries, breast cancer being one of them. "This data will tell us how we can improve diagnostic capabilities," he said.

Let's Pink is a joint initiative by The Times of India and Ponds. This is the first in a series of 7 articles on breast cancer

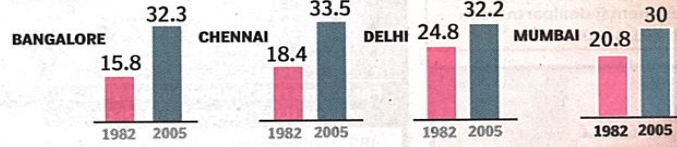
Make Time For Yourself

You can get a preliminary breast examination done for free from any of these doctors between October 18 & 24

AREA	DOCTOR	CONTACT
1. New Marine Lines	Dr Suryakant Choudhari Bombay Hospital	9920774977
2. Dadar TT	Dr Boman Dhabhar BND Oncocentre	9224448355 24173003
3. Mahim	Dr Vinay Deshmane Hinduja Hospital	24447128
4. Andheri (W)	Dr Chetan Shah Criti Care Hospital	99200 55216
5. Ghatkopar (W)	Dr Vimal Jain Medico Surgical Hospital	98210 61965
6. Borivli (W)	Dr Ashish A Joshi Mandapeshwar Hospital	2895 1502, 2893 8685
7. Mulund	Dr Anil Heroor	9930817801
8. Naupada, Thane	Dr Satish V Kamat Asha Cancer Hospital	9324514265 25435609
9. Thane (W)	Dr Navin Bhambhani Jupiter Hospital	21725570

Spiralling Incidence

An analysis of cancer cases among women in Delhi, Mumbai, Chennai and Bangalore from 1982 to 2005 shows that the incidence of breast cancer has nearly doubled in metropolitan cities. The figures below represent incidence per one lakh women in %



PREDICTION | India's National Health Profile 2010 predicts that by 2020, breast cancer will affect 1.24 lakh women across India



Risk Factor

- DELHI** | 1 in 11 women run the risk of cancer by the time they are 64 years. (1 in 8 by 74 years)
- MUMBAI** | 1 in 14 women run the risk before 64 years. (1 in 9 by 74 years)
- KOLKATA** | 1 in 14 women may get cancer before 64 years. (1 in 10 by 74 years)
- CHENNAI** | 1 in 12 women are at risk before 64 years (1 in 8 by 74 years)
- BANGALORE** | 1 in 10 women may get cancer by 64 years, (1 in 7 by 74 years)

Source: ICMR

Annually:
➤ 115,000 New cases
➤ 150,000 by 2015

Source: The Times of India, October 18, 2011



Western lifestyle leads to rise in breast cancer rates

Updated: 2011-10-17 07:56

By Shan Juan (China Daily)

Print Mail Large Medium Small Share 0

TIANJIN - Breast cancer has become the most lethal form of the disease among Chinese women, with city dwellers being hit harder than those in the countryside, medical experts said.

In the past 30 years, the period covered by China's large and rapid urbanization, the incidence of breast cancer increased about 6 percent annually, which was higher than the global average of 4 percent, said Zhang Jin, deputy director of the breast cancer center at Tianjin Cancer Institute and Hospital.

“Breast cancer has now become the most prevalent cancer among Chinese women, replacing lung cancer, and that's in line with the international trend.”

ZHANG JIN, DEPUTY DIRECTOR OF THE BREAST CANCER CENTER AT TIANJIN CANCER INSTITUTE AND HOSPITAL

"Breast cancer has now become the most prevalent cancer among Chinese women, replacing lung cancer, and that's in line with the international trend," Zhang said at a media event on the

Breast cancer in China - Annually:

- 126,000 new cases
- 37,000 deaths
- 1/10 of the world's total

Diet, Obesity & Diabetes



“Coca-colonisation”



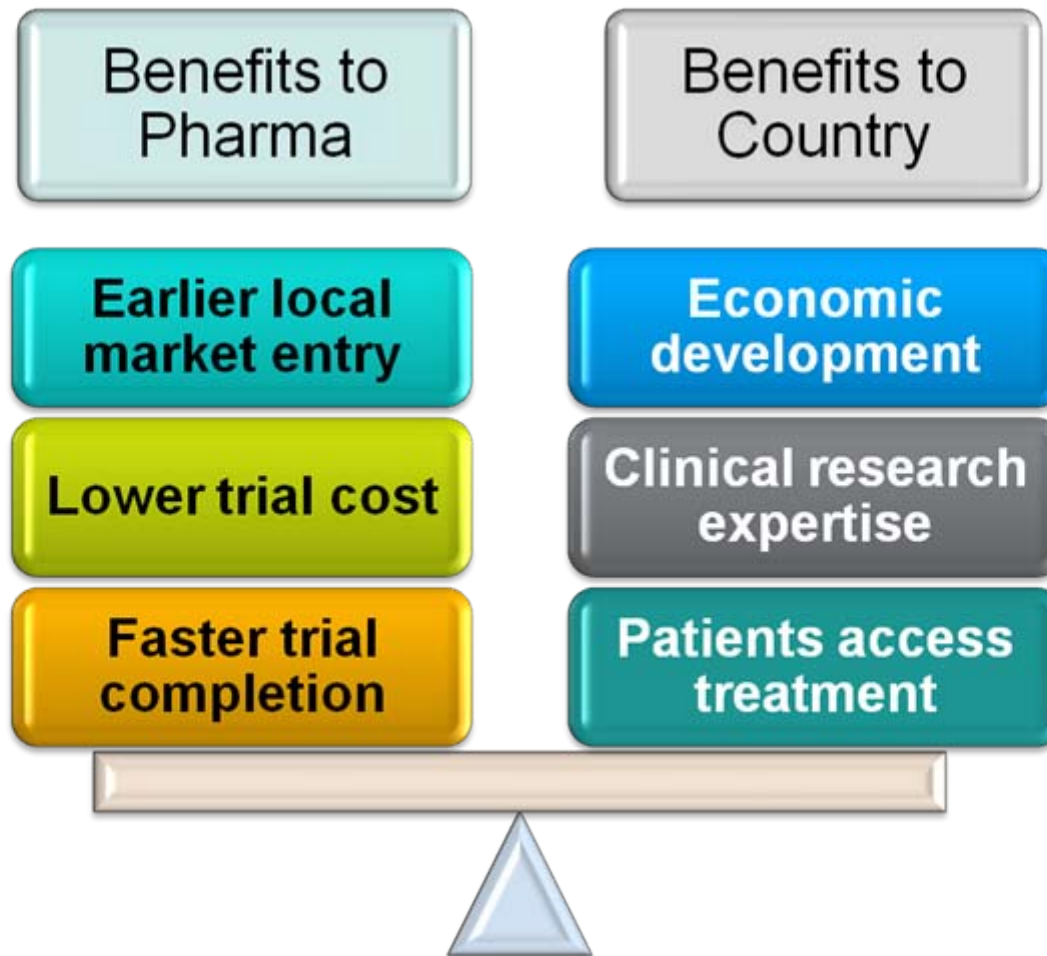
Smoking in China



- A government survey in 2010 found that 40% of male doctors light up every day in China.
- Only 1 in 4 adults in China believe exposure to tobacco smoke causes heart diseases and lung cancer
- China has more than 320 million smokers, a third of the world's total, and 53 percent of men there smoke.
- About 1 million Chinese die from tobacco-related illnesses every year.

“The tobacco industry is a very important part of local government income. There is a lot of internal government lobbying to make sure the health consequences of smoking are not addressed.” – Wang Shiyong, World Bank’s senior health specialist in Beijing

The Benefits of Conducting Clinical Trials in Developing Countries



Declaration of Helsinki – 1964-2008

- Developed by the World Medical Association for use by the medical community following dissemination of the Nuremberg Code.
- Cornerstone document providing framework for ethical conduct of clinical research.

“The well-being of the individual research subject must take precedence over all other interests”

International Conference on Harmonization: Good Clinical Practice (GCP)



“A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.”

Historical Landmarks

- ❖ Nazi medical experiments 1939-1945
- ❖ US human radiation experiments 1944-1974
- ❖ Tuskegee Syphilis Study 1932-1972
- ❖ Jewish Chronic Disease Hospital Study 1963
- ❖ The Willowbrook Study 1963-1966

The Nuremberg Code



Informed consent is absolutely essential

Participant must be free to stop at any time

Qualified researchers use appropriate research designs

Favorable risk/benefit ratio

Good Clinical Practice (GCP)



Sponsor's Responsibilities

- Comply with the local ethical, regulatory and legal requirements
- Ensure the local relevance of the research while involving local partners in the development stages
- Select qualified researchers
- Ensure appropriate review, approval and supervision by an EC
- Provide policies and procedures
- Monitor the research
- Promote research integrity



Investigator's Responsibilities



- Appropriate informed consent
- Protection of human participants
- Compliance with EC requirements
 - Report adverse experiences, protocol violations, participant complaints
- Scientific rigor and professional integrity
- Conduct research according to protocol
- Confidentiality protection
- Post-study
 - Long-term interests of participants



Ethics Committee Membership & Responsibilities



- Medically and scientifically qualified to review study protocol (therapeutic alignment)
- Diverse and representative of community

Scientific Design and Conduct of the Research

- Appropriate research design?
- Qualified researchers?

Recruitment of Research Participants

- Informed consent?
- Appropriate recruitment methods?
- Safeguards for vulnerable populations?

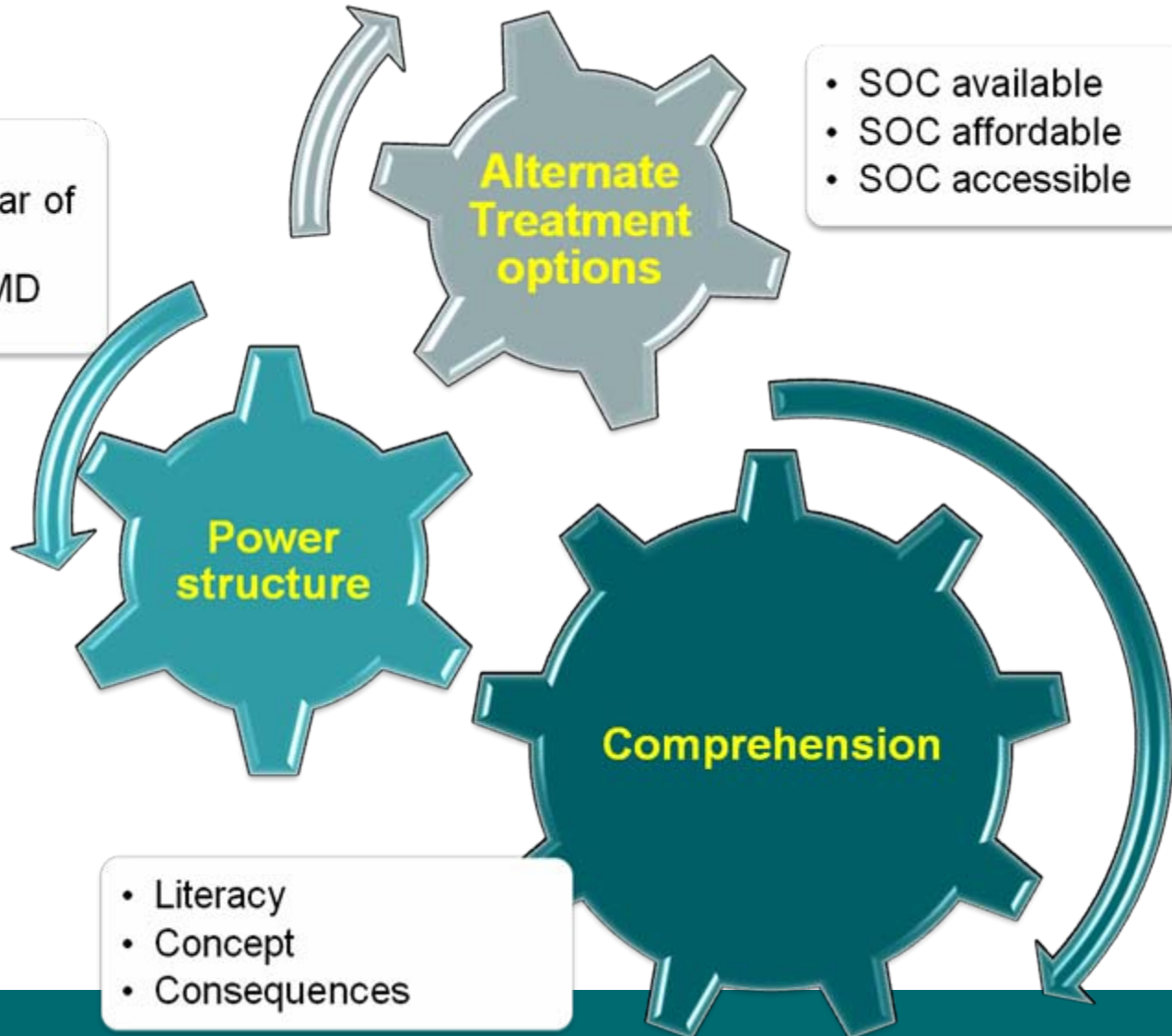
Community Considerations

- Benefit to community?
- Consultation with community?

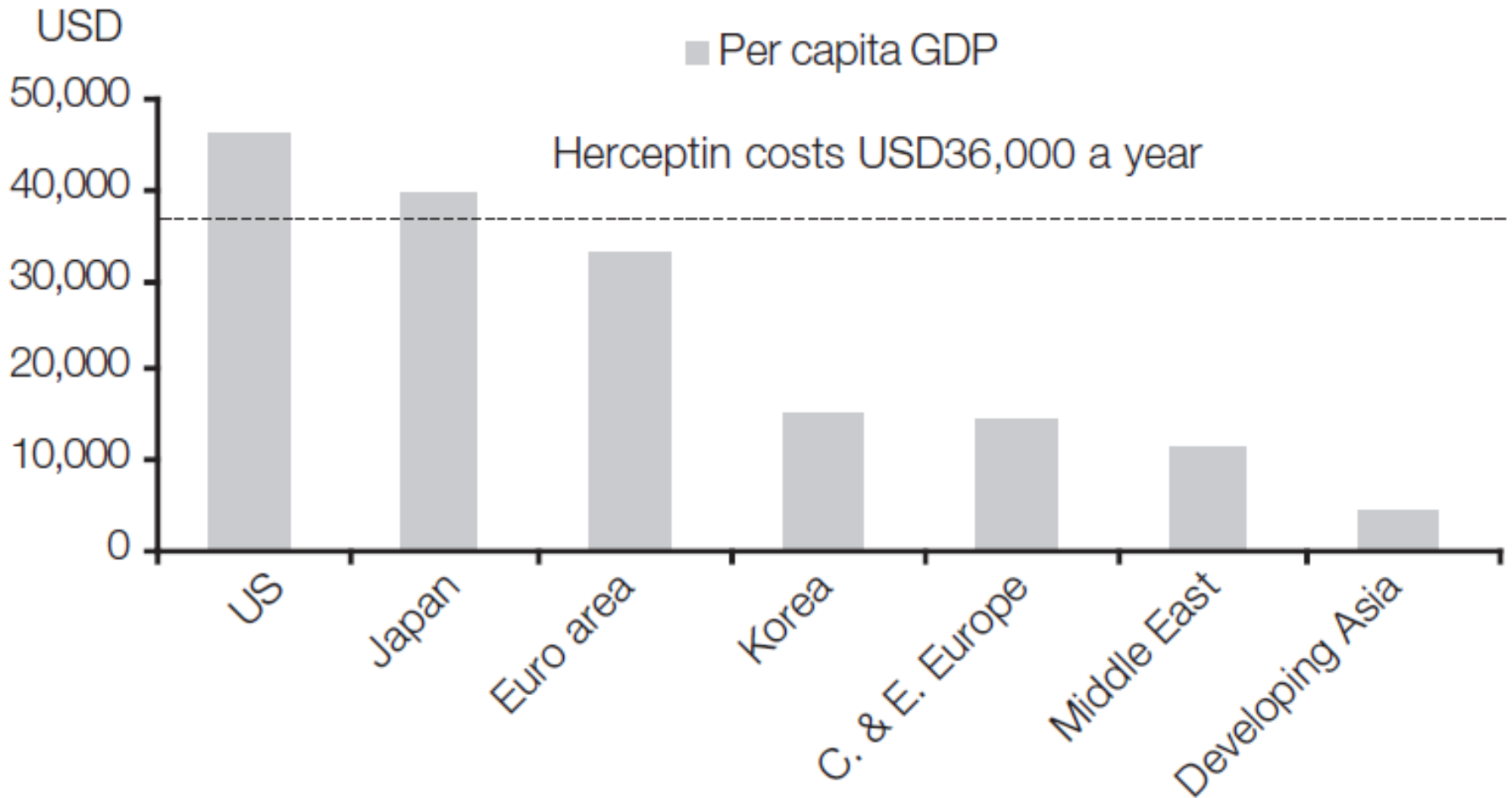


The Ethics of Conducting Clinical Trials in Developing Countries – What constitutes Informed Consent

- Able to refuse or withdraw without fear of repercussions
- Excessive trust in MD

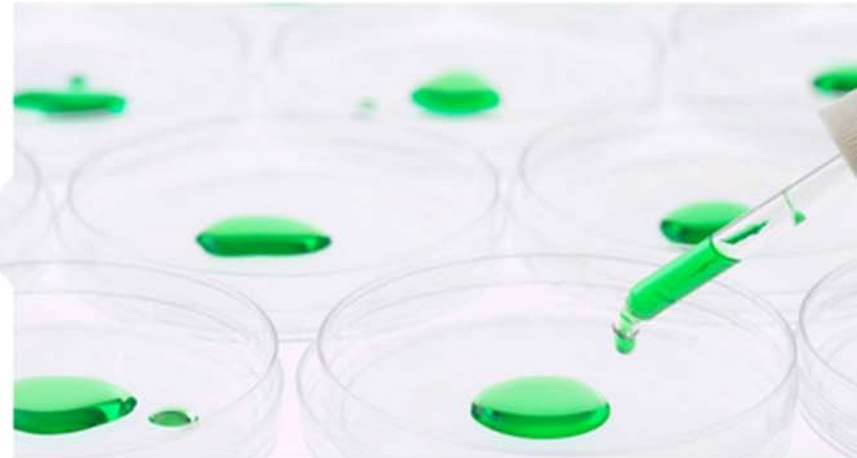


Annual Cost of Herceptin vs. Per capita GDP





Thank you



clinical | commercial | consulting | capital

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