Clinical Trials in Asia: The Context

Mini Summit II: Asia Pacific Compliance Issues
Asia Pacific Pharma Congress
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Dr. Amar Kureishi
Chief Medical Officer & Head
Drug Development Asia
Quintiles
Global Biopharma in Distress

- Patent expiration of major blockbuster products
- Major failures in late stage drug development
- Reduced availability of venture funding
- Products withdrawn from the market

Evolution of Bio-Pharma in Asia

- Entry into Asian markets for global products
- Entry into Asian markets with localized products
- Access to patients for clinical trials
- Asian disease trends & medical need to guide R&D
- Globalization of Asian healthcare solutions
Changing Pharma Landscape – World Pharma Market

2010 market: $865 Billion

2015 market: $1.1 Trillion

<table>
<thead>
<tr>
<th>Region</th>
<th>2010</th>
<th>2015</th>
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<tbody>
<tr>
<td>US</td>
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<td>308 bn</td>
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Source: IMS / Scrip World Pharmaceutical News
Breast cancer nearly doubles in urban India in 24 years

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

Source: The Times of India, October 18, 2011
Breast cancer in China - Annually:

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

Western lifestyle leads to rise in breast cancer rates

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 said at a media event on the
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

Benefits to Pharma:
- Earlier local market entry
- Lower trial cost
- Faster trial completion

Benefits to Country:
- Economic development
- Clinical research expertise
- Patients access treatment
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”
“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

Alternate Treatment options
- SOC available
- SOC affordable
- SOC accessible

Power structure

Comprehension
- Literacy
- Concept
- Consequences
Annual Cost of Herceptin vs. Per capital GDP

Herceptin costs USD36,000 a year

Source: IMF, Hyundai Securities
Thank you