For Japanese, Asian and Worldwide patients

The 9th Kitasato- Harvard School of Public Health Symposium
-Advanced and Global Drug Development Techniques-
Significance of Asian Studies in Simultaneous Global Clinical Trials

Masatoshi Narita
Evaluation and Licensing Division
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare
For the Better and Faster Approval Review of Drugs

Our Goals are to ...

• **(Maximization of benefits)**
  Make innovative drugs and medical devices developed in the world quickly available to patients worldwide

• **(Minimization of risks)**
  Minimize damage to patients in terms of quantity and quality through whole life cycles of drugs

• **(Optimization of cost)**
  Encourage innovations in medical area by promoting efficient development, production and safety measures
5-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices

April 2007  MHLW, MEXT, METI

To provide our populace with access to the best pharmaceuticals/medical devices in the world

To boost the pharmaceutical/medical device industry to become the driving force of Japan's growth

Measures aiming for development originating in Japan and Japan’s participation in simultaneous global development

1) Concentrated Research Financing
2) Nurturing Ventures, etc.
3) Improvement of the Clinical Research/Trial Environment
4) **Collaboration with Asia**
5) **Faster and Better Reviews**
6) Appropriate Assessment of Innovations
7) Public-private dialogue
Countermeasures / Goals and Objectives to Reduce the Drug Lag

1. **Expand the Consulting Service**
   - Increase the number of staff
   - Improve the quality and quantity of consultations

2. **Clarify the review criteria**
   - Further promote Global Clinical Trials

3. **Expand the Review System**
   - Increase the number of staff
   - Enhance and improve the Review System
   - Liaise more closely with the FDA and other overseas regulatory authorities

- **1.5 year** of development time

- **Reduce Total TC by 1.0 year.**
  For applications after FY2004
Global Drug Development

Overseas

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Phase IV(PMS)</th>
</tr>
</thead>
</table>

Global Clinical Trials

Approval Review

Japan

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Phase IV(PMS)</th>
</tr>
</thead>
</table>

Domestic drug approvals can be synchronized with overseas!

Simultaneous NDA submission

Simultaneous approval
Global Clinical Trials Consultations

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Number of Global Trials Consultations</th>
<th>Total Number of Consultations</th>
<th>% Global Trials Consultations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>0</td>
<td>186</td>
<td>0.0</td>
</tr>
<tr>
<td>2005</td>
<td>100</td>
<td>284</td>
<td>0.0</td>
</tr>
<tr>
<td>2006</td>
<td>200</td>
<td>338</td>
<td>0.0</td>
</tr>
<tr>
<td>2007</td>
<td>250</td>
<td>343</td>
<td>0.0</td>
</tr>
<tr>
<td>2008</td>
<td>300</td>
<td>331</td>
<td>0.0</td>
</tr>
</tbody>
</table>
Trends of Global Clinical Trials including Japan
- Operational Regions -

![Bar chart showing the trends of global clinical trials in East Asia only, Include Asia, No other Asia, and Uncertain regions for different years.](chart)

- Early FY2007: 17 (East Asia only), 21 (Include Asia), 10 (No other Asia), 0 (Uncertain)
- Late FY2007: 17 (East Asia only), 21 (Include Asia), 10 (No other Asia), 0 (Uncertain)
- Early FY2008: 34 (East Asia only), 20 (Include Asia), 15 (No other Asia), 4 (Uncertain)
- Late FY2008: 48 (East Asia only), 32 (Include Asia), 20 (No other Asia), 8 (Uncertain)
Asian drug development as global player

- More experience & scientific research
- Networking & collaboration in Asian region
- Develop best fit drugs for Asian populations