

# Global Development: Japan's perspective and the Role of MHLW

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# Drug Regulatory Authority's Mission

Promote and Protect  
Public Health by assuring that  
Safe and Effective Drugs are Available  
to the Nation's Public



1. Quick Delivery of Innovative Drugs to Patients with Precise Review
2. Maintenance of Drug Safety through Pharmacovigilance
3. Assurance of Drug Quality through Regulating Facilities/Products

# FACT

- Simultaneous Global Clinical Trials is the World's Trend. Why ?
- To counter Drug Lag and deliver World's Newest Drug to Patients, Development at and Participation in Global Trials is now obviously one of essential factors to attain the goal.

## Japan's Reaction

1. Improved Clinical Trial Environment for Participating in Global Trials
2. Rationalized Handling of Clinical Data obtained abroad (Evaluation of Ethnic Factor)

# Improving PMDA's Consultations



## NDA Reviewers (doing Consultation )

Ca.280 (April '08)

Ca.440 (March '10)

## Clinical Trials Consultations

(1) Fast Track for Global Development

(2) # Increase 300 ('06) to 1,200 (by March '12 )

(3) Waiting Period 3 mo. to 2 mo. (by March '09)

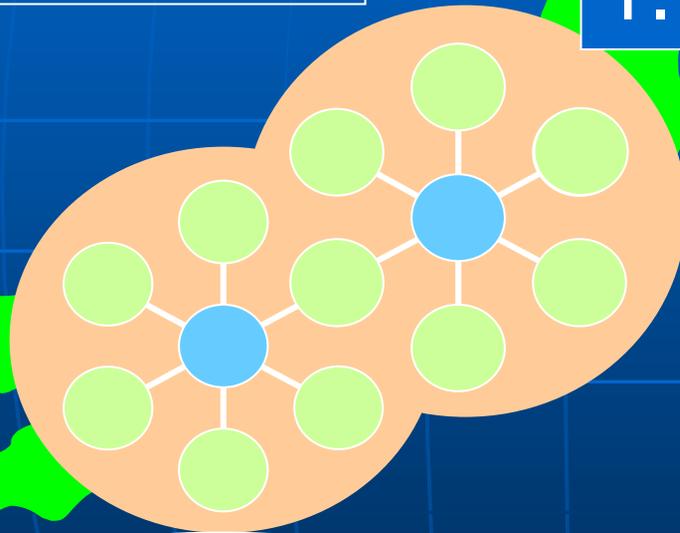
## Guideline (with MHLW)

“Basic Principles on Global Clinical Trials” (Sep. '07)

# Clinical Trials Activation 5-Year Plan (2007-2011)

Networking of  
Trial Sites

Budget:  
1.75 billion Yen (FY2007)



- 10 National Centers
- 30 Trial Hubs

General Promotion  
on Subjects  
Information, Incentive

Doctors' Incentive  
Infrastructure  
CRCs, IRB  
Efficiency  
EDC

# Ethnic Differences

## 1. Approved Doses

- Capecitabine (anti-cancer)  
1,657 (Japan), 2,500 (EU/USA) mg/m<sup>2</sup>/day
- Telithromycin (antibiotics)  
600 (Japan), 800 (EU/USA) mg/day

## 2. Reported ADR Incidences

- leflunomide (anti-rheumatis)  
interstitial pneumonia (Japan>USA/EU)
- Irinotecan (anti-cancer)  
diarrhea (Japan>USA/EU)



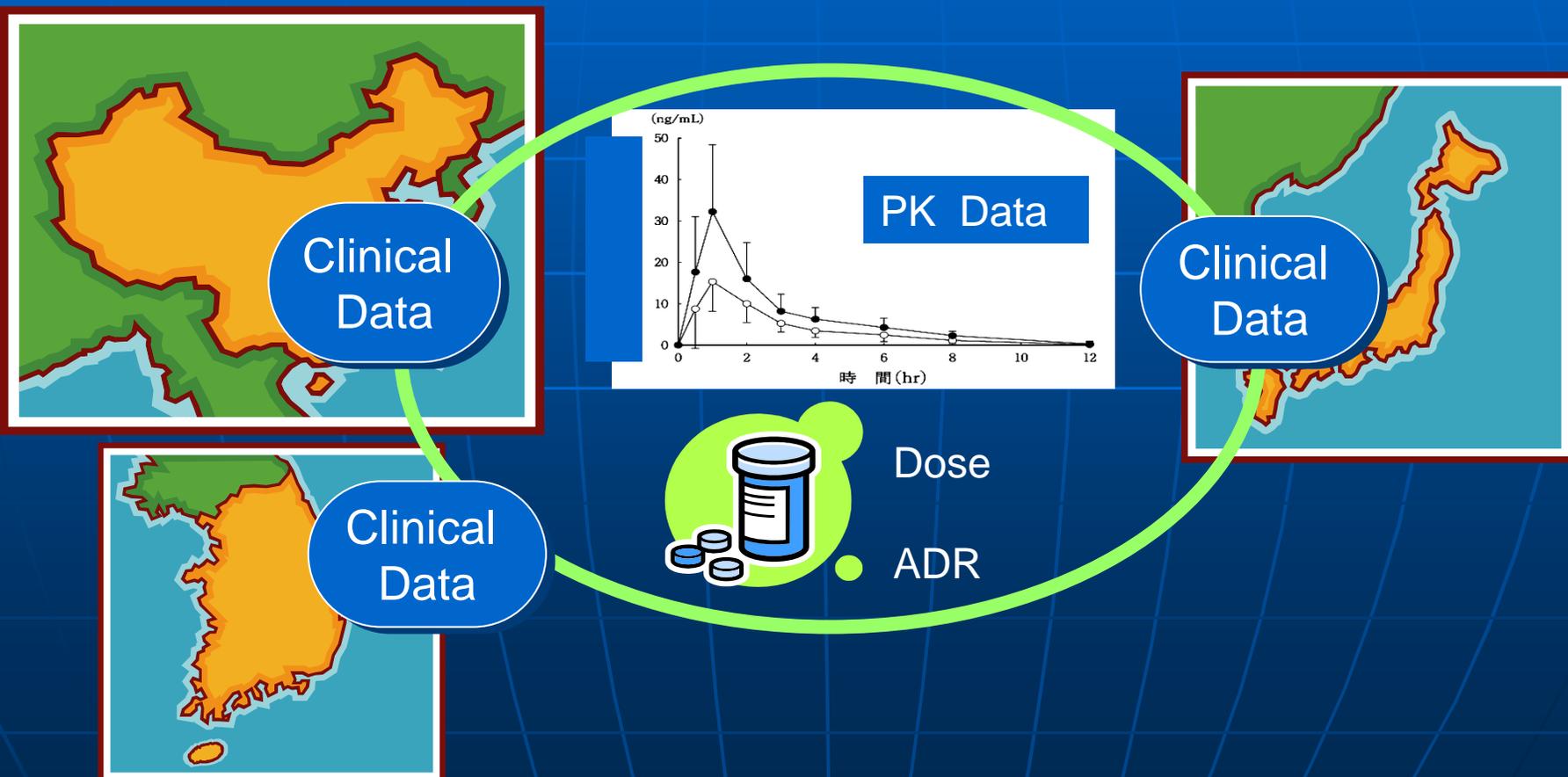
But what do we know until now  
about Ethnic Differences among  
Asian Populations ?

# Points for consideration

- Need for sharing ADRs information on drugs of newly launched and/or under development so that we could avoid unnecessary ADR cases.
- Need for quickly establishing the most efficient way of use of new drugs in terms of efficacy and safety : in other words, to be able to describe drug profile as soon as possible, among Asian countries/region
- Anyway, we should know more about each other's system, experience and way of thinking through communication and collaboration

# Initial Step

## China/Korea/Japan Joint Research Project on Ethnic Factors in Clinical Data



# Adequate Drug Development in Asia



**ASIA**

60% of World's  
Population

25 % of World's  
Economy

We obviously shoulder very important role and responsibility to provide majority of total world population with new and Improved drugs.

# By what means ?

- Through organized efforts for :
  - knowing each other's Ethnic Factors & Medical Environments more
  - sharing each others experience and direction for improving clinical development environment at private sectors as well as public sectors
  - overcoming with stumbling blocks in new drug development through collaboration
- Asia has great potential as venue to develop drugs necessary in Asia and other areas and regions

# Conclusion

- Efforts and commitment for collaboration have already started at high level.
- Now the time has come for us here to realize that world people now longed for our much more collaboration at various stage in drug development, among private sectors, public sectors, scientists, patients and people.

Thank you for your  
attention.

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ありがとうございました