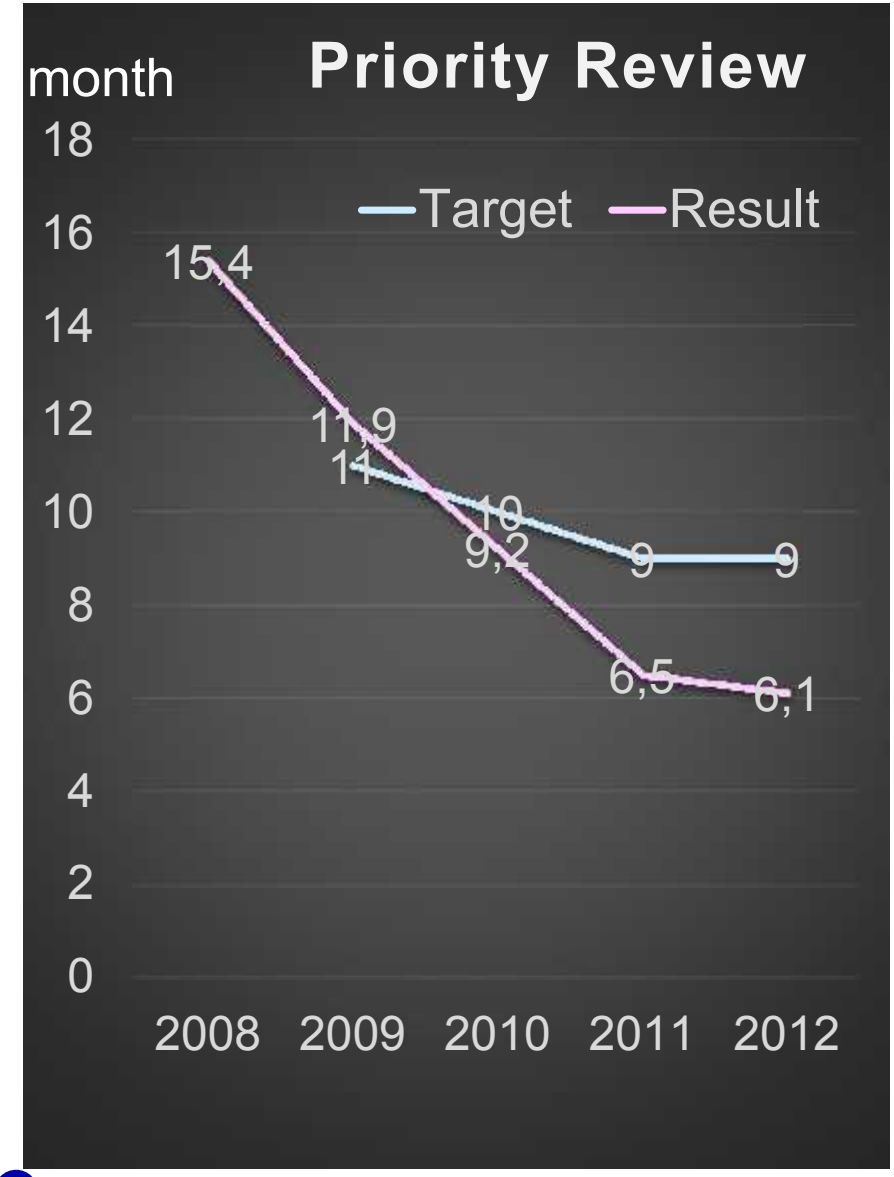
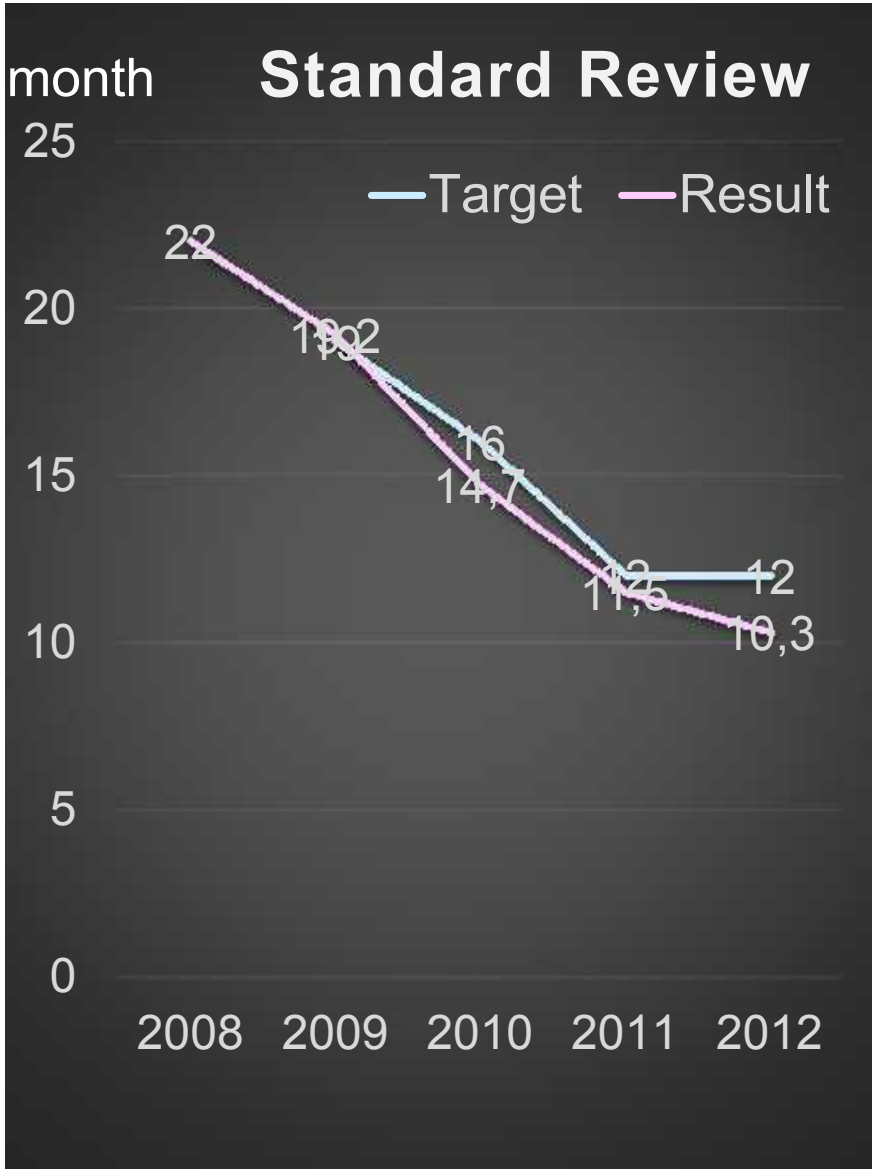
New Challenges of PMDA
&
New Drug Development in Asia

Strengthening cooperation with Indonesia

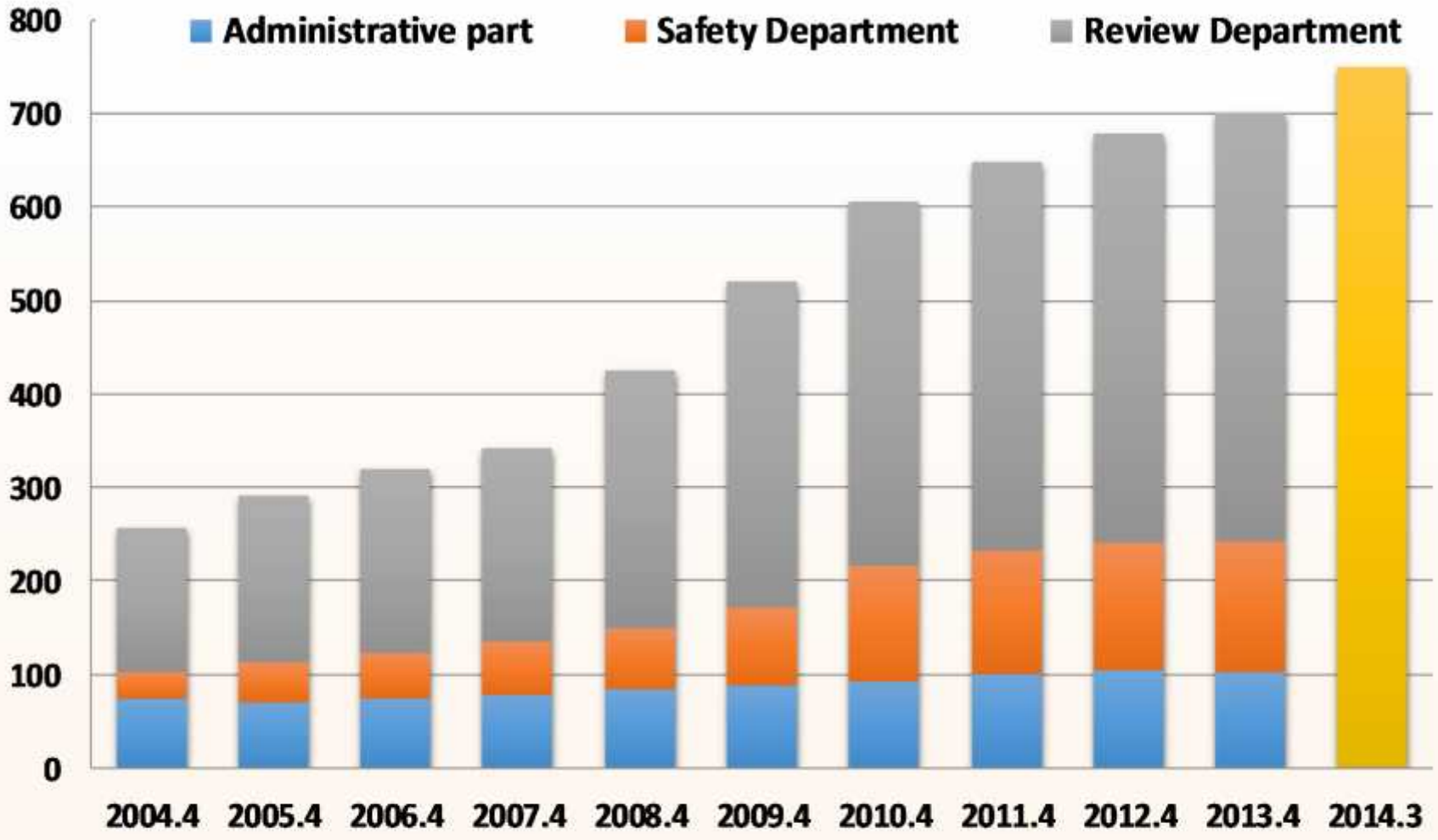
(Pharmaceuticals and Medical Devices Agency)

Target and Result of total New Drug Review time





Staff Size



Plan to increase staff size in next 5 years to cope with new challenges for introducing safe drugs timely

3

Accumulation and Utilization of Data

NDA submission

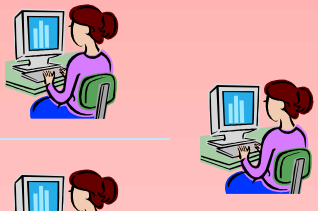
Submission of electronic data from clinical and nonclinical studies

Visualization and analysis of data, supported by browsing software

Regulatory Review

Use of electronic data

Scientific discussion and decision making on the basis of internal analysis result



Utilization of Accumulated Data

Integration of cross-products information

Contribution to efficient development through review/consultation and GL publication based on further analyses by dry-lab

Initiative to Develop Infrastructure for Medical Information Database

- Build database hubs at 10 cooperating medical institutions nationwide.
- Target is to make more than 10 million patients data ready for use in 2015 to allow Faster and more appropriate safety measures.

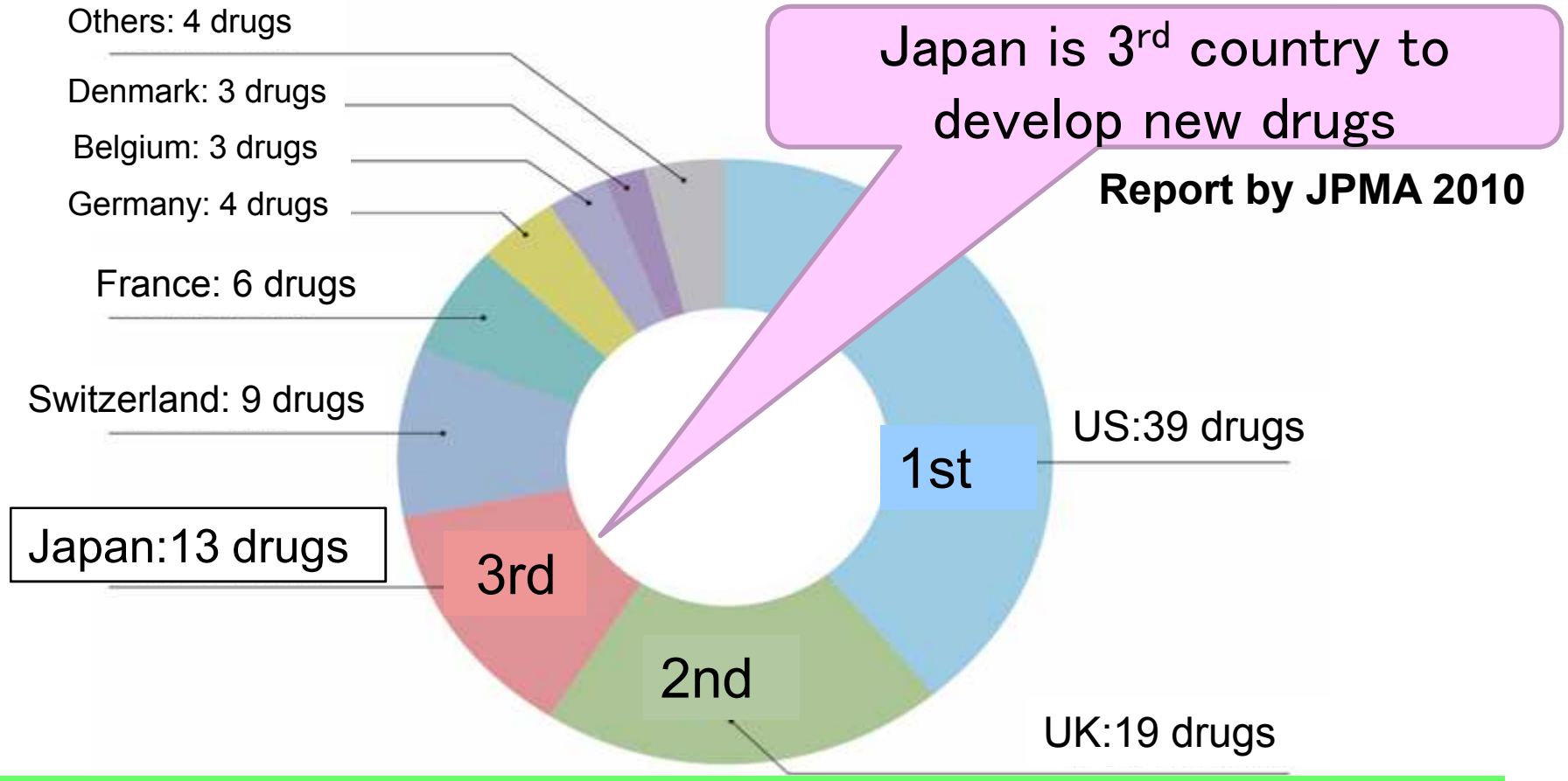
Cooperating medical institutions (10 University and group hospital sites)

Associated medical institutions of hub medical group

Utilization by PMDA and researchers

New Drug Development

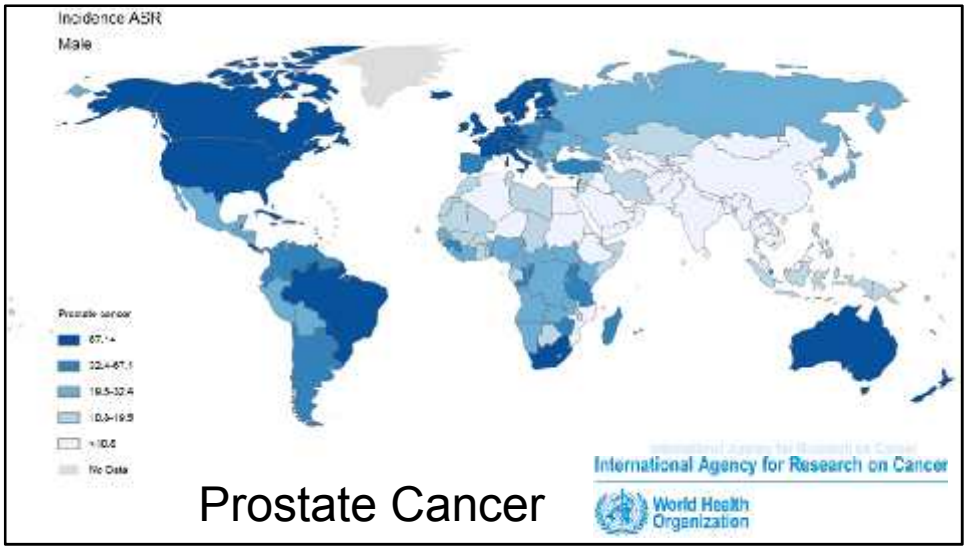
Origin country for top 100 sales drugs in the world



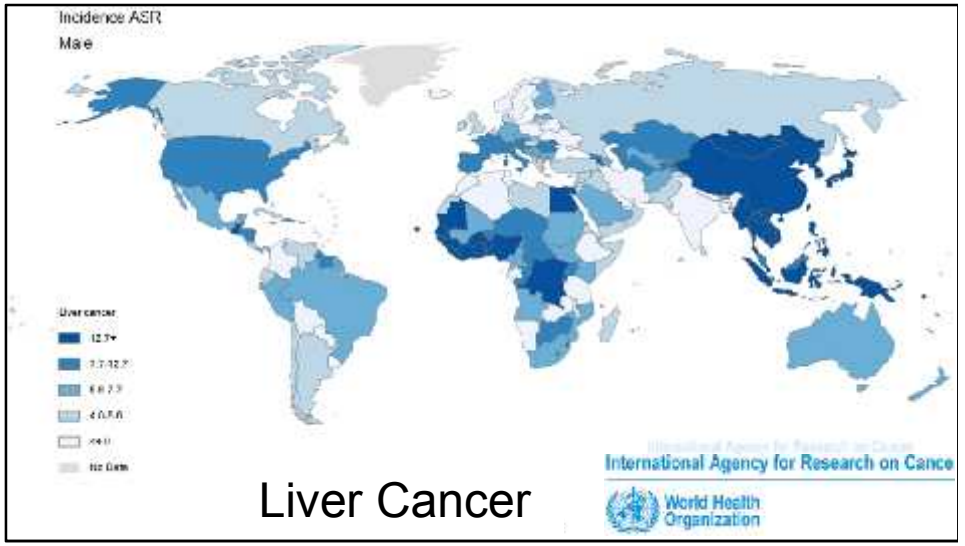
Do we have drugs timely & find suitable doses for Asian People?

Do we have drugs timely for Asian People ?

- ✓ Incidents rates of diseases differ among regions.
- ✓ Some diseases, such as Liver cancer, Stomach cancer are prevailing mostly in Asia.



Prostate Cancer



Liver Cancer

"Basic Principles on Global Clinical Trials (Reference Cases)"
issued on Sep 5, 2012 by MHLW.

Recommended therapeutic areas

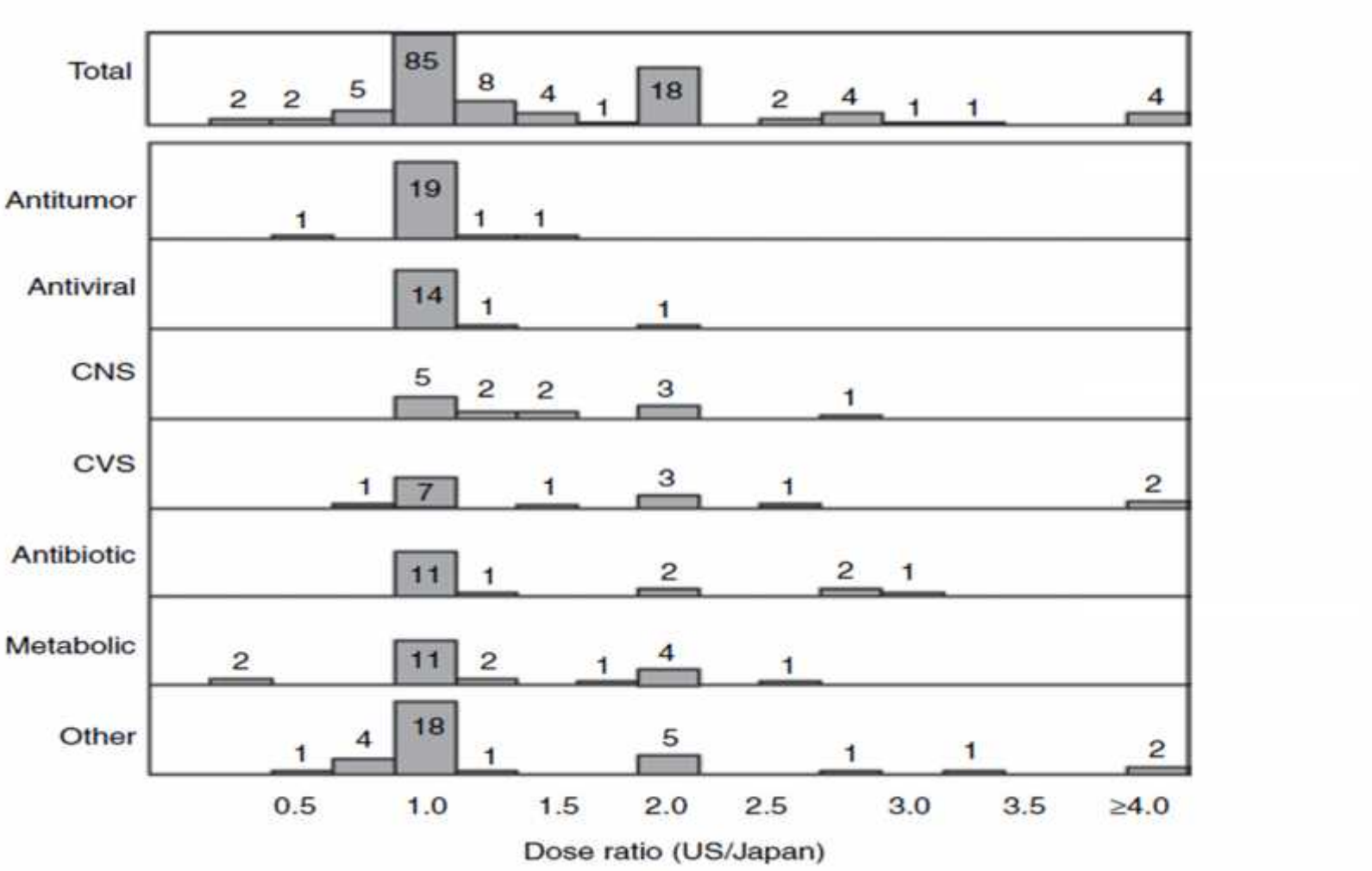
"proactive planning of a global clinical trial in East Asia may contribute to the improvement of the efficiency and quality of clinical development of a drug."

Asian trials may contribute to new drug development

Do we find suitable doses for Asian People?

For 32 % of drugs, US/EU dose was ≥ 2 times higher than Japanese dose

Approved drugs during 2001-2007



Arnold FL et al , Clin Pharmaco Therapeut., 87: 714-720, 2010

Advantages of MRCT among Asia ?

Differences for Diabetes mellitus
BMI: Japanese < Caucasian
Insulin : Japanese < Caucasian
Insulin resistance: Japanese < Caucasian

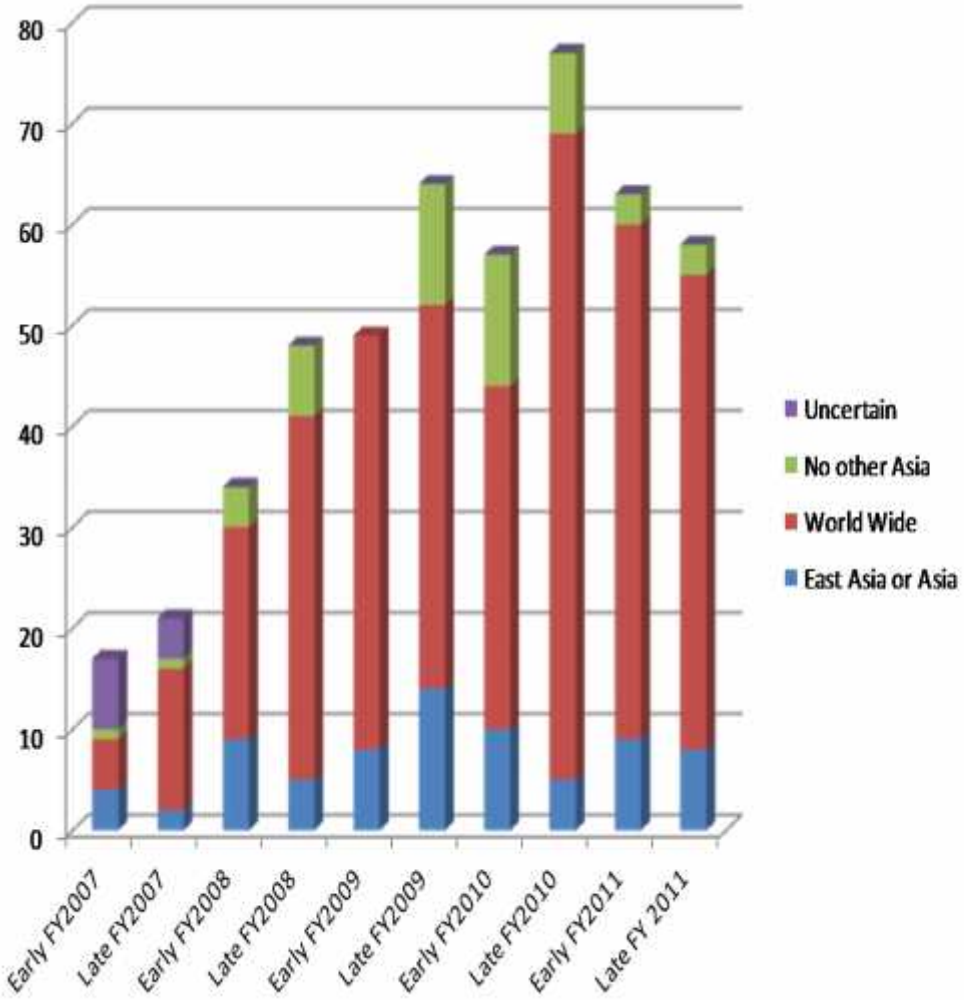
	JPN Trial	US Trial 1	US Trial 2
BMI	24.72	32.07	32.02
HOMA-β(%)	25.22	-	73.42
HOMA-R	2.58	-	8.58

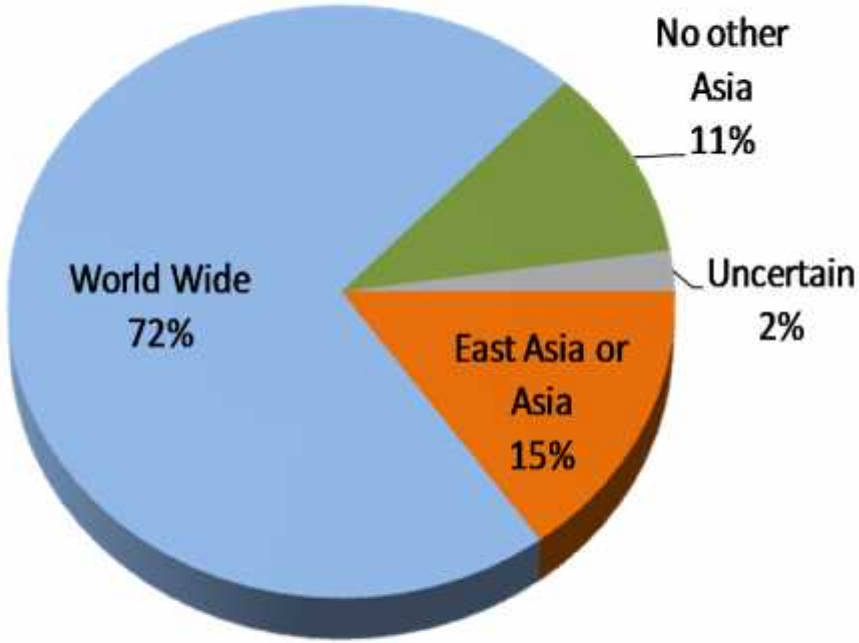
Data from the review report of alogliputin

The difference can affect the drug safety and efficacy.

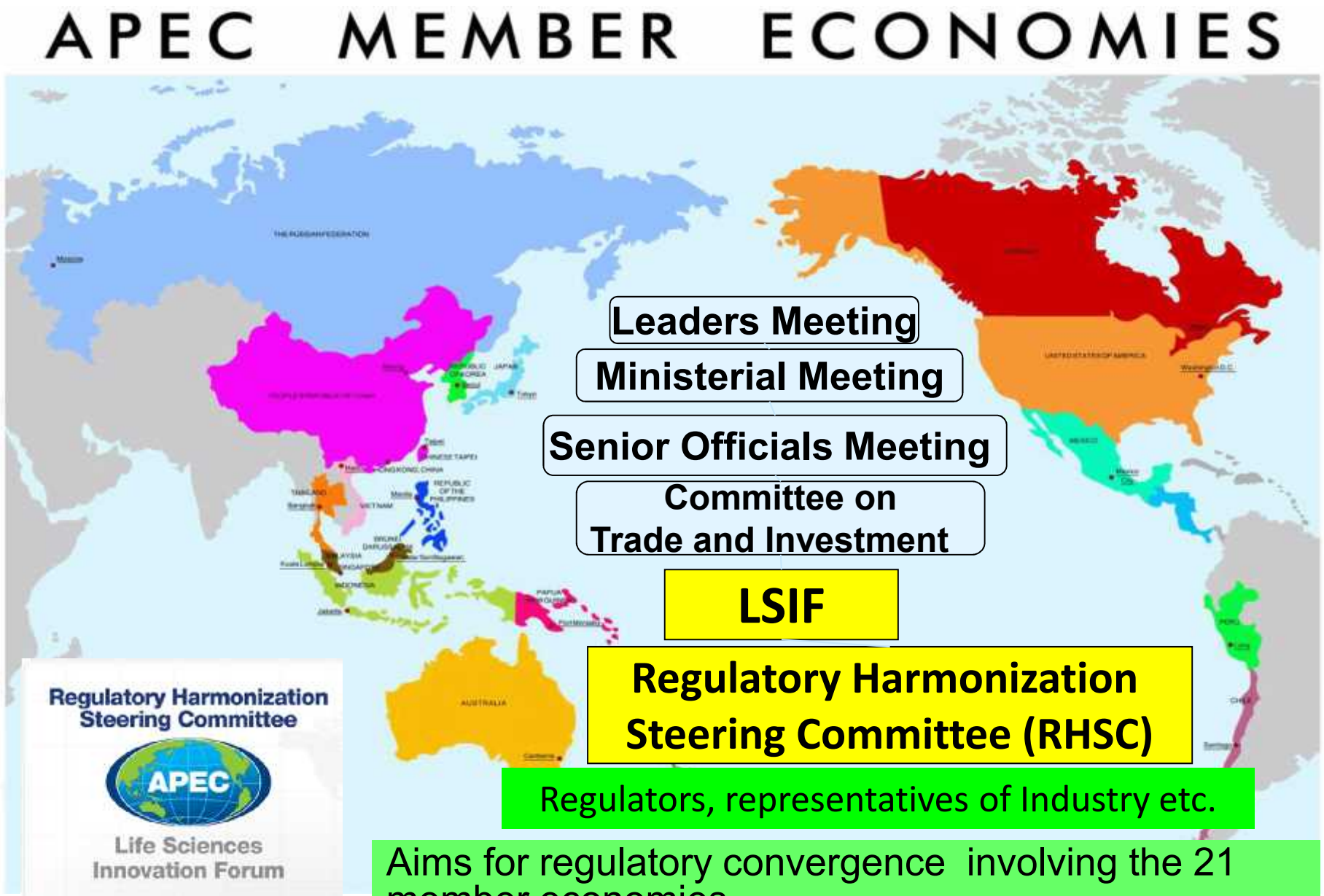
Ethnic difference among Asia may be smaller than that between Caucasian and Japanese?

MRCT is a key for New Drug Development





APEC LSIF (Life Science Innovation Forum)



Regulators, representatives of Industry etc.

Aims for regulatory convergence involving the 21 member economies

Roadmap to promote MRCT

Goal : To facilitate MRCTs and acceptance of MRCT results for drug review by regulatory authorities in APEC region

Points :

- Evaluate current practices
- Establish common understanding

[Key]

- Operational/Regulatory procedure to facilitate MRCT efficiently
- Cooperative regulatory approach to facilitate MRCTs on diseases prevalent in sub-regions of APEC.

- Implement training for those involved in MRCT
- Develop necessary items for Training/Workshop to promote MRCT
  - APEC economies share best practices
  - MRCTWS as well as each economy considers developing training curricula

Sharing information & experiences -1

Symposium under cooperation with Asian Countries

Recent Symposia etc.

1st Thailand-Japan Symposium (Oct 24-25, 2013)
1st Joint Conference of Taiwan and Japan on Medical Products Regulation (Dec.23-24, 2013)
1st & 2nd Indonesia-Japan Symposium

1st Indonesia-Japan Symposium in 2013

Sharing information & experiences -2

13 participants from
6 economies

Case Study

Program

Day1	Regulatory system, GCP, GMP
Day2	Review process & Management Biosimilar, Bioequivalanve
Day3	Tour of the Generic Drug Factory
Day4	Japanese Pharmacopeia Master File Quality review & Case study
Day5	PMS, Relief Services, Regulatory Science

150 or 300 WD for NDA Review ?

- Utilizing PMDA review reports for efficient review -

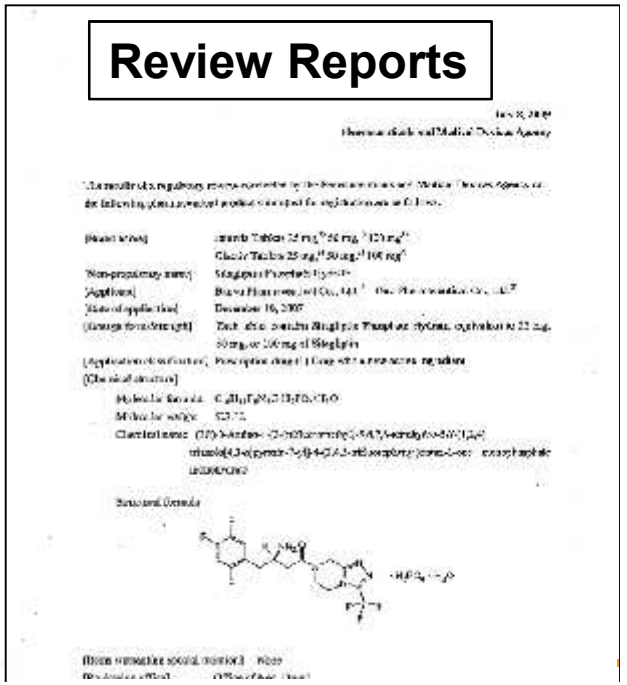
150 WD

- **Drug which has been marketed in the countries which have implemented harmonized evaluation system.**
- **Major Variation (New Indication/posology) which has been marketed in the countries which have implemented harmonized evaluation system.**
- **Copy drug without Electronic Standardized Information**

300 WD

- **New drugs, Biological Products, Similar Biotherapeutic Products, Major Variation (New indication / posology) which are not included in path 100 WD and 150 WD**

■ **PMDA "Review Reports"** that describe the details and results of reviews are released on PMDA's website.
http://www.pmda.go.jp/english/service/drugs.html



Conclusion

It is the time to work together for Asian people.

Key:

- ✓ New Drug Development for Asian People
  Promoting MRCT in Asia through WS, Training etc.

- ✓ Efficient New Drug Review

  Sharing experiences such as PMDA review reports

- MHLW http://www.mhlw.go.jp/english/index.html
- PMDA http://www.pmda.go.jp/english/index.html
- Review Report
  http://www.pmda.go.jp/english/service/review.html
- Japanese Pharmacopoeia
  http://www.std.pmda.go.jp/jpPUB/index_e.html