PMDA's efforts for China-Japan cooperative relationship

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Urgent Message on 2011 Tohoku-Pacific Ocean Earthquake

"We continue our endeavor to overcome this hardship."

Tatsuya Kondo, M.D.,Ph.D.

Chief Executive

Pharmaceuticals and Medical Devices Agency

China- Japan symposium

Purpose of the Symposium

- Acceleration of drug development in China and Japan
- Promotion of mutual understanding regarding view on drug regulations between China and Japan
- Identification and discussion on emerging issues of mutual interest

2010 China-Japan Symposium on Global Clinical Trials and Ethnic Factors

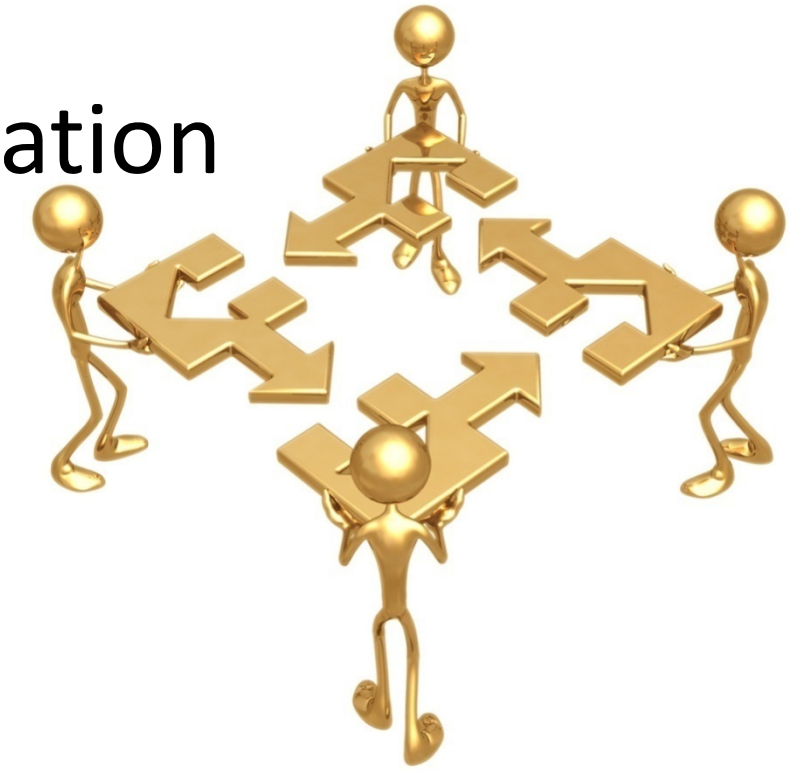
(Beijing, on May 28th, 2010)

- Government efforts
- Current situation
- Future trends
- Challenges
- Panel Discussion

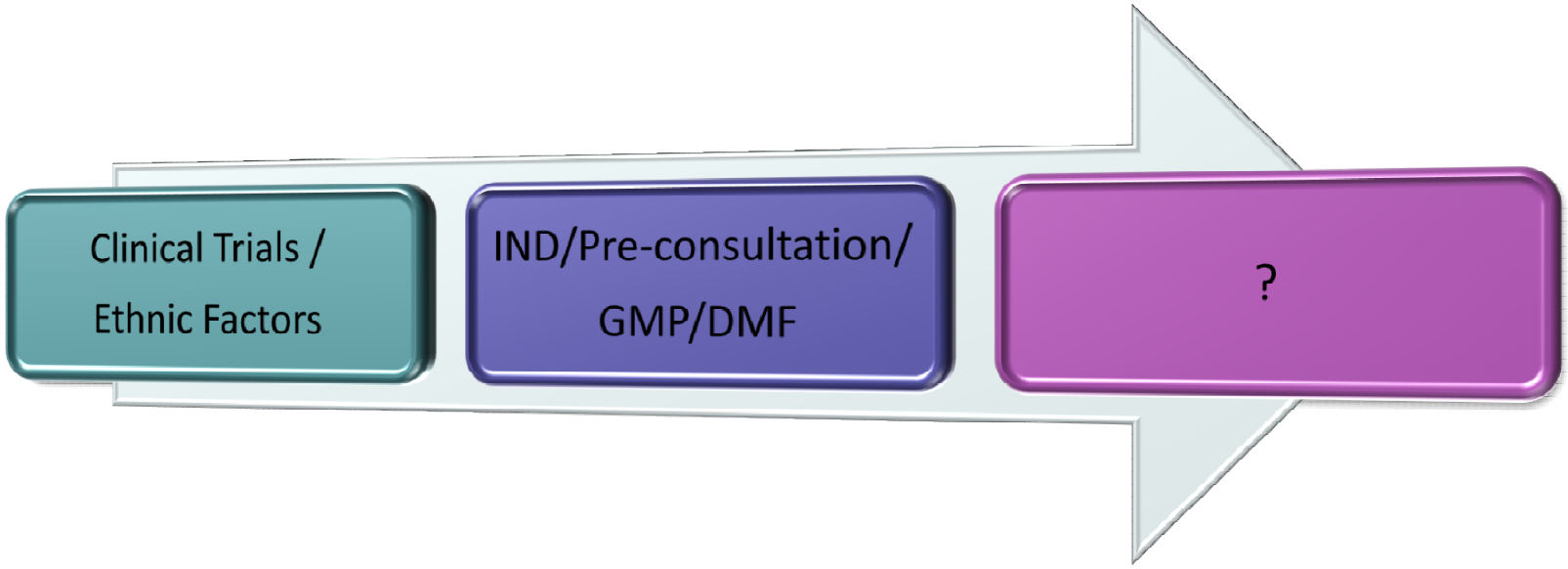
2011 Second China - Japan Symposium on Drug Development

Topics

- IND
- Pre-NDA Consultation
- GMP
- DMF system



Future direction of the Symposium



- Meet challenges in drug regulation in China & Japan
- Reflect needs in China
- Relate to issues in China-Japan bilateral meeting

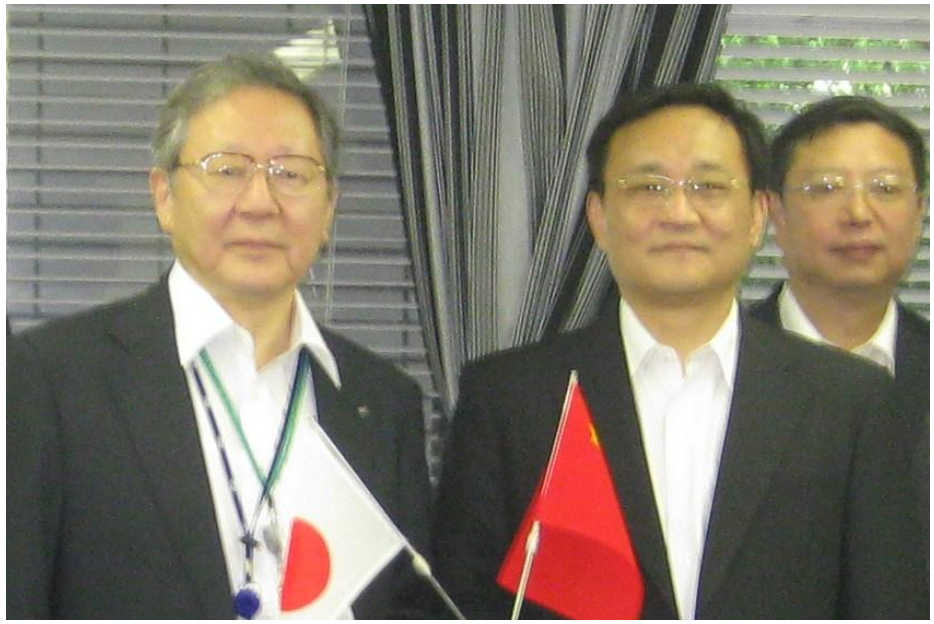
China – Japan cooperative relationship

Why China and Japan ?

- ✓ East Asia
  -Geographical & Cultural Proximity
- ✓ Manufacturing Sites
- ✓ Clinical Trials / Ethnic Factors
- ✓ Potential Gigantic Market
  -Drugs for Asians developed by Asians in Asia

China-Japan bilateral cooperation

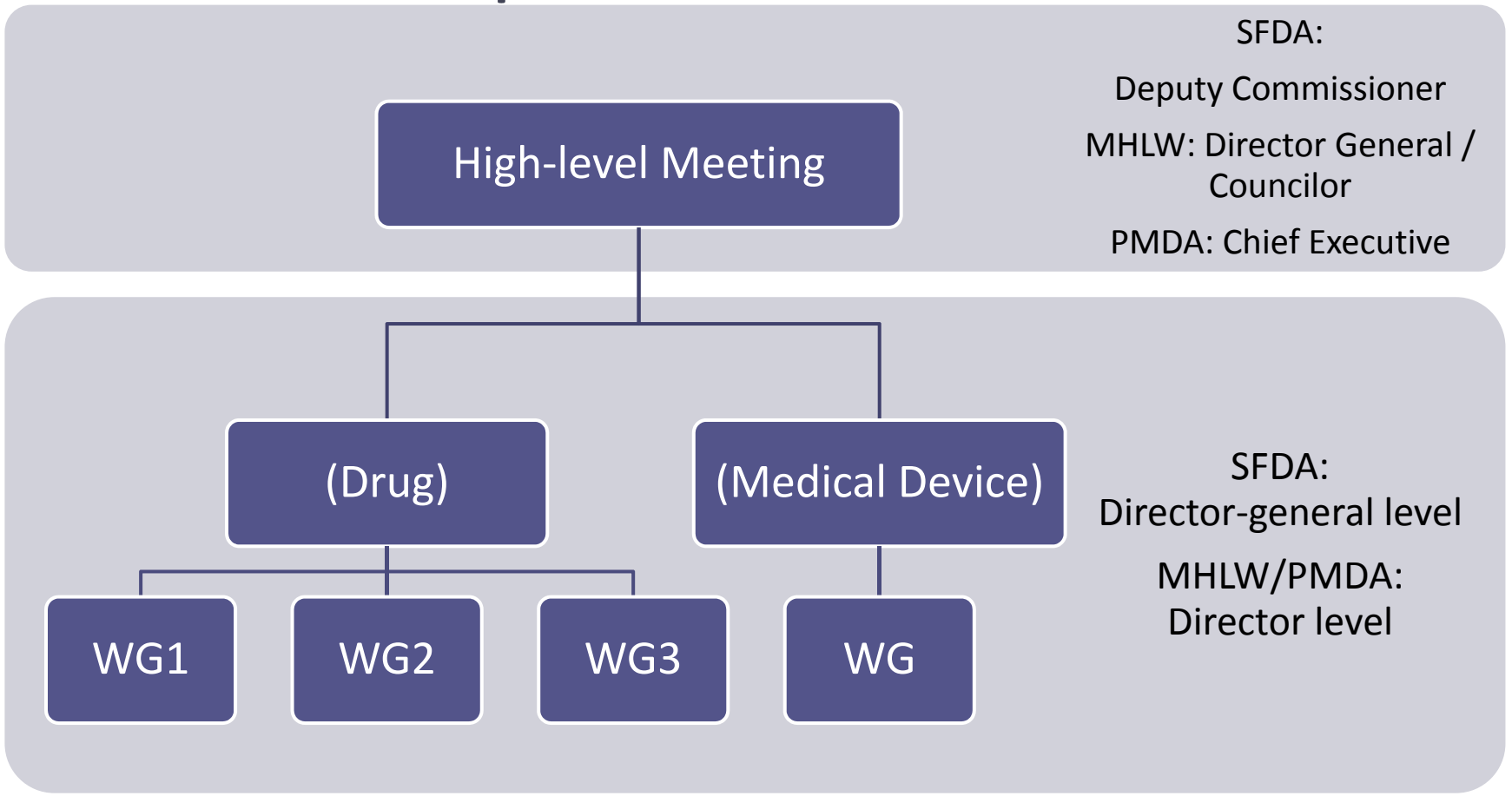
- **January 2009: MOU (China SFDA & Japan MHLW)**
- **May 2010: China-Japan Symposium on Clinical Trials and Ethnic Factors**
- **July 2010: China-Japan Bilateral meeting**



Outline of the 1st Bilateral Annual Meeting

- WGs (Drug/Medical Devices) to found
- SFDA CCPIE/PMDA/JPMA Symposium
- Training of SFDA Officer at PMDA
- PMDA Training Seminar for Foreign Regulators
- China-Korea-Japan Tripartite Cooperation
- Exchange of Information/Views on Drug Regulations in China & Japan

Discussion for cooperation between China and Japan



For win-win relationship

1. Wider Involvement of stakeholders
   A) Regulators (administrator, experts (reviewers, vigilance info. analysts, inspectors, etc.)
   B) Industry
   C) Academia
2. Improved communication to find areas of cooperation
3. Sharing a common vision on drug regulation in East Asia

Where to build/strengthen Win-win relationship b/w China & Japan

Ongoing

- Promotion of MRCT
- Research on ethnic factors
- Information exchange

Possible Areas

- GxP (frameworks & implementation)
- Exchange/Training of regulators
- Utilization of clinical data collected in east Asia
- Formulation of guidelines

Enhance PMDA's ability to perform its mission

Our challenges:

- Promote Multi-regional Clinical Trials
- Improve consultation and NDA review

OR

- Reduce Drug Lag while keeping quality in drug development and NDA review

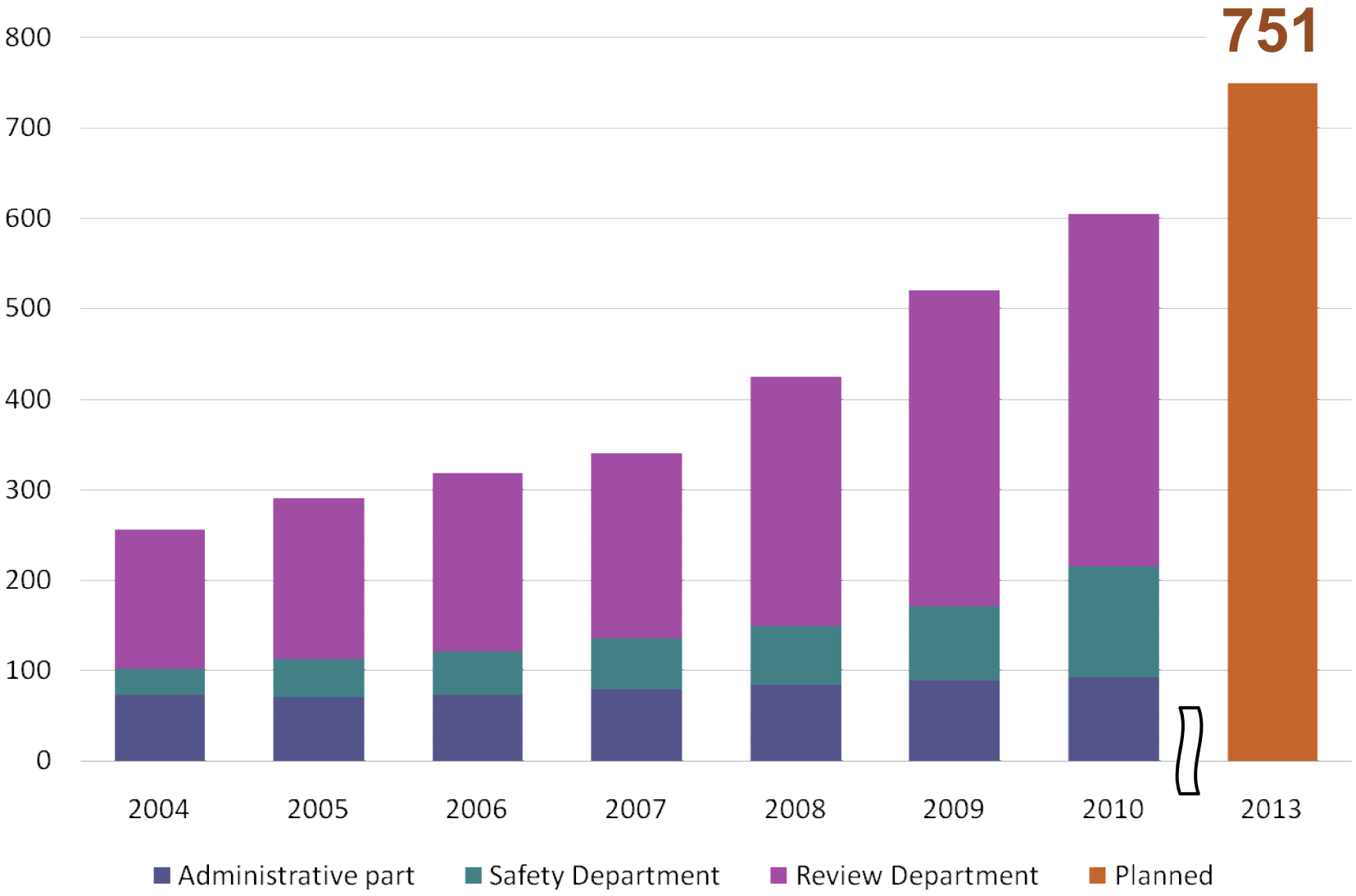
Drug Lag against USA (provisional calculations)

	FY 2006	FY 2007	FY 2008	FY 2009
Pre-Application Lag	1.2	2.4	1.5	1.5
Post-App. (in Review) Lag	1.2	1.0	0.7	0.5
Drug Lag (Sum)	2.4	3.4	2.2	2.0

Pre-Application Lag: Median years of difference between USA/Japan application for each product

IN-Review Lag: Median years of difference between Review time (USA/Japan) for each product approved in Japan

Size of the PMDA Staff



New IND consultation

(1) NDA Pre-review Consultation

-Review all available data before formal NDA submission (e.g. Quality, Non-clinical & Early Phase clinical data)

(2) Consultation on PGx/Biomarker Qualification

– Promote international harmonization in PGx

(3) Consultation on Development Strategy

– Help start-ups without know-how in drug development

PMDA International Programs regarding Asia

PMDA International Strategic Plan

1. Strengthen cooperation and build collaborative relations with the US, the EU, Asian countries, and relevant international organizations
2. Participate in international harmonization activities and further contribute to such activities
3. Improve and strengthen information provision to overseas countries

Growing partnership with Asian countries

1. China-Korea-Japan trilateral cooperation
2. China-Japan bilateral cooperation efforts
3. APEC Life Sciences Innovation Forum (LSIF) Regulatory Harmonization Steering Committee(RHSC*)*
4. PMDA training seminar
5. training of foreign colleagues

China-Korea-Japan trilateral cooperation

Chronological table

2007 :Joint statement on Tripartite Health Ministers Meeting

2008, 2009, 2010 :Director-General level Meeting

2011 :Director-General level Meeting is scheduled in Japan

***China-Korea-Japan Working Group on Clinical Trials* :**

2 projects

1. Research Project on ethnic factors (Japan coordinates)
   - Joint research on ethnic factors

   Research Group was established based on TOR
2. Exchange of information on clinical trials (Korea coordinates)

First PMDA Training Seminar Nov. 29 to Dec. 3, 2010

- PMDA welcomed 6 reviewers from SFDA

PMDA training for foreign colleagues in 2010

A: China SFDA: GLP/GCP Inspector (May –July)

B: Korea FDA: Reviewers in New drugs, Generics and Pharmacovigilance (Nov. – Dec.)

谢谢　　Thank you !!

http://www.pmda.go.jp/

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