Summary Report APEC 2006

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Current Situations of Drug Development

Challenge & opportunity on the critical path to new medical product, US-FDA, March 2004

Figure 1: 10-Year Trends in Biomedical Research Spending

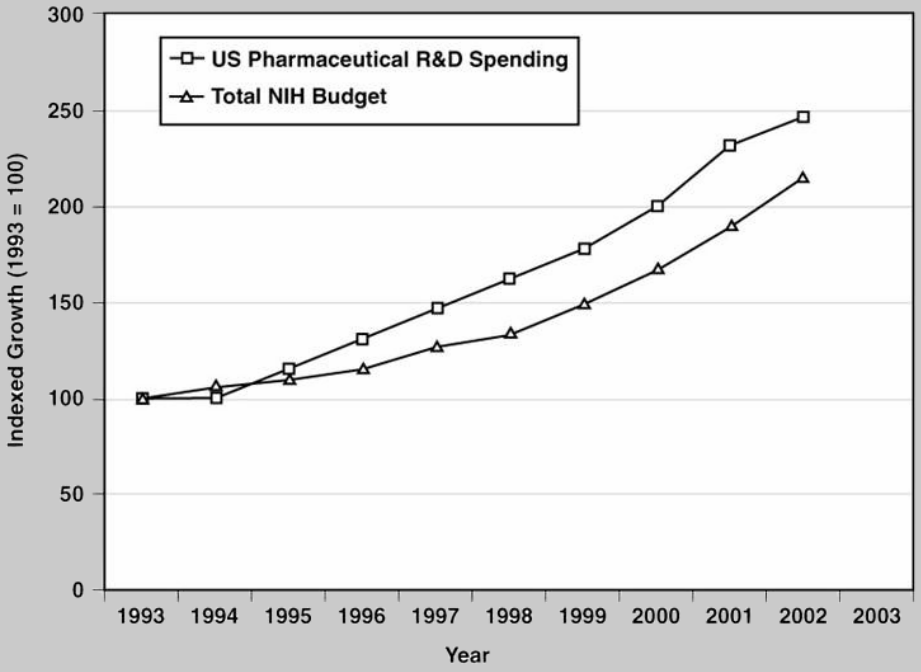
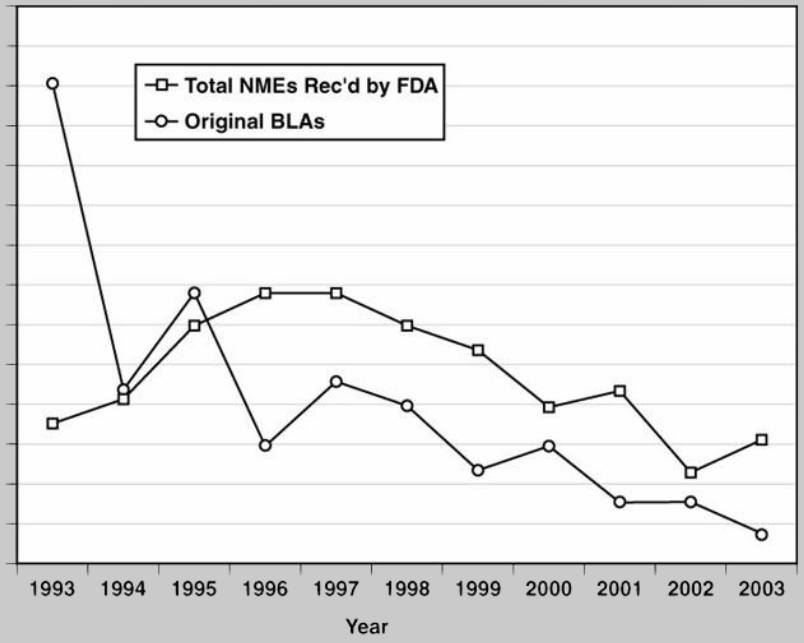
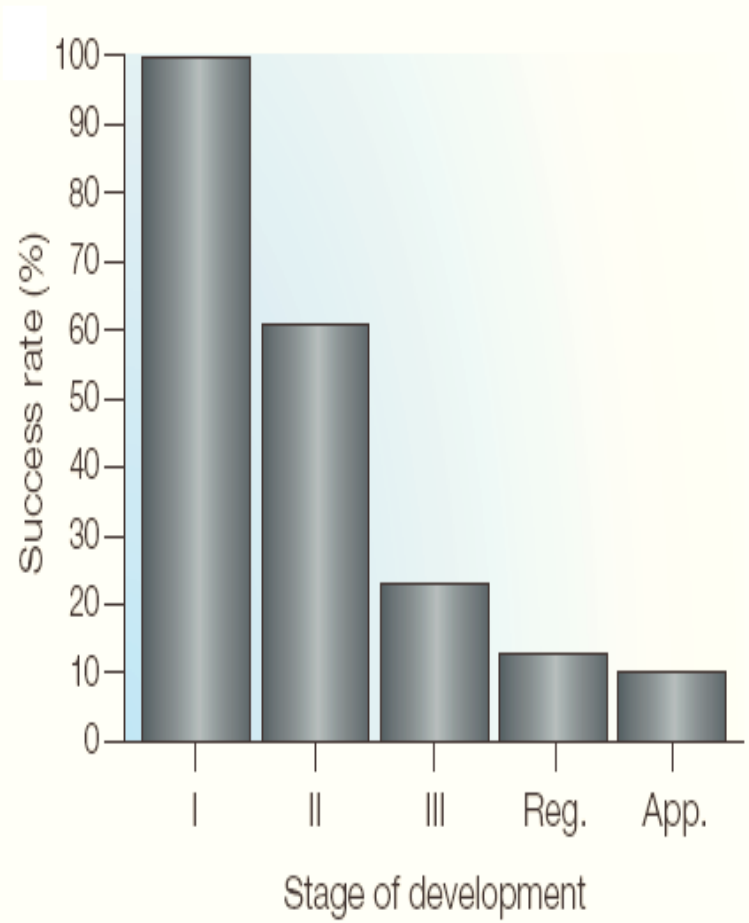
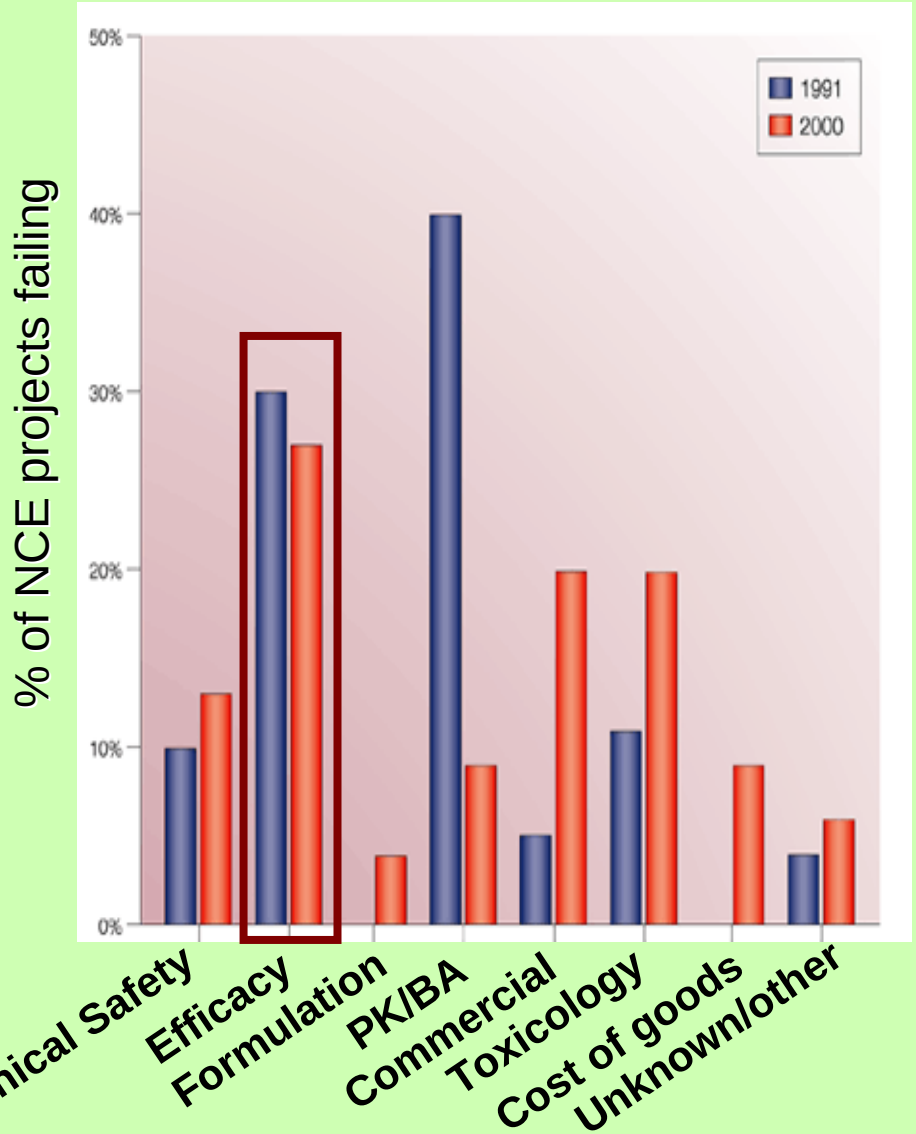


Figure 2: 10-Year Trends in Major Drug and Biological Product Submissions to FDA



Increase R&D cost, but decrease a number of NCEs

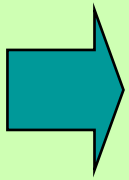




Kola I et al, Nature Rev Drug Discov, 3: 711-715, 2004 Frank R et al, Nature Rev Drug Discov, 2: 566-580, 2003

- More difficult situations
  - very low success rate
  - very high R&D cost

- To promote and to protect public health
  - keep drug development activities
    - Speed & Cost are critical factors
  - have data in various ethnic populations (Mr Mori (PMDA))
  - minimize a delay of drug approval (Mr Miyajima (PMDA))



Global Drug Development

Promote Global Drug Development (1)

- Epoch-making tool for drug development
  - Critical Path Initiative (US-FDA, Dr Chern (CDE))
  - Biomedical Science Initiative (Dr Lim (HAS))
  - EMEA Road Map (Mr.Lönngren (EMEA))
  - PMDA Challenges ”Clinical Trial Issue Review Committee: Interim Report”

- Global Standard of regulatory requirements
  - ICH guideline
  - Ptc for designing global study (Dr Mori (PMDA))

Promote Global Drug Development (2)

- International harmonization
  - APEC countries (Dr Liao (DH) & Dr Chern (CDE))
  - ICH & non-ICH region: GCG (Dr Kubota (JPMA))
  - ASEAN（Dr Javroongrit (Thai FDA)）
  - FDA/MHLW/PMDA confidential agreement
  - EC/EMEA/MHLW/PMDA confidential agreement (Mr. Lönngren (EMEA)
  - Medical Devices (Mr Gropp (Abbott Vascular))

Good Progress of Global Drug Development

- ICH-GCP implementation in non-ICH regions
- Setting-up infrastructures
  - accredited hospital & clinical trial center
  - central IRB
- Increase experiences of multinational clinical trials, specifically in Asian region

Singapore (Dr Lim (HSA)), Chinese Taipei (Dr Liao (DH) & Dr Chern (CDE)), Korea (Dr Park (KFDA)), Japan (Dr Saito (JPMA), Dr Mori (PMDA))

Global Drug Development is a challenge!

- Various factors among regions/countries

  Dr Lumpkin (US-FDA)

  - Mission is impossible by one country
  - A better decision than last one based on sound science
  - More regulatory cooperation
  - Share information & knowledge
- Critical Success Factors (Mr Cook (PhRMA)
- New evaluation tool; e.g. TGN1412 case (Dr Breckenridge (MHRA))

More cooperation will make synergism effects to promote and to protect public health

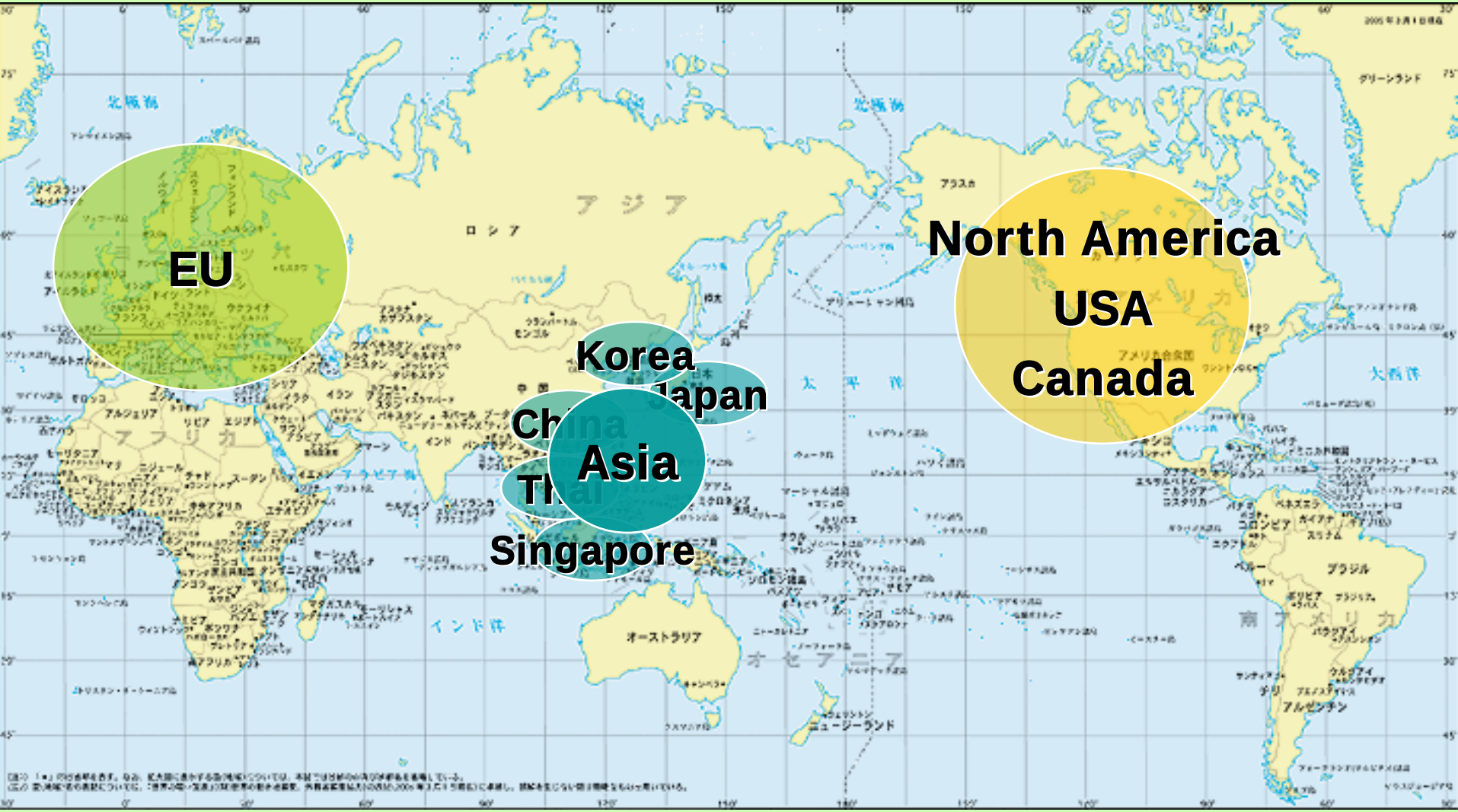
Where we should go!

Benefits of Global Drug Development

- Synchronize a timing of drug development among regions (Mr Miyajima (PMDA))
- May reduce an potential risk after drug approval
  - many data among various populations (Mr Mori (PMDA))
  - can detect ethnic differences before approval (Mr Nakajima (JPMA))

Each regions should **equally contribute** to Global Drug Development

A drug for world wide populations



Asian Collaboration Network

- Global Drug Development

  Multinational Clinical Trial in Asian Region

- Cooperation among APEC countries
  - ICH and non-ICH region (Dr Kubota(JPMA))
  - Cooperation among Asian Countries
  - exchange reviewer among Asian regulatory agency; e.g. CDE-PMDA joint program (Dr Liao (DH), Mr Miyajima (PMDA))
  - promote Asian Global Clinical Trial (Mr Nakajima (JPMA)
  - information sharing (Dr Liao (DH), Mr Miyajima (PMDA))

Pharmaceuticals and Medical Devices Agency

Our more cooperation will make a better drug for all patients in the world

Thank you very much