Global Clinical Trials in Korea

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For APEC, OCT.13, 2006

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- Current Status of Clinical Trials in Korea
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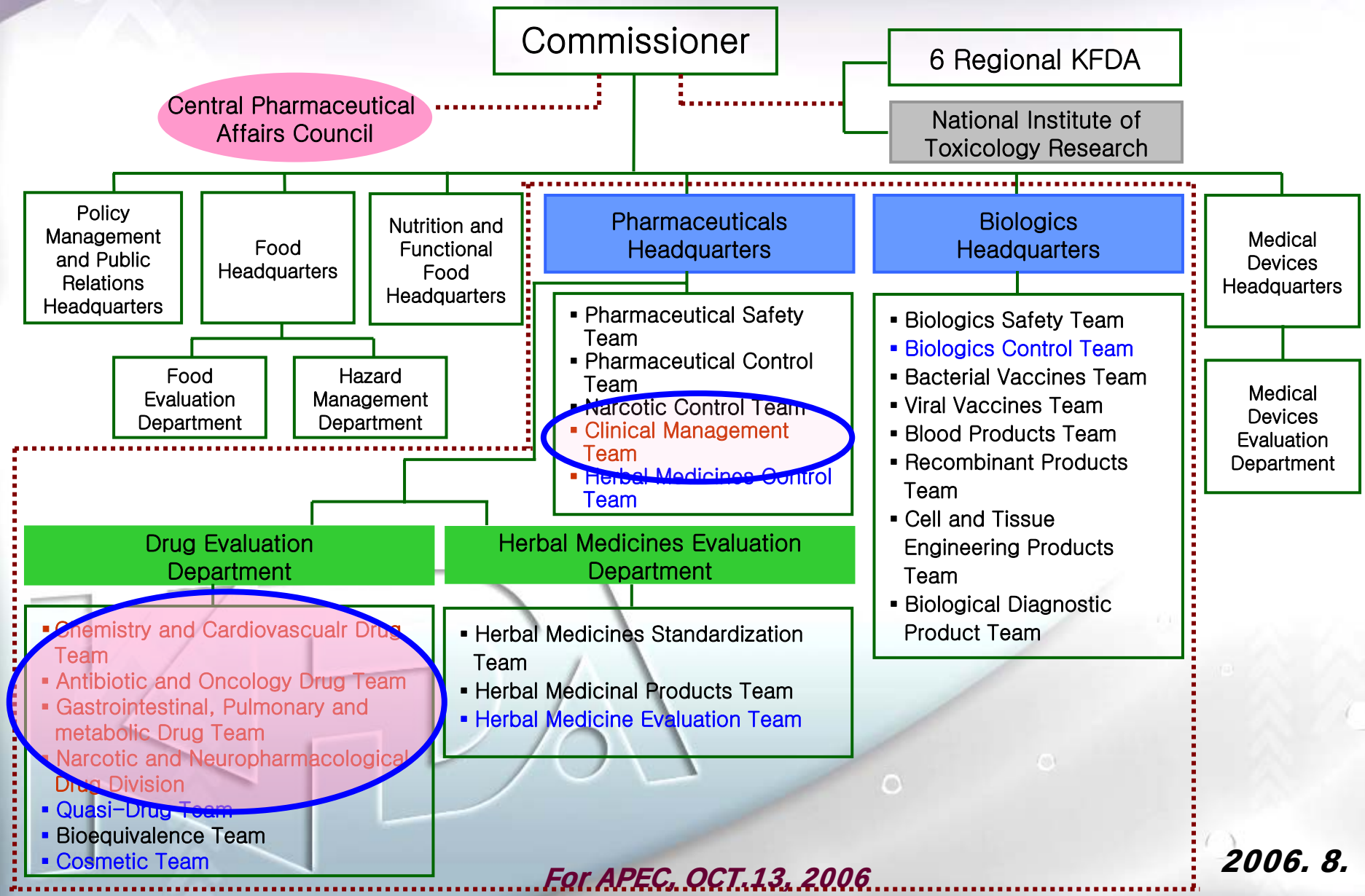
Korea Food and Drug Administration



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2006. 8.

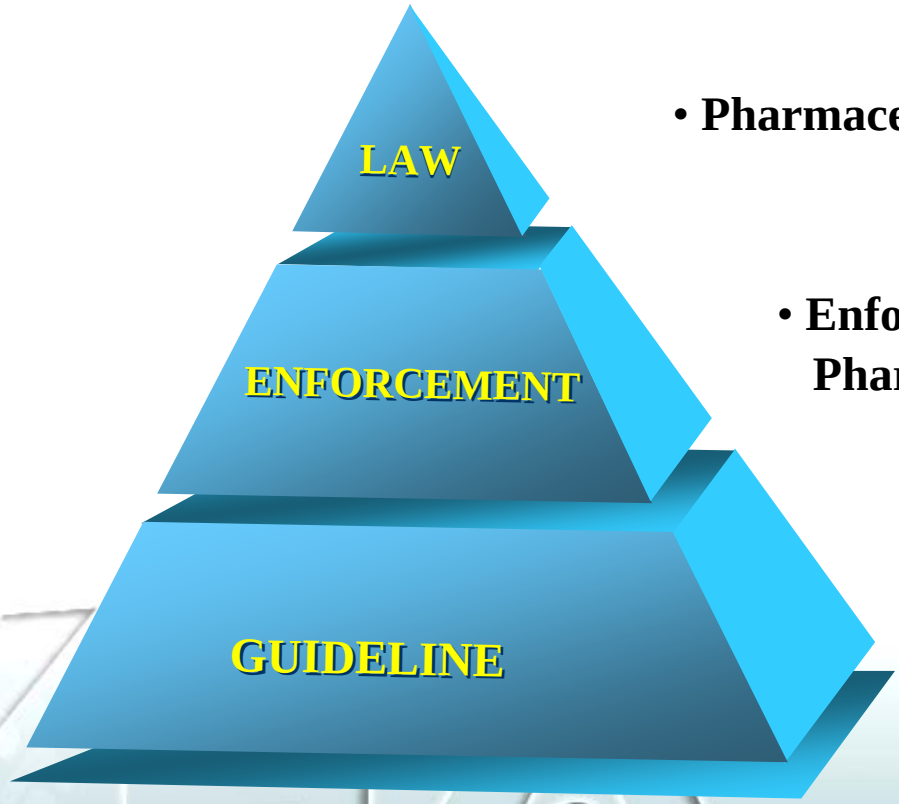
Major regulatory changes in Korea

since 1999

- **Jan 2001 : Total revision of KGCP according to ICH GCP**
- **June 2001 : Adoption of the Bridging Concept**
  - Diverse bridging strategies were required
  - Effective since 2001 for NDA
- **Dec 2002 : Separation of IND from NDA**
  - Participation in international study enabled

Regulatory Hierarchy

Regulations for Clinical Trials



- Pharmaceutical Affairs Law

- Enforcement regulation of Pharmaceutical Affairs Law

- Korea GCP Guideline
- CTA Guideline
- Guideline for Accredited Clinical Institutes

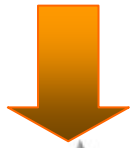
Essential Elements in a Clinical Trials

defined in the Enforcement regulation of PAL

- Protocol approved by KFDA
- Only at the accredited sites
- Qualified investigator
- Protect the right and safety of subjects
- Informed consent before enrollment of subjects
- Investigational drugs

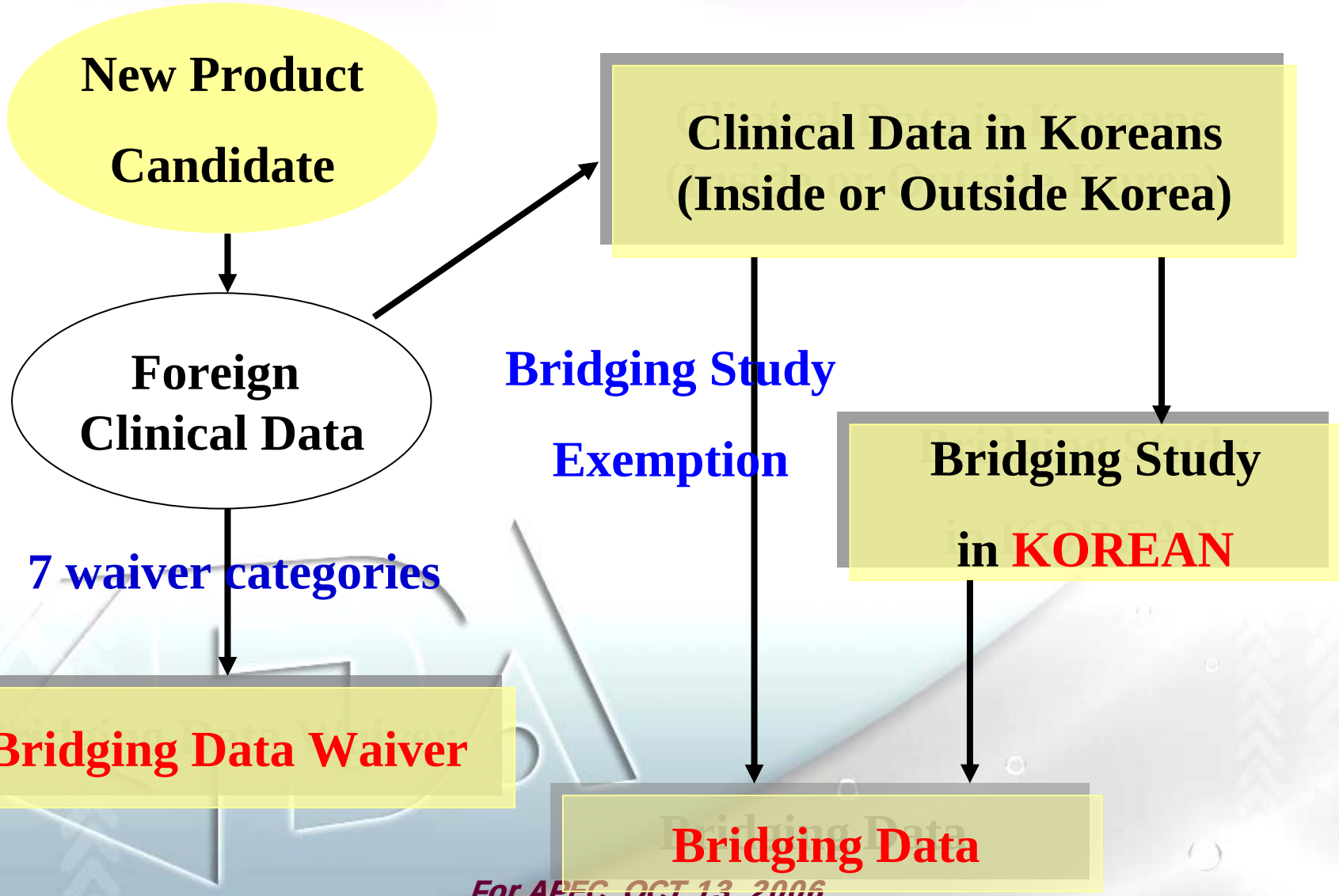
History of KGCP

- Established as of December 28, 1987
- Enforced since October 1, 1995
- Revised as of January 4, 2000
- Legislation of IND system August, 2001
- Preparation of detailed regulations for IND system December, 2002



- Harmonize with ICH guideline E6
- Clarify the responsibility of investigator
- Reinforce the function of IRB
- Protect the rights and safety of subjects

Evaluation on Foreign Clinical Data and Bridging data in Korea



Bridging Waiver Categories

- Orphan drugs or drugs used as orphan drugs
- Drugs for AIDS
- Drugs for Life-threatening Disease
- Anticancer drugs of the followings :
  - ✓ No standard therapy
  - ✓ Therapy followed by a failure in a standard therapy
- Diagnostics or Radioactive drugs
- Topical drugs with no systemic effect
- No ethnic differences

Introduction of IND

- Separation between developmental clinical stage and commercial product approval, such as IND and NDA
  - Effective since December 2002
  - Different submission requirement according to the drug developmental stage
  - Shortening of review period (30 days)
  - Encouragement to participate in multinational clinical trials
  - Activation of Pre-IND consultation programs
  - Flexible regulation on manufacturing/importing of clinical supplies
  - Alleviation of qualifications for IND applicant

Guidance of Accredited Clinical Institutes

- Purpose
  - To assure the quality of clinical study and institutes
- What are Essential to Accredit?
  - Appropriate facilities and equipments
  - Pool of personnel to support the clinical study
  - Activities of IRB
  - Education program of GCP
  - Structures and activities to manage the clinical study

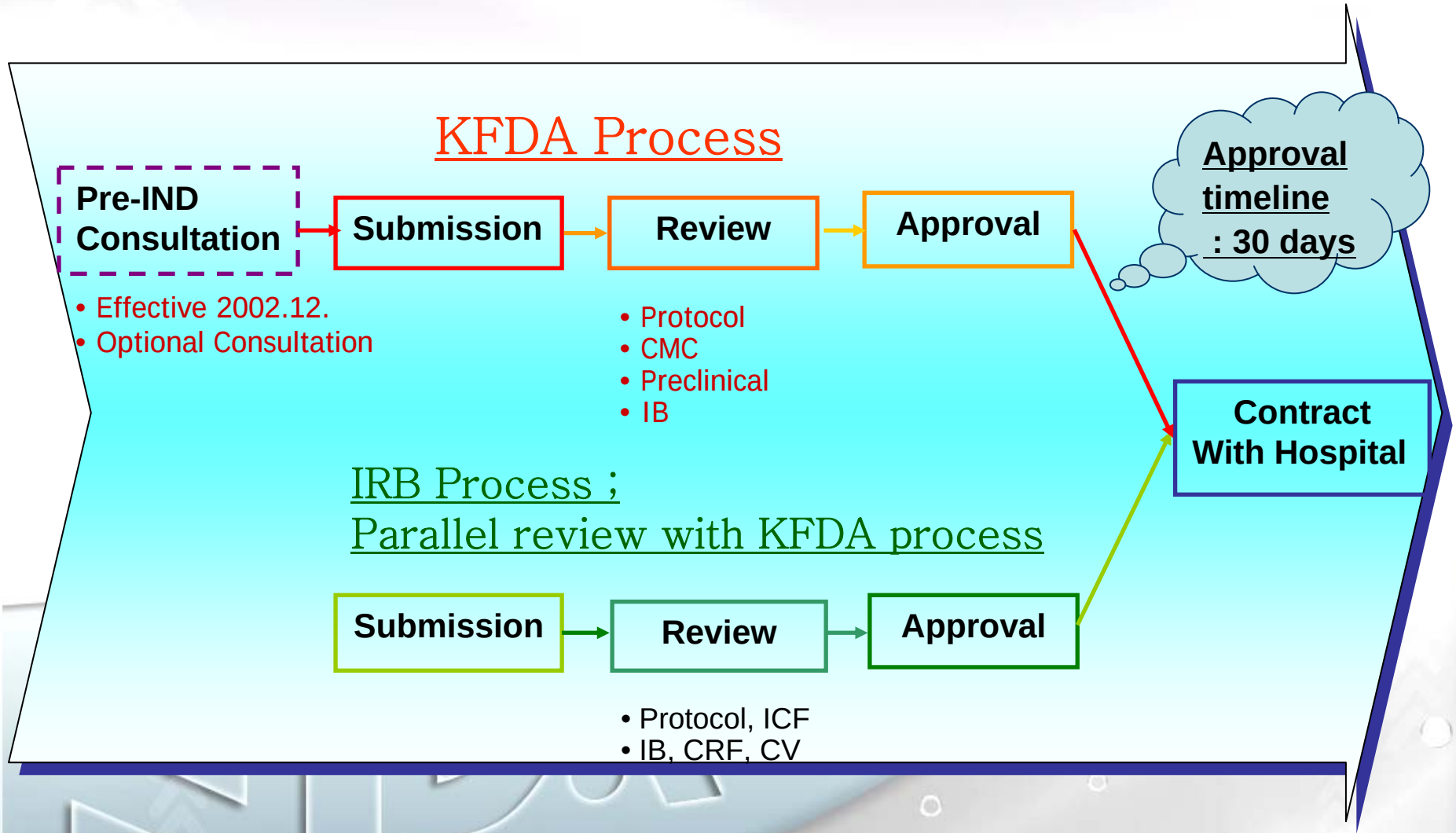
Qualified Institutional Pool

Number of accredited clinical institutes

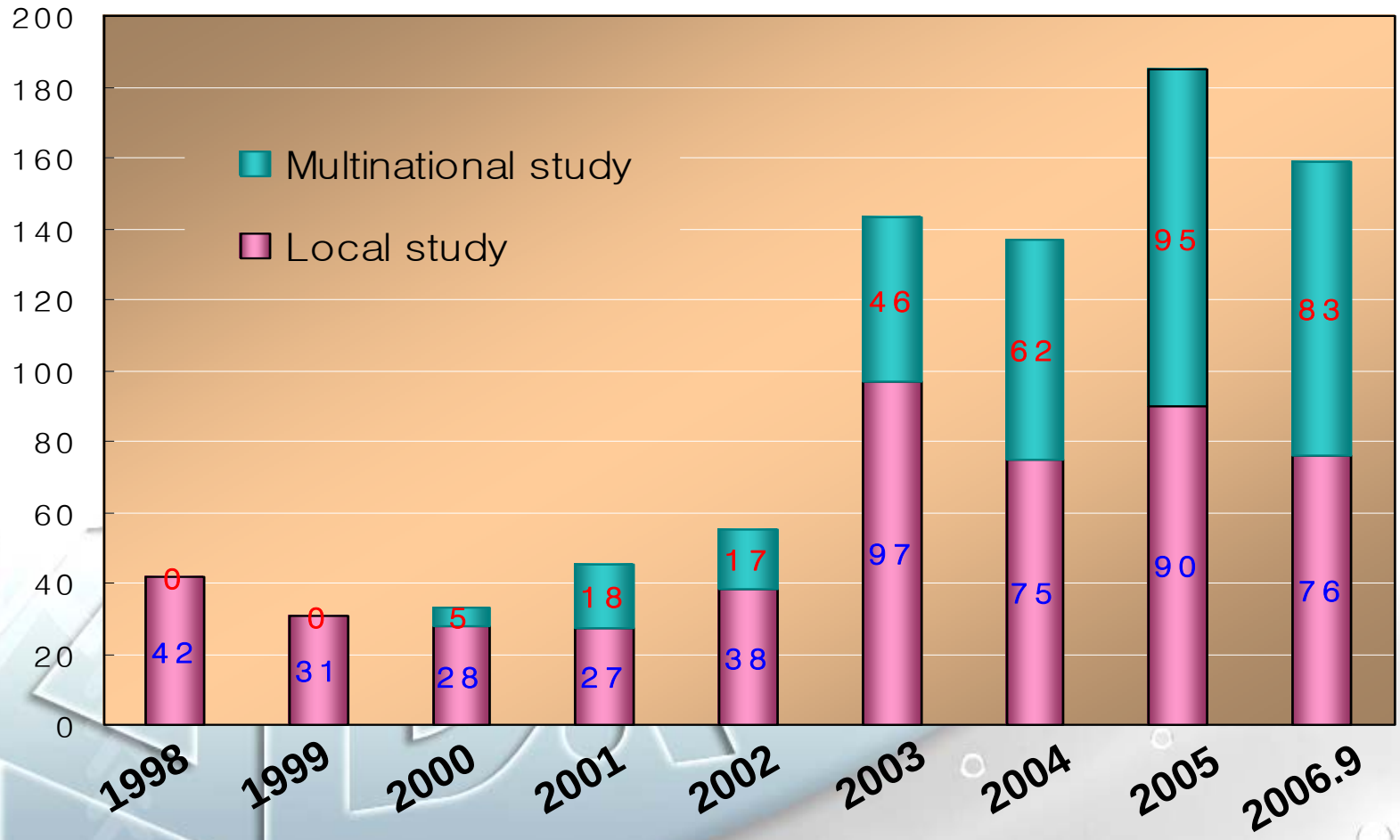
Class	Phase I	Phase II	Phase III
Hospital	32	84	107
Dental Hospital	1	6	6
Total	33	90	113

(by 2006. 8.)

Clinical Trial Approval Process



Increased Number of Clinical Trials



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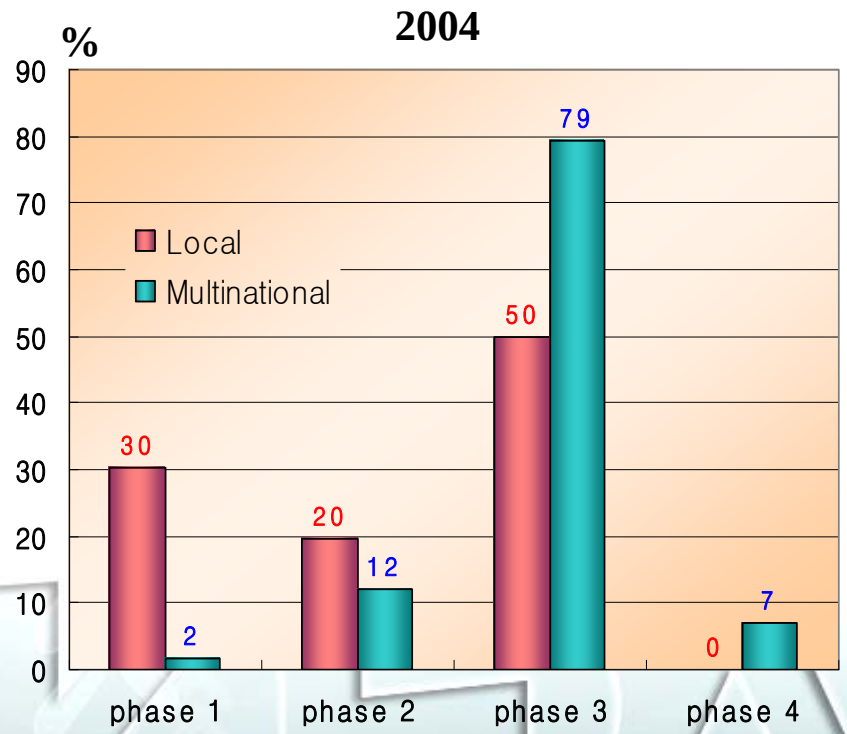
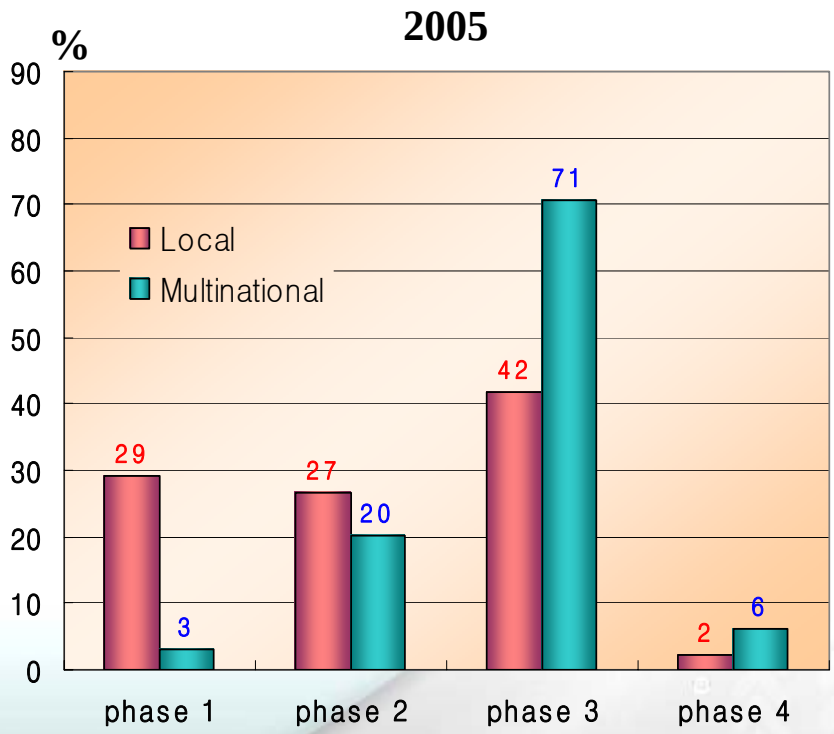
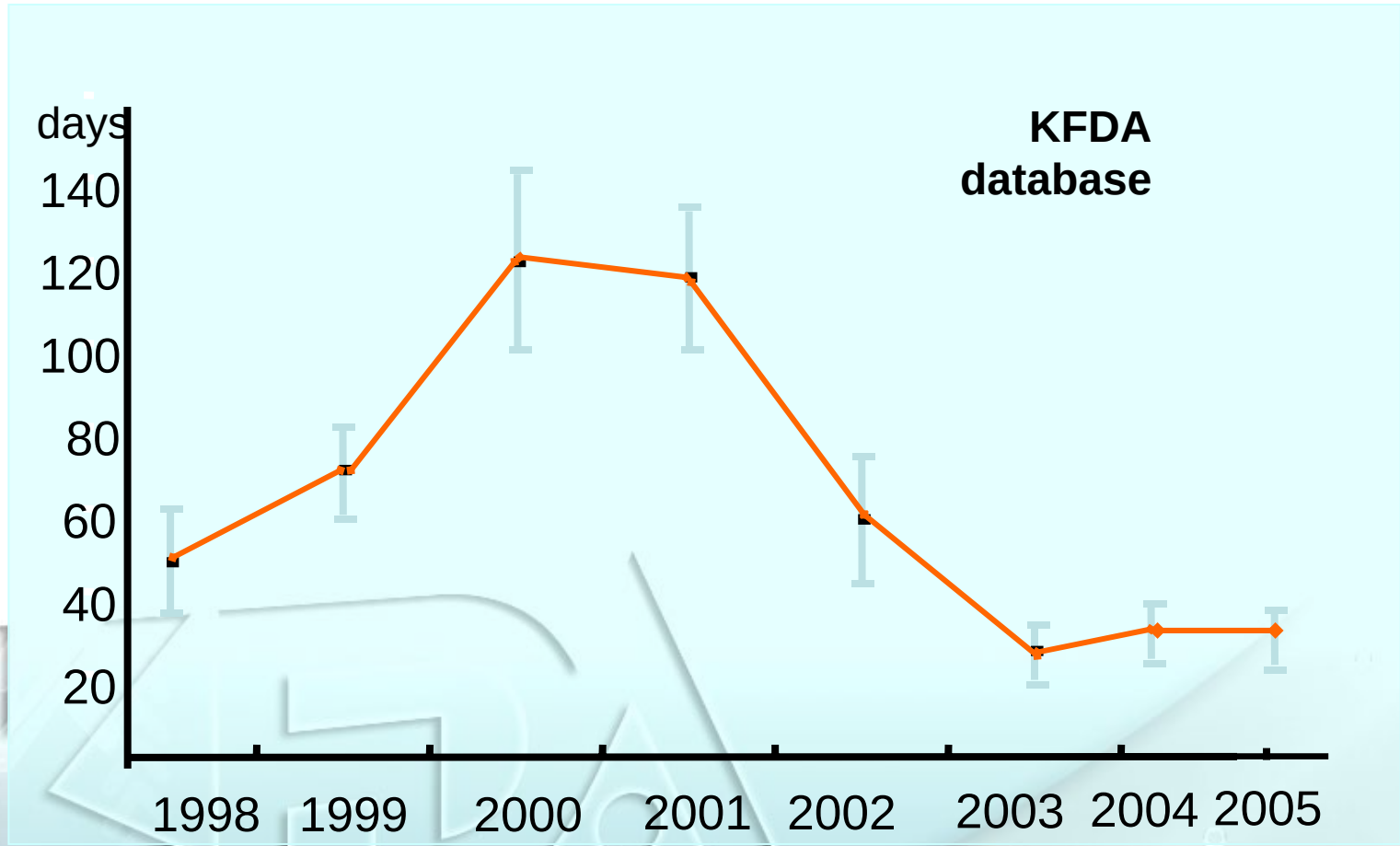
Status of Clinical Trials by Study Phase





Course of CTA average Review Time



Reinforcement inspection system

- Inspection for IRB management system
- Inspection for Investigator (on-going C/T)
- Systematic Inspection for clinical trials
  - ✓ Regular report on the status of on-going clinical trial
  - ✓ Notification on the completion of clinical trial
  - ✓ Sponsor, CRO, IRB, Investigator etc.
- Develop and disseminate check-list for Inspection to facilities

Good Regulation Practice in Cinical Trials of KFDA

- Amendment of Regulations
- Good Review Practice
  - Assurance consistency, clarity, transparency
  - Promotion and application of Guidelines for Clinical Evaluation by indications
  - Development of Training program for the reviewers
  - Meeting within KFDA and sharing the review experiences
  - Activation the consultations by formal meetings with sponsors
- Disclosure of Review Summary
- Dialogues between customers and the KFDA
- Restructure KFDA to functional team for review quality and efficiency

Amendment of Regulations

- Task Force Team
  - ✓ Regulator, experts from industries and academia
- Draft regulations
- Open to the public for hearing the opinion
- Evaluation for unnecessary restriction by regulatory reform committee
- Amendment of Regulations

What we have learned :

- Qualification of Investigator
- Importance of IRB review
- Importance of SOP
- Need for Clinical Research Resources
- Need for Regulatory Service from Authorities
- Need for communication and harmonization with Foreign Authorities

Improvement in Clinical Study Institutes

Hospital

Improvement in hardware

- Increased number of accredited hospital
- Major hospitals have specialized clinical trial centers and laboratories

IRB

Improvement in software

- IRBs are well-organized and well-operated in accordance with the KGCP requirements
- IRBs hold regular training as to KGCP and ICH-GCP for the investigators, pharmacists, CRC and other medical staffs

Improvement in Clinical Trials Staff

Investigator

Improvement in qualification

- Increased opportunities to participate in global study since 2001 and good awareness of GCP
- Enthusiastic to join in early development stages of new drugs
- Proficiency in strict regulatory inspection

Clinical Research Coordinator

Improvement in qualification

- Increased number of research nurses with clinical expertise
- Major hospitals are able to utilize CRC pools in and out of the hospitals
- Well-organized and qualified annual trainings for CRCs are available

Future Plan

- IRB management
- Resource management
  - Support the training course for investigators, CRC, CRA, IRB members
  - Develop the training program for reviewers
  - Keep the transparency of review process
- Supporting plan for Clinical Centers by MOHW
  - 9 Regional centers designated in 2004-2006
  - Support for Facilities, Operation systems, R&D etc.
  - $ 0.5 ~ 1 million/center/yr for 5 years
- Revise the regulations to harmonize with international ICH guidelines
- Encouragement the industries to participate in multinational clinical trial

Thank you very much for your attention !!

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