An Oversight :

GCP IMPLEMENTATION IN INDONESIA

National Agency of Drugs and Foods Control (NA-DFC)
National Institute of Health Research and Development, MoH
Republic of Indonesia

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I. INTRODUCTION

Potential to conduct clinical trial

Population and ethnics:

- population: +/- 220 million with pop. density of 113 Persons/km^2
- there are > 300 ethnic groups
- Established clinical trial system since 2001
- Experienced investigators and centers
- Research institution owned by MoH
- Established Institutional Ethics Committee
- National Ethic Committee
- Increased number of global study conducted in Indonesia

II. GCP IMPLAMENTATION IN INDONESIA (1)

Quality System

Health Law

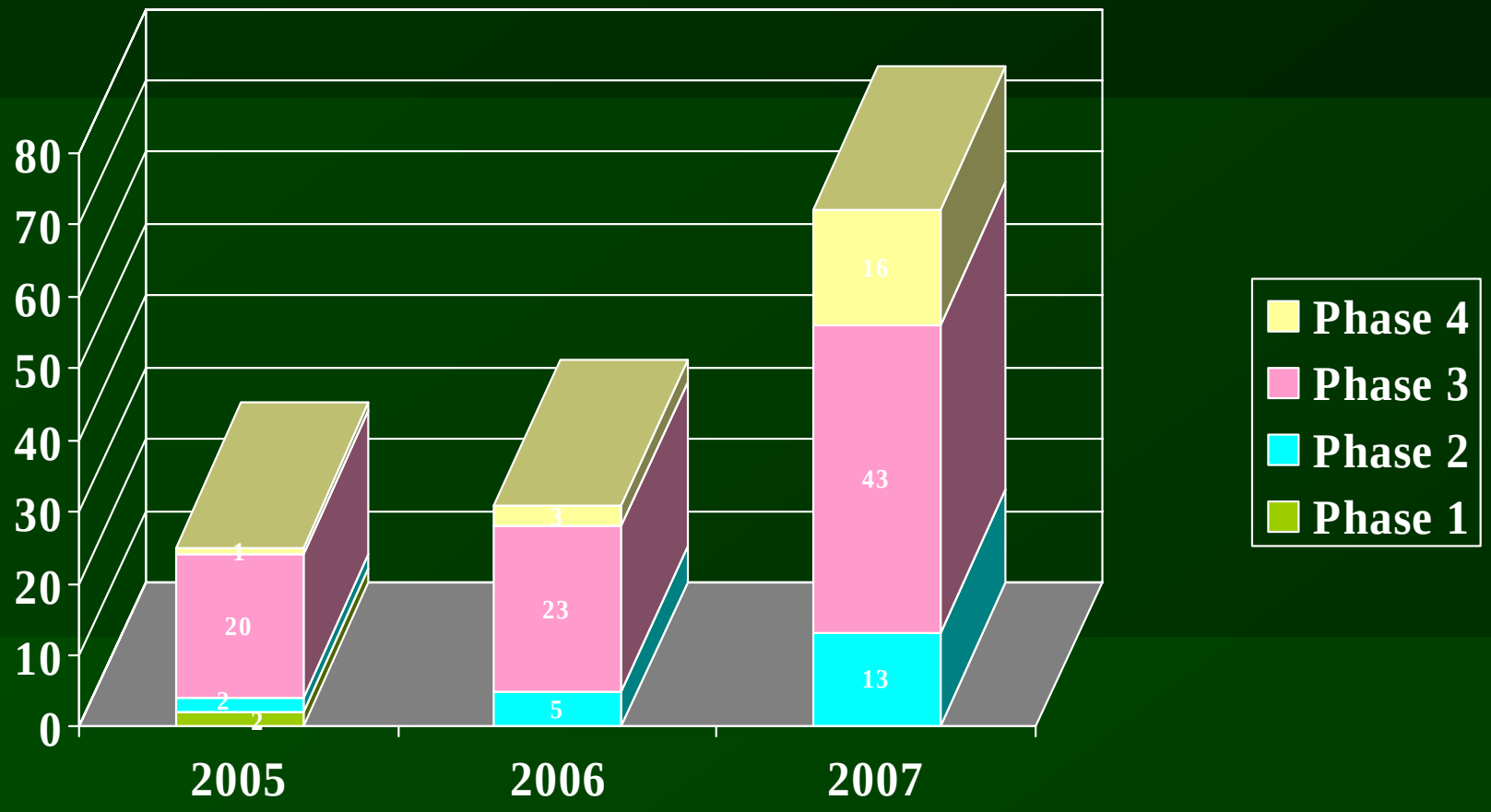
- Ministerial Decree on National Committee on Ethical in Health Research
- Ministerial Decree on informed consent

II. GCP IMPLEMENTATION IN INDONESIA (2)

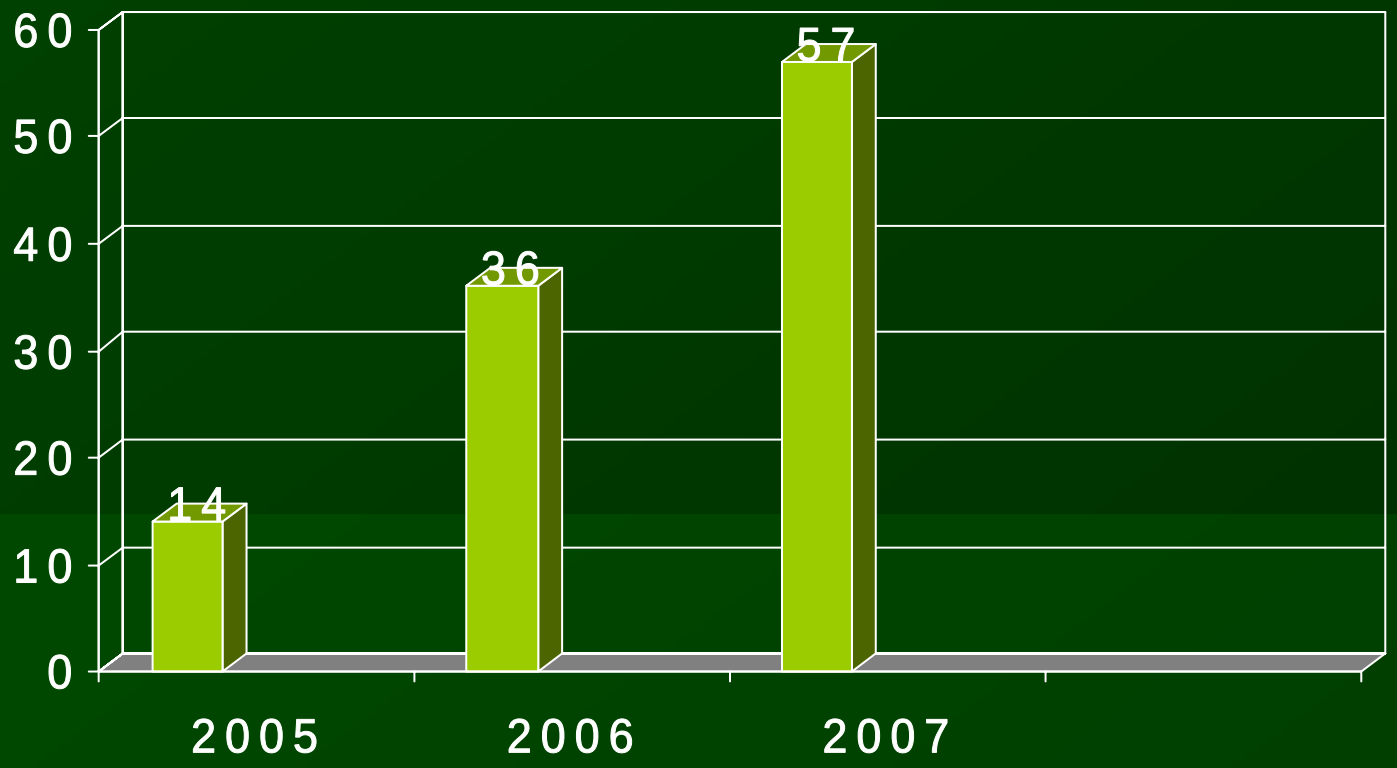
- Government Regulation on Health Research & Development
- NADFC Decree on Procedures for Clinical Trial (CT)
- NADFC Decree on Procedures for Bioequivalence Trial
- NADFC Decree on Indonesian GCP Inspection
- Guideline and SOPs :

  SOP : - GCP Inspection CT Authorization
  - GCP Checklist
  - Manual Checklist
- GCP Inspection Report Form

CT APPLICATION IN INDONESIA *



BE STUDY APPLICATION IN INDONESIA



GCP Inspection

- Started in 2004
- 10-12 site GCP inspection per year
- Quality system: in place
- 5 GCP inspectors

- GCP Inspection Mechanism
  - **Pre Inspection**
    - **Contact with sponsor and investigator to arrange inspection schedule**
    - **Letter to the sponsor and investigator about the date of inspection**
  - **GCP Inspection on site**
    - **Introduction and Interview**
    - **Inspection (facilitation and documentation):**
      - ✓ **Supported with checklist & report form for Inspection consistency**
      - ✓ **Clarification (if any)**
    - **End of Inspection :**
      - ✓ **Discussion**
      - ✓ **Clarification**
      - ✓ **Investigator and GCP inspector sign the finding form**
  - **Post Inspection**
    - **Letter to the sponsor/CRO and Investigator about result of inspection (based on finding form)**
    - **In some cases, response from sponsor/Investigator is required (corrective actions which are taken)**

Classification

- Critical : patient safety implications or regulatory offence or cast doubt on validity of data
- Major : non compliance with regulations that could have impact
- Minor (others) : minor non-compliance may add up to a major non compliance

- Regulatory action:
  - ***NAI (No Action Indicated)***

    No objectionable conditions or practices were found or no significant deviations during the inspection.
  - ***VAI (Voluntary Action Indicated)***

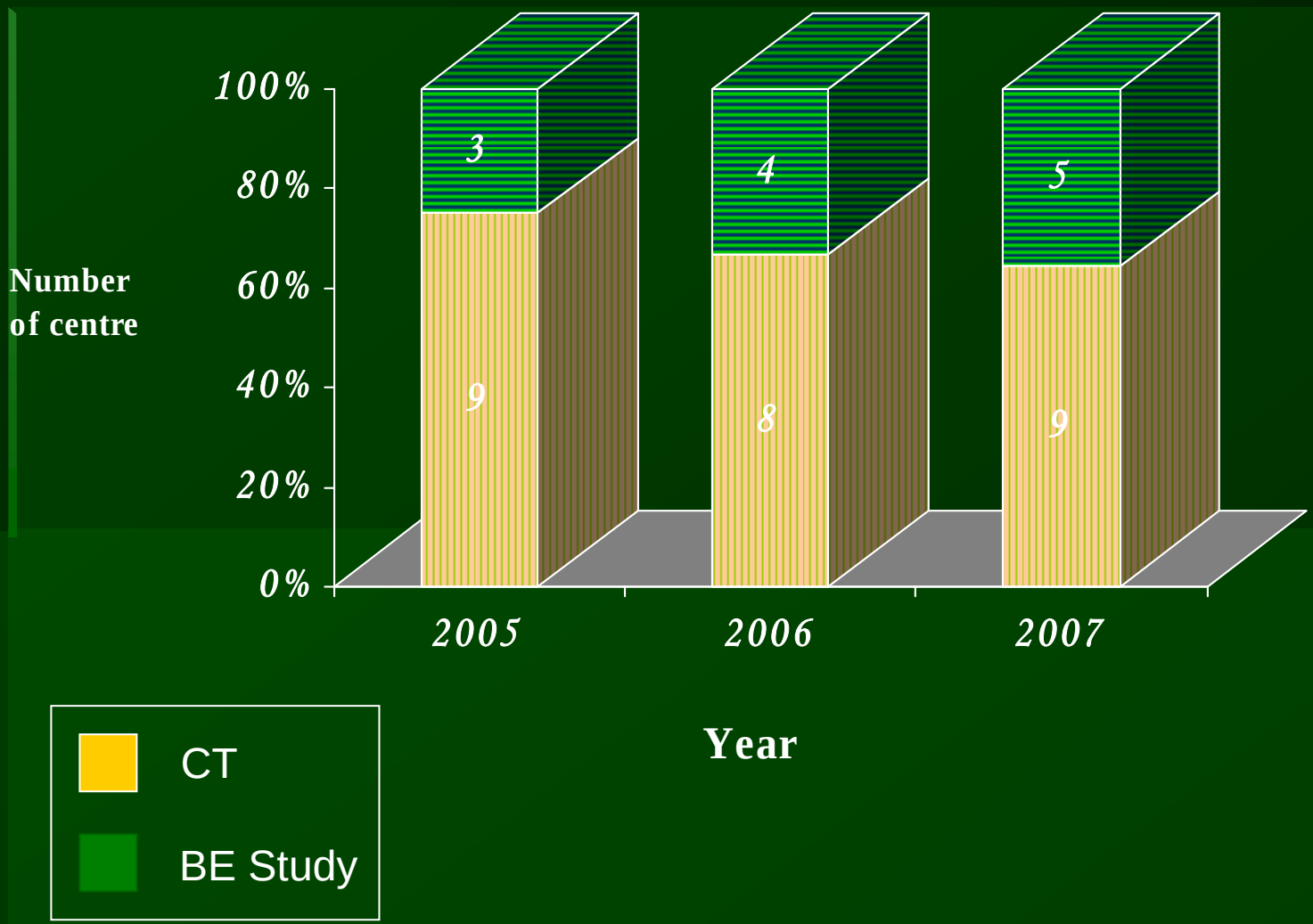
    Objectionable conditions or practices were found. A letter that identifies deviations occasionally request a response from the clinical investigator/sponsor.
  - ***OAI (Official Action Indicated)***

    Regulatory and/or administrative action will be recommended.

    Serious deviations were identified and a warning letter generally request a prompt correction by clinical investigator/sponsor and a formal written response to the national Agency

    NAI, VAI and OAI consideration based on clinical, major and minor findings

GCP Inspection



III. EFFORTS

- Periodic GCP training for regulatory and CT players
- Established of Indonesia Clinical Trial Working Group
- Attending international training and workshop
- Participantion in the GCP global activities

Global Participation

- WHO NRA Assessment for CT authorization in China (2005) and Thailand (2006)
- DCVRN GCP Inspection Workshop to develop GCP Inspection Checklist for DCVRN training module, 2006
- WHO Agreement of Performance Work to develop GCP Inspection Checklist Manual for DCVR Training Module (as a team), 2007
- Trainer in the GTN WHO GCP Inspection Training Course (as a team) in Zimbabwe , 2007

- Trainer in the GTN WHO GCP Inspection Training Course (as a team) in Phillipines, February, 2008.

- Joint GCP Inspection in Phillipines, February, 2008.

IV. FUTURE CHALLENGES

- To increase GCP compliance among parties involved in CT conduct
- Exchange information in the global study, particularly on SAE, CT termination, CT rejection
- To be one of the clinical trial centers for global studies

V. CONCLUSION

- Indonesia has potential to conduct CT
- Multicentre - multinational trials increased
- Some efforts have been done to increase the GCP compliance among CT players





Thank You