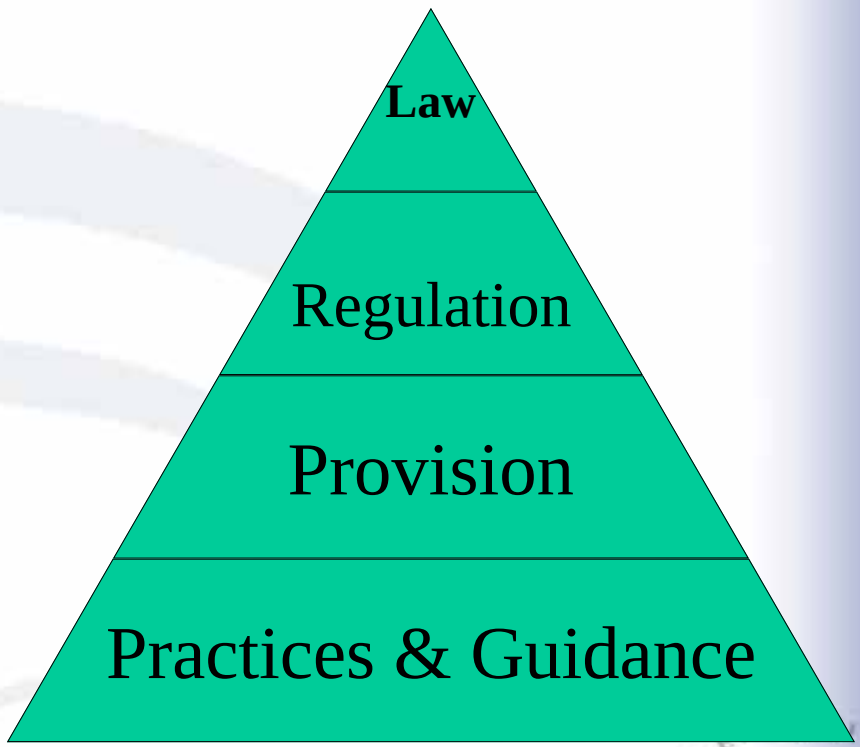
Multinational Clinical Trial Review and Administration in China

Chief of Review management , Feng Yi
Centre for Drug Evaluation
State Food & Drug Administration

Legislation in China

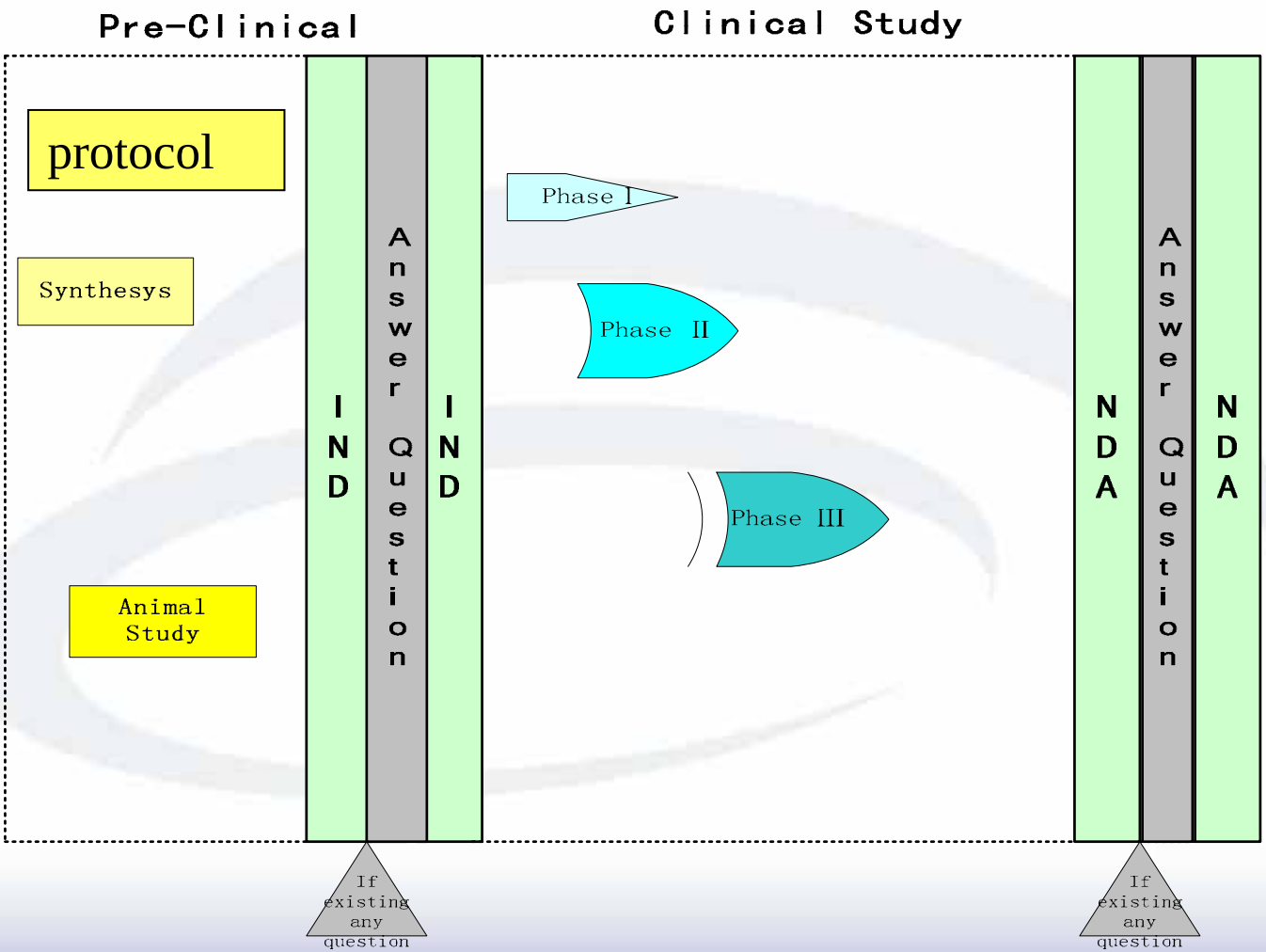
- Drug Administration Law of P. R. China
  - Manufacturers
  - Distributors
  - Pharmaceuticals in Medical Institutions
  - Drug Administration
  - etc
- Regulations for Implementation of the Drug Administration Law of P. R. China
  - Detail Requirements of the Law
  - Definition of New Drug, Period of monitoring for New Drug, Data Protection
  - etc
- Provisions for Drug Registration
  - Definition of the Drug registration
  - Category of Drug Registration Procedure
- Relevant Practise and Guidance
  - GCP/GLP/GMP Guidance



Requirement of the Provision on Multinationals Clinical Trial

Before 2002	No detail requirement Some R&D trial conduct in hospital
After 2002	The provision for drug registration set relevant item, make the clear requirement to conduct multinational trial in China

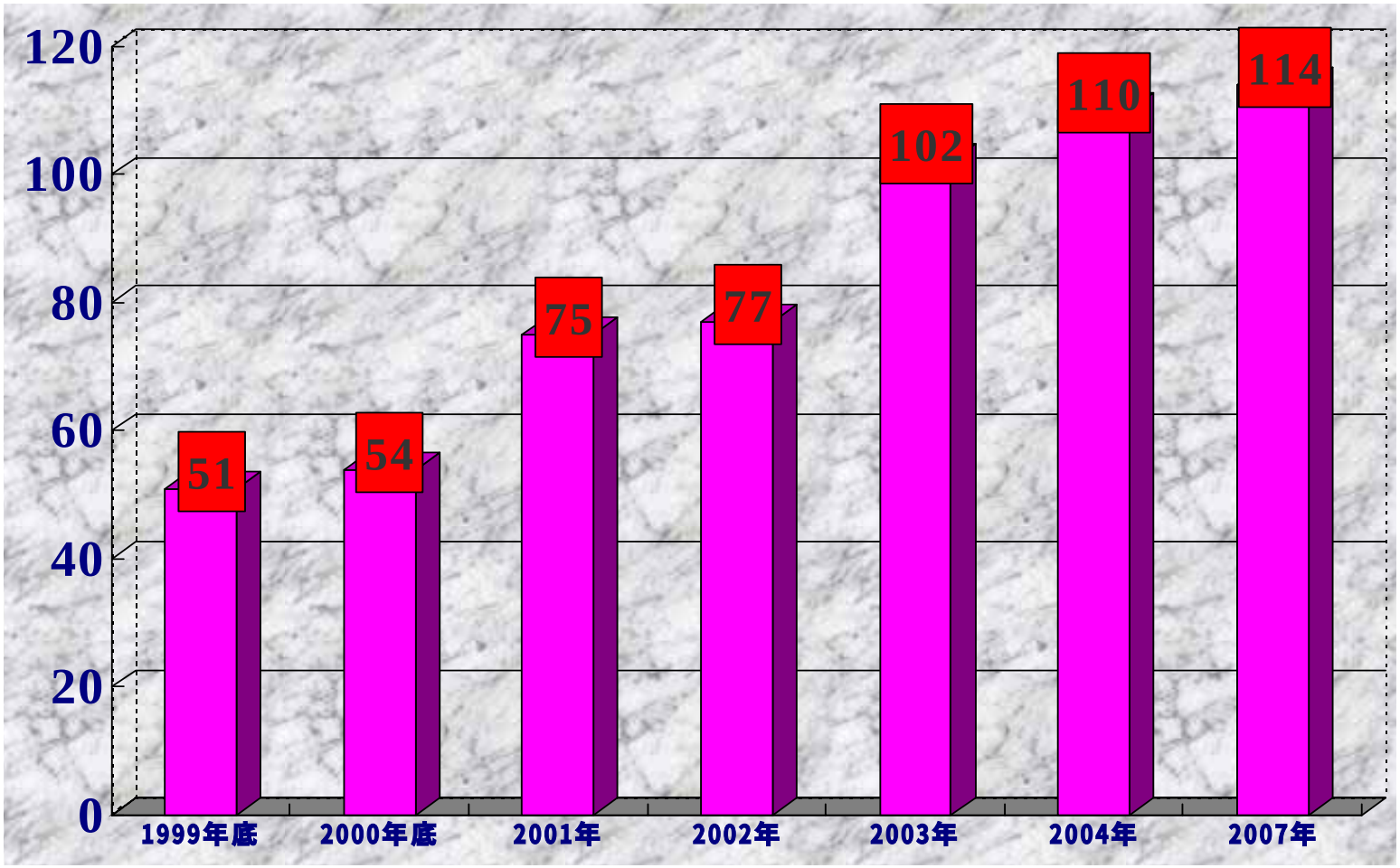
Drug registration Procedure



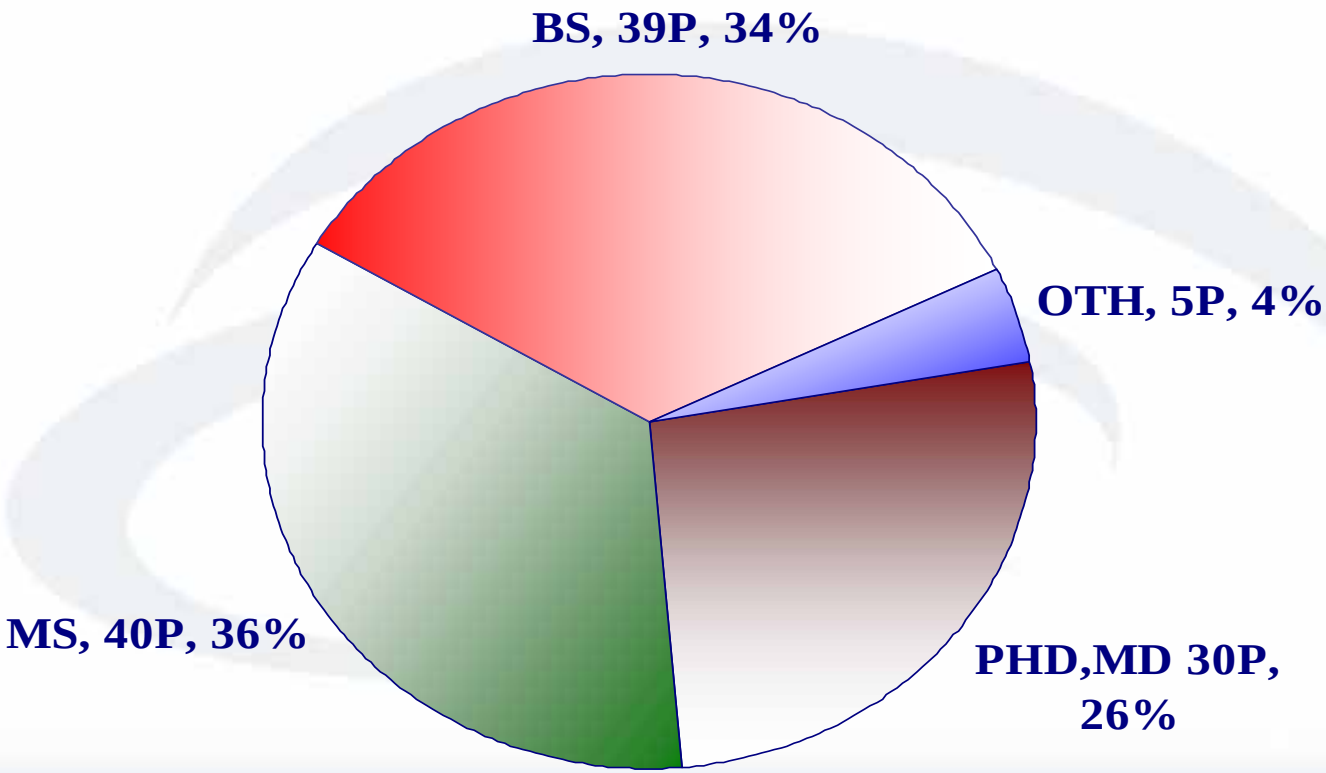
Responsible Organization

Centre for Reception	Receipt dossier Screen the file
Department of Drug Registration, SFDA	Issue relevant provision Issue guidance Make clinical and marketing Decision, etc,
Centre for drug evaluation	Take charge the technical review
National Institute of China Pharmaceutical and Biological Product	Validate and test the sample ,etc
Department of drug Safety Supervision, SFDA	Supervise the clinical trial, etc

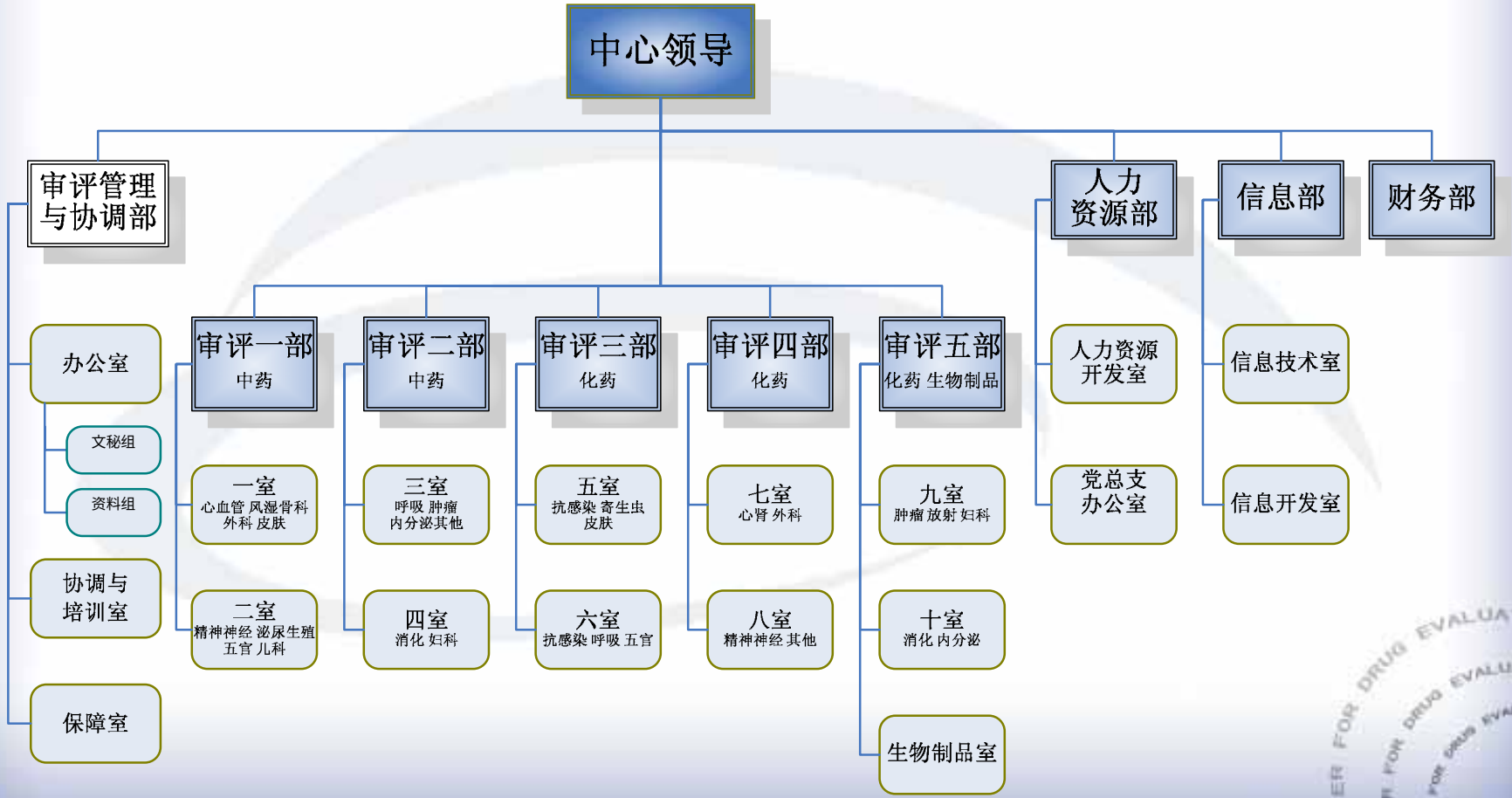
Staff in Centre for Drug Evaluation (1)



Staff in Centre for Drug Evaluation (2)



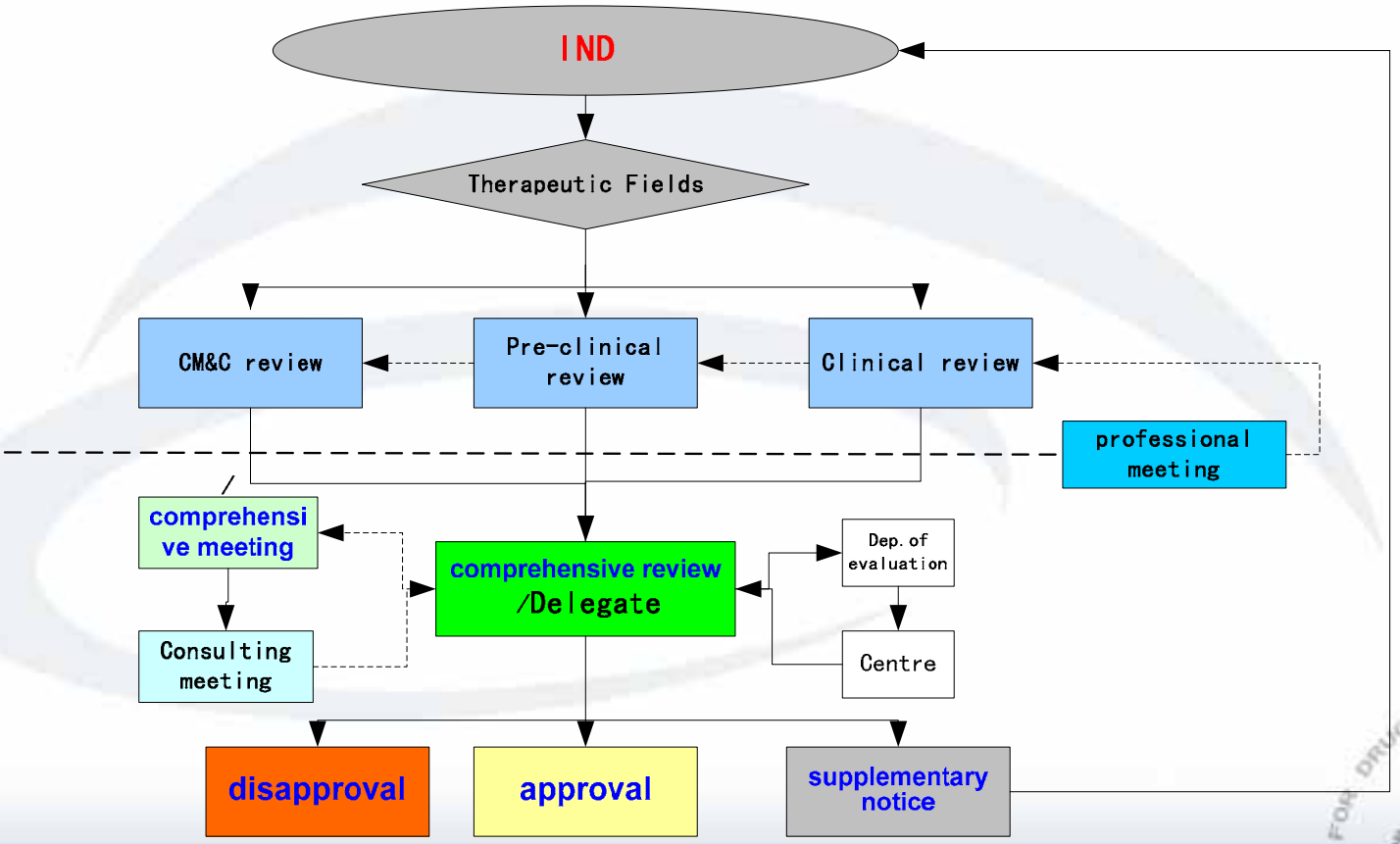
Structure of Centre for Drug Evaluation



Review Stream Line

- **Chemical Drug**
  - **Oncology, Respiration, Anti-infection, Cardio-Renal, Gastrointestinal product, etc(13, fields)**
- **TCM**
  - **Oncology, Respiration, Cardio-Renal, Gastrointestinal product, etc(14, fields)**
- **Biological product**
  - **Vaccine, Biological product for treatment, Diagnostic reagents in vitro**

IND Review Procedure

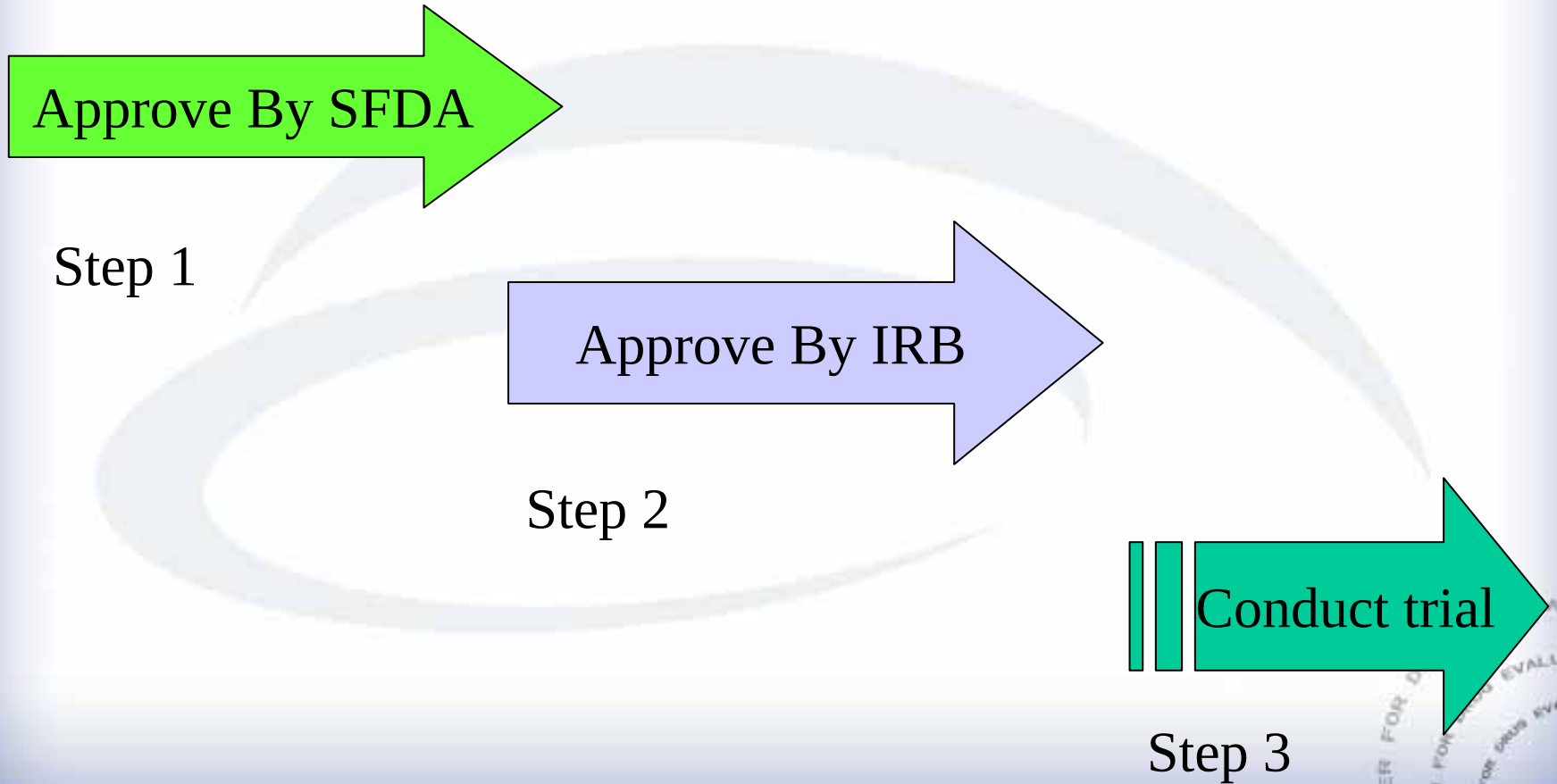


IND review focus on

- Safety
  - Protocol and Plan
  - Pharmacological and toxicological data
  - CM&C
- Conclusion of the technical review
  - Submission detail data by sponsor
  - Disapproval （Clinical Hold）
  - Approval

Consult outside experts when there are some important question

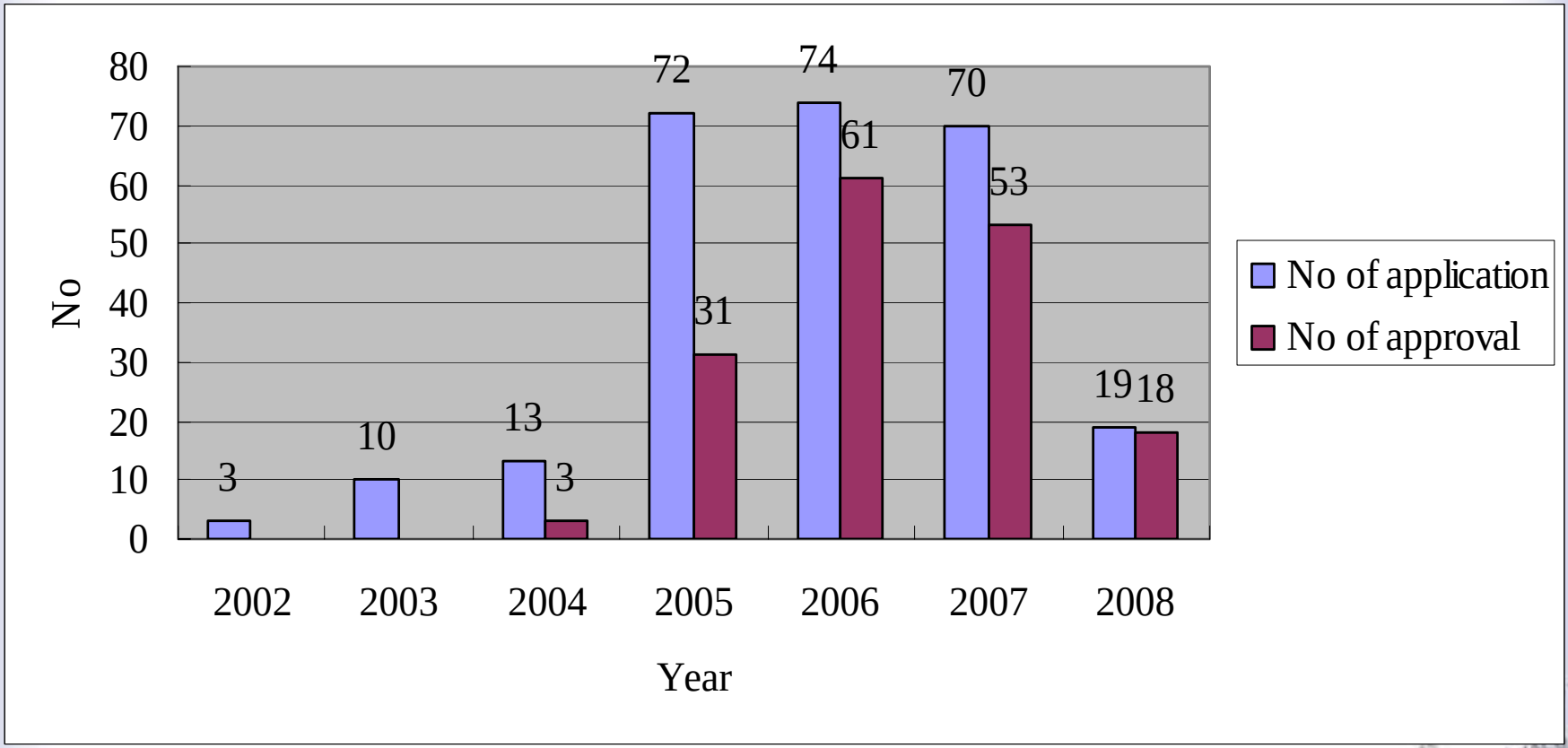
Trial from submission to conduction



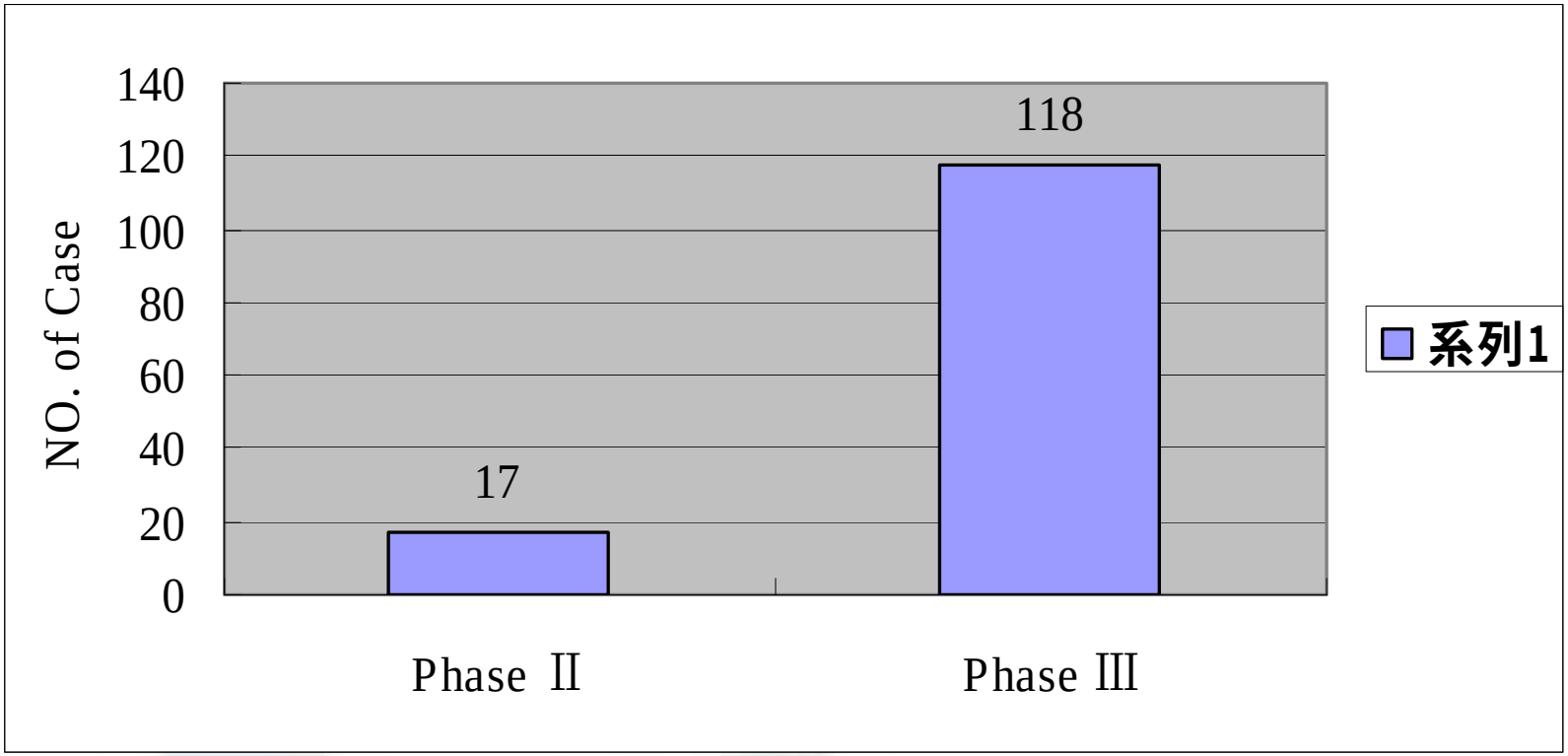
Type of IND

Type	Amount
Multinational trial	Minority
Import drug registration	Middling
Domestic drug registration	Majority

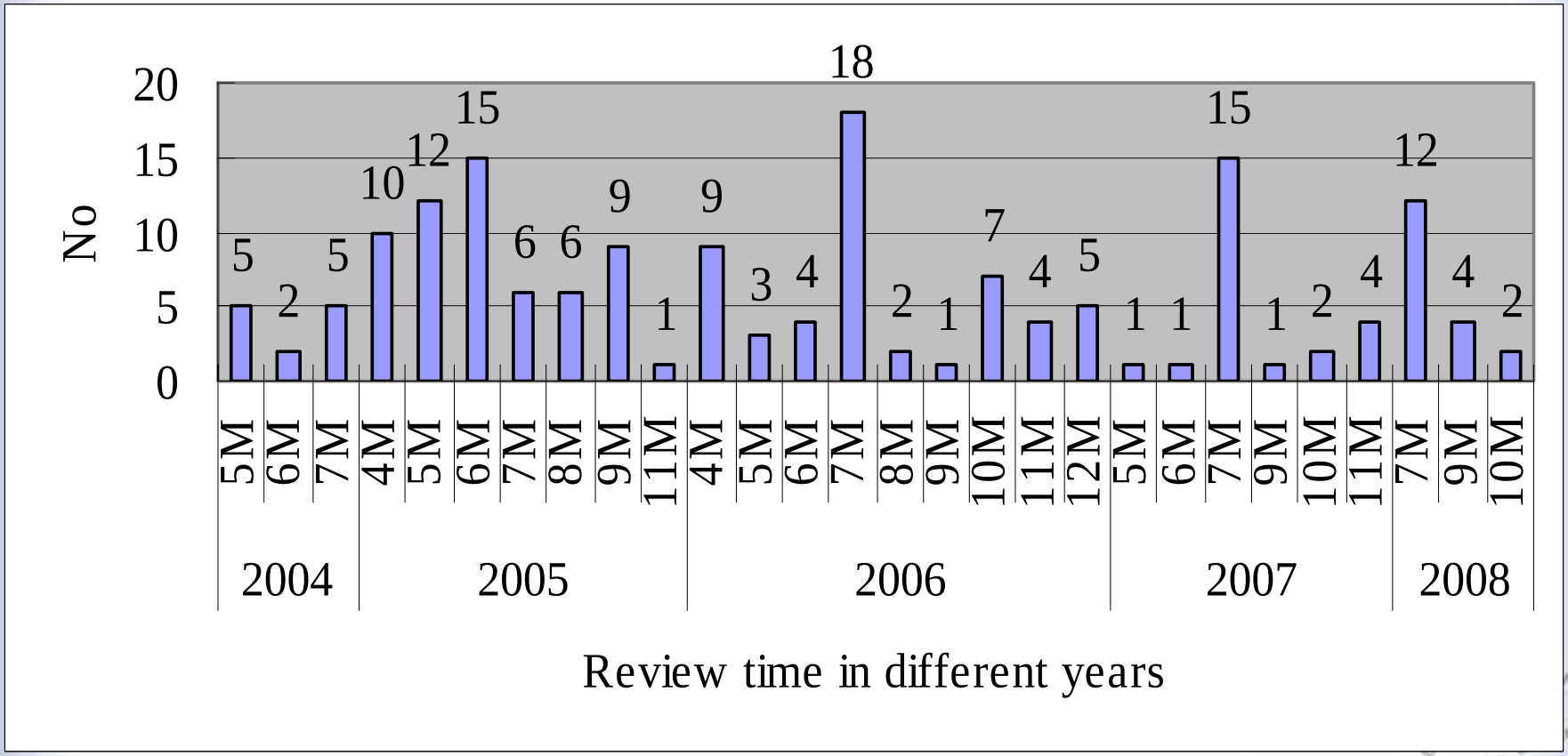
Multinational trial in China from 2002 to 2008



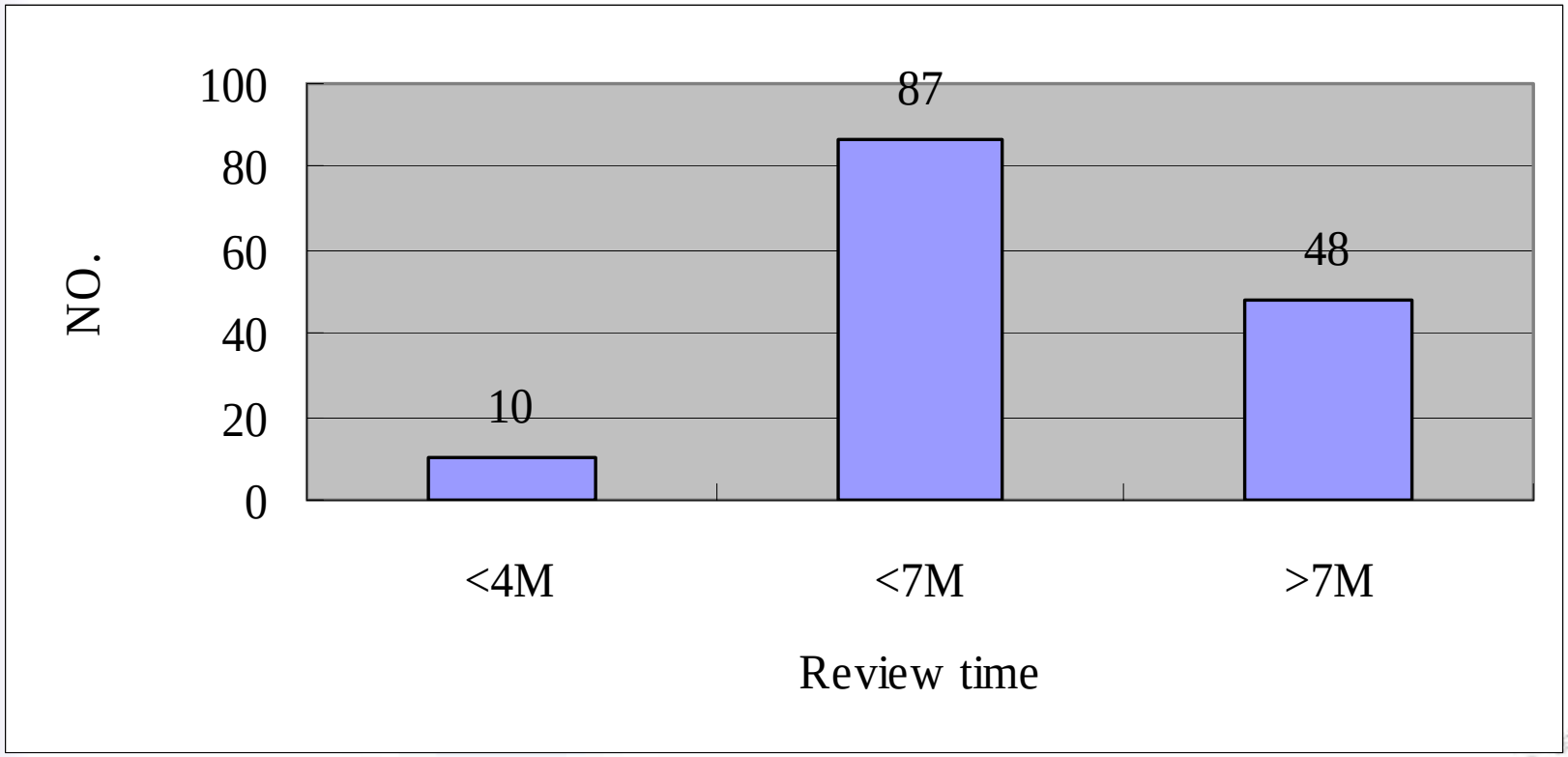
Phase of trial



Review time of multinational trial （1）



Review time multinational trial (2)

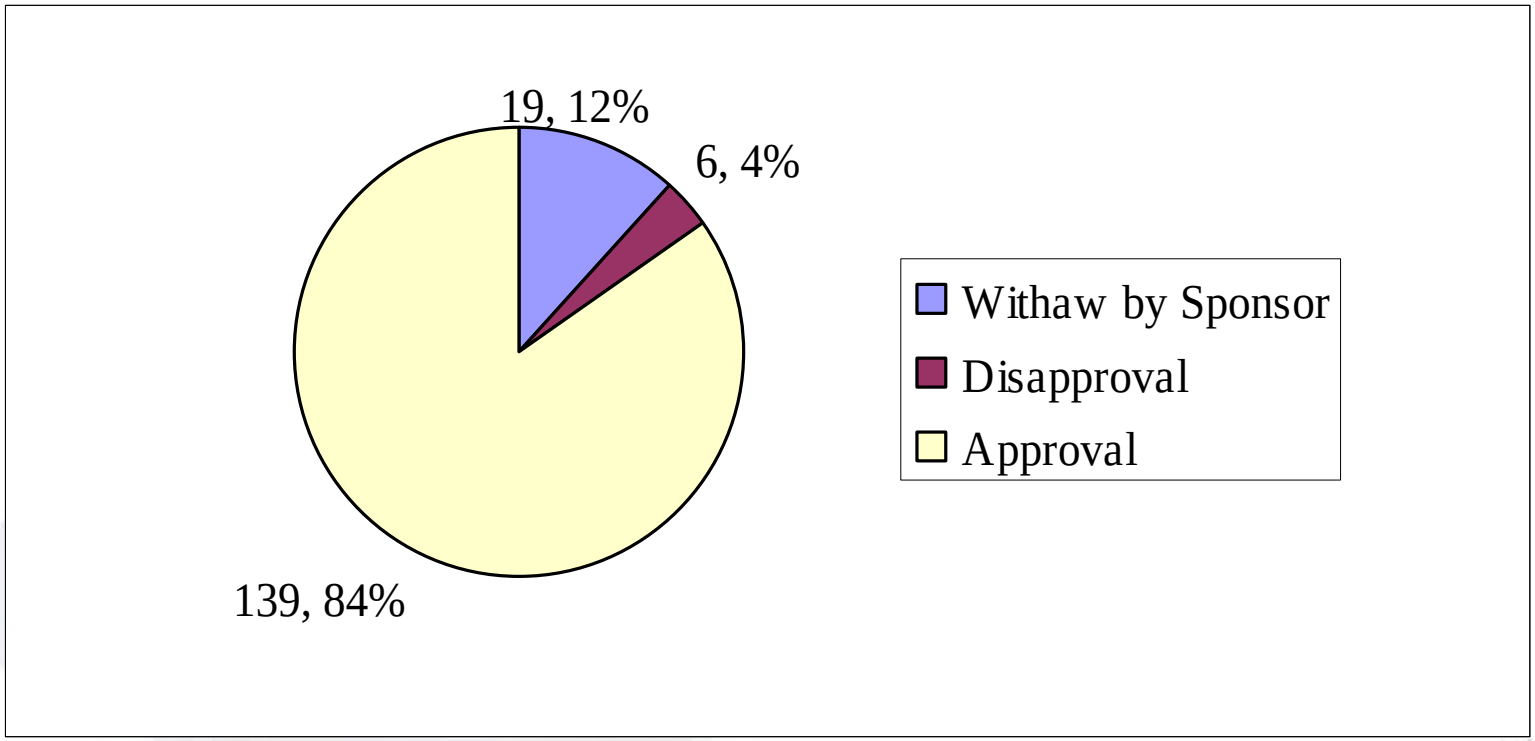


Review time multinational trial (3)

- **The main reason of > 4M review**

Protocol	Not very clear, need sponsor answer question
Quality of data	Not satisfy the requirement
Communication	Local sponsor need get the support from the oversea headquarters
Shortage of evaluators	Cde need recruit more staff

The result of review



Need to be solved in future

Regulatory science	IND function need sound establish Possibility of conduct the phase Ⅰ trial
Operation and performance	CDE review and IRB review More evaluators
Clinical R&D process	Safety report system
Guidance	ICH E5
Cooperation and communication	Other agency ,PMDA、KFDA，etc. Sponsor

Beijing 2008

Thanks