

# Overview of Regulatory System in the Philippines



# Philippine National Health Research System

- Department of Science and Technology
  - Philippine Council for Health Research and Development
  - Philippine Health Research Ethics Board



# Department of Health

- National Unified Health Research Agenda
- Bureau of Food and Drug Authority



# IRB Initiative

- Registration of IRBs
- SIDCER training programs
  - 4 times a year
  - GCP
  - Research Ethics
  - SOP
  - Clinical Trial



# Drug Registration

- Accept results of trials in sponsor countries
- Requirements for local registration
  - Import license
  - IRB review
  - ADR reporting



- Mostly Phase 3 trials – multicenter
- Phase 4 ADR Monitoring
- Training of regulatory authorities

