Clinical trial classifications in Japan (1)

- Medical Researches
  - Clinical Researches
    - Interventional researches / observational researches for human
    - Ethical Guideline for Clinical Trials, etc.
  - Clinical Trials ("Chiken")
    - Clinical trials intended for application for marketing authorisation under the Pharmaceutical Affairs Law
- GCP (Good Clinical Practice)
Clinical trial classifications in Japan (2)

Clinical researches other than “Chiken”

- Stem cell clinical trials: Guideline for Stem Cell Clinical Trials
- Gene therapy Clinical trials: Guideline for Gene Therapy Clinical Trials
- Epidemiological researches: Ethical Guideline for Epidemiologic Researches
- Other clinical trials: Ethical Guideline for Clinical Trials

“Chiken”

GCP under the Pharmaceutical Affairs Law

Non-commercial clinical trials

Commercial clinical trials

Investigator initiated

Company initiated