1. Clinical Trials

Clinical trial is defined as a prospective study comparing the effect and value of intervention(s) against a control in human beings. Note that a clinical is a prospective, rather than retrospective. The clinical trial is the most definitive tool for evaluation of the application of clinical research. In this course, we hope to assist investigators and statisticians in improving the quality of clinical trials by discussing fundamental concepts with example from various experiences and the literature.

- **Time:**
  - W4 (Thursday) 1:10pm–4:00pm; Classroom: 台北民生校區 9 樓
  - W3 (Wednesday), 1:10pm–4:00pm; Classroom: 三峽校區商學大樓 7 樓
- **Office Hour:**
  - W3 (Wednesday), 三峽, 8:00–9:00am; 12:00noon–1:00pm
  - W2 (Tuesday), 台北, 3:00pm–5:00pm
- **Textbook:**
  - Lecture Handouts (Slides): distributed in class
- **Evaluation**
  - Homework and Discussion in class
  - Projects: Special Topics for Design and Analysis of Clinical Trials
    Each student prepare one of the topics
2. Design and Analysis of Clinical Trials: Outline

(a) Introduction
(b) What is the question?
(c) Study population
(d) Basic design
(e) Randomization process
(f) Blindness
(g) Sample Size
(h) Baseline assessment
(i) Recruitment of study participants
(j) Data collection and quality control
(k) Assessing and Reporting adverse effects
(l) Assessment of health-related quality of life
(m) Participant adherence
(n) Survival Analysis
(o) Monitoring response variables
(p) Issues in data analysis
(q) Closeout
(r) Reporting and interpreting of results
(s) Multi-center trials
(t) Meta-analysis
(u) Phase I and Phase II trials
(v) Bioequivalence Trials
(w) Combination of multiple therapies
(x) Other trial designs
References


