General Information

▶ Introduction
▶ Go through the syllabus and other important information about the course
▶ Big picture of the course
▶ Office: 210B Cullimore Hall
▶ Contact information: most convenient way is email
▶ Office hours: Th 1:30 pm-3:30 pm, or by appointment
Textbook


**Other references**

- ICH Guidances E4, E8, E9, and E10.
Email List

- Email list for the class, to deliver syllabus, lecture slides/notes, homework/solutions, exam/solutions and some important notifications
- Computing: We will freely use **SAS** and **R**.
- Will talk more about computing when we need it
Big Picture of the Course

▶ Part I: Introduction to Clinical Trials
▶ Part II:
  ▶ Phase I – III Clinical Trials
  ▶ Randomization
  ▶ Sample Size Calculation
  ▶ Early Stopping of Clinical Trials
▶ Part III:
  ▶ General Multiple Comparisons Methodology
  ▶ Analysis of Multiple Endpoints
  ▶ Gatekeeping Strategy in Clinical Trials
▶ Midterm (Parts I – II)
▶ Paper Presentation
▶ Research Project (Parts I – III)
Course Evaluation

- Letter grade will be given based on Homework(20%) + Paper Presentation(15%) + Midterm(30%) + Project(35%)
- Homework: bi-weekly. 5 homeworks in total.
- Midterm: two hours, in-class, open book/notes. Tentatively scheduled at 3/11
- Paper presentation: Tentatively scheduled in the last half hour of each class
- Project presentation: Tentatively scheduled at 5/6
- No Final Exam.
Paper Presentation

- Form a group of two members
- For each group, I will send you one paper.
- Read the paper carefully and present it in front of the class
- For other groups, also read the paper carefully and prepare one or two questions for the presenters.
Project

- Find a research question relevant to clinical trials yourself
- Interesting and complicated to some extent
- Use the statistical methods you have learnt in this class to analyze it
- Demonstrate the performance of your proposed method through real data analysis
- Write a report, 8-10 pages
- Give a presentation in front of the class

Any questions/comments?