

# ST 520: Statistical Principles of Clinical Trials and Epidemiology

Fall, 2009

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| Textbook           | None. Lecture notes and slides are available for download from the class website <a href="http://www4.stat.ncsu.edu/~dzhang2/st520/index.html">www4.stat.ncsu.edu/~dzhang2/st520/index.html</a>   |
| Reference          | <ol style="list-style-type: none"><li><b>Fundamentals of Clinical Trials</b><br/>by L.M. Friedman, C.D. Furberg and D.L. DeMets</li><li><b>Group Sequential Methods with Applications to Clinical Trials</b><br/>by C. Jennison &amp; B.W. Turnbull</li></ol>   |
| Class Hours        | Tuesday & Thursday, 8:30 - 9:45 am  |
| Location           | Room 1216 SAS Hall  |
| Instructor         | Dr. Daowen Zhang<br>5122 SAS Hall<br>Tel: 515-1933<br>Email: <a href="mailto:zhang@stat.ncsu.edu">zhang@stat.ncsu.edu</a>   |
| Office Hours       | 10:00-11:00am Tuesday, Thursday or by appointment   |
| Teaching Assistant | Justin Replogle<br>Email: <a href="mailto:jdreplog@ncsu.edu">jdreplog@ncsu.edu</a>  |
| TA Office Hours    | 11:15am-12:15pm Wednesday (Room 1101, SAS Hall)   |
| Evaluation         | Homework: 20%<br>Mid-term (in class, open book & open notes): 35%. It will be given sometime (10/6/09?) before the fall break (10/8/09-10/9/09).<br>Final (in class, open book & open notes, comprehensive): 45%. Tuesday, 12/15/09, 8:00-11:00am   |
| Course description | This course will introduce some basic statistical concepts and methods used in Epidemiology and will focus on the statistical principles and methods used in clinical trials, including phase I to IV clinical trials. Although the class will have emphasis on phase III trials, we will also discuss the feature and statistical issues in phase I and II clinical trials. For phase III trials, we will discuss ways of treatment allocation that will ensure valid inference on treatment comparison. Other topics include sample size calculation, survival analysis and early stopping of a clinical trial and noncompliance. |
| Online evaluation  | Online class evaluations will be available for students to complete during the last two weeks of class. The website is <a href="https://classeval.ncsu.edu">https://classeval.ncsu.edu</a> . Any comments and suggestion on this course are greatly appreciated.  |