

BIOSTATISTICS 740 (BIOS7400)
Clinical Trials

Lecture 16

Data Analysis II
(Study Closeout, Handling of Various Issues)

Closeout Phase

- A *fairly complex* process that requires *careful planning and scheduling* if it is to be accomplished in an *orderly* fashion
- Starts from the *last follow-up visit* (called “*final visit*”, which marks the *end* of treatment and the *follow-up*) of the *1st enrolled study participant* to the *time when all data analyses are completed*
- Be prepared to *implement* or to *modify this plan* prior to the *scheduled termination* because the trial *could be stopped early* during interim monitoring by DSMB
- Needs its *own written protocol or operating procedures* with respect to *termination (i.e., a component of the closeout phase) activities, data cleanup and storage, as well as dissemination of results*

Termination Procedures

- *Planning and Scheduling of Closeout Visits*
- *Final Ascertainment of Response Variable*
- *Posttrial Care*