Treating Depression: A Randomized Clinical Trial

Background:
Clinical depression is a recurrent illness requiring treatment and often hospitalization. Nearly 50% of people who have an episode of major depression will have a recurrence within 2-3 years. To be able to prevent the recurrence of depression in people who are at risk for the disease would not only go a long way to alleviate the pain and suffering of the individual patient but would also save society many thousands of dollars per patient in medical expenses and lost wages due to an inability to work.

The Study:
During the 1980's the Federal government, through the National Institutes of Health (NIH), sponsored a multi-centered randomized controlled clinical trial to evaluate two drugs to prevent the recurrence of depression in patients who have had at least one previous episode of the illness (Prien et al., Archives of General Psychiatry, 1984).

The Study Design:
The study was multi-centered. There were 5 medical clinics across the country that participated in this trial. Using many clinics enables the investigators to enroll many more patients into the study and allows for a diversity of patients to participate. There were 3 treatment groups. Patients received either Imipramine (Imip), Lithium (Li), or a Placebo (Pl). Imip and Li are active drugs. Patients were randomized to one of the 3 treatment groups, using a random device (like rolling a 3 sided die). Patients were followed from 2-4 years to see whether or not they had a recurrence of depression. If they did not have a recurrence within this time frame, then their treatment was considered a Success. If they did have a recurrence, it was considered a Failure. The study was double-blinded. A number of additional background variables were measured for each patient.

The variables in the data set are:

HOSPT	Which hospital: 1, 2, 3, 5 or 6.
TREAT	0=*Lithium*; 1=*Imipramine*; 2=*Placebo*.
OUTCOME	0=*Success* 1=*Failure* (recurrence of depression)
TIME	number of weeks until a recurrence (if OUTCOME=1) or until study ended (if OUTCOME=0)
ACUTET	How many days the patient was depressed before the start of the study
AGE	Age in years
GENDER	1=*Female* 2=*Male*.

Your Task:
Write a report with your analyses and conclusions. The report should be aimed primarily at a psychiatric researcher who is interested in treatments for depression. You should assume this person is statistically literate, in the sense of having had a basic statistics course and having seen how basic statistics is used in clinical studies. The report should be succinct and to the point; it should avoid excessive emphasis on statistical technique. However, you should, in addition, create a technical appendix. This appendix should be designed as a resource for you and the psychiatric researcher, together. The appendix should contain additional information, including various plots and summaries, but does *not* need to be self-contained in the sense of being completely comprehensible to the psychiatric researcher. You should assume that you would be sitting next to him or her when you went through these details. Each item in the appendix *should* be referenced somehow in the report itself (for example, you might say, "see Figures 3-5 for boxplots"). In addition, one or more essential tables or figures should be displayed in the body of the report itself. Inclusion of the technical appendix is supposed to make it easier for you to write the report, and also to be useful to you should you ever want to refer back to the report.

36-711: : Use LaTeX to create your document and Splus or R for the quantitative analysis and statistical output. You will be learning about these in 711.