SBCC – Statistical Biomathematical Consulting Clinic
Meeting preparation-background information for the biostatistician

Some of these questions may not apply to some studies - This information is needed to write a statistical analysis plan and carry out sample size calculations

1. What is (are) the primary study question(s) or aims – the purpose of the study?

2. What is the study design (retrospective, prospective, cross sectional, clinical trial, case study ...). Is this an experiment/trial or an observational study? Is there a deliberate intervention or therapy (experiment)? Is this a systematic review or "meta analysis"? Is this a survey?

3. Is the study being conducted on humans (adults, children, gender)? Animals? Cells?. What is the "unit" of analysis, a person? a person-visit? a city? a cell plate?

4. What is the target population? Where are the subjects being recruited from? What are the study inclusion/exclusion criteria?

5. What are the primary outcome measures? Can you prioritize the outcome measures in importance? Are they binary (yes/no) outcomes (for example: alive or dead), continuous outcomes (for example: blood pressure) or ordinal outcomes (for example: poor, fair, good)? Do they involve "survival" – time to some event such as death or disease recurrence?

6a. Is there a deliberate intervention or treatment? What is the primary intervention, if any? Are the investigators and subjects masked (blinded) to the identity of the treatment?

6b. If there is no intervention, what are the primary explanatory factors, if any?

6c. What other factors may have a strong influence on the outcome other than the primary factor(s) of interest. These are potentially confounding factors or effect modifying factors (covariates). Often one needs to compare/investigate these factors as well.

Sample size needed (not relevant to all studies-done when planning studies)

In order to compute sample size (if needed), we need an estimate of the "effect size"

A. When comparing continuous outcomes among groups, often by comparing means, what is the within group variability between one subject to the next for the primary outcome? One measure of this is the standard deviation (SD) of the primary outcome. Often, the SD is approximately ¼ the range after outliers have been omitted.

B. How large an average or typical change or difference is being created in the outcome by a change in the treatment or primary explanatory factor? For example, one can use previous reports, pilot data or speculation about the mean difference in the primary outcome between the group with the intervention versus the group without the intervention. What is the smallest mean difference that is of any clinical or scientific importance? (Perhaps this is a percent such as a 10% difference).

C. If the primary outcome is binary, what sort of difference or change is expected in the proportion who experience the outcome? We don't need an estimate of within group variability for binary outcomes since they only have two values (i.e. yes and no).

D. If the interest is in the correlation between two continuous variables (ie X vs Y), what is the smallest correlation of interest? How much will Y change for a one unit increase in X?

Some of this information is available from the literature or from pilot data. In the literature, means may change with treatment but SDs usually are the same in the same population.

Doing a pilot study first (even on one or two patients) irons out the bugs.

Call your friendly neighborhood statistician in the planning stage!