

Guidelines for pre-award statistical consultation with SPCTRM

To enhance the initial statistical consultation for planning a new clinical study

- Please **schedule** the consultation with the SPCTRM office and provide information on your timelines, including critical deadlines for grant applications, presentations, etc.
- Identify one or a few plausible statistical **endpoints**. A statistical endpoint is a variable that measures the effect of therapy, or otherwise captures the main outcome you are studying.
- Identify a plausible, clinically relevant **therapeutic effect** (difference in the endpoint between treatment arms, or between groups to be compared). This effect is something your study will estimate, so it will usually reflect a numerical difference you want to be able to detect; it will usually not be based on any data.
- What sort of **design** would work in your context: comparative designs include parallel groups (e.g. treatment A versus B), statistical crossover (e.g. arm 1 gets treatment A then washout then treatment B, arm 2 gets the treatments B then A). Non-comparative designs are aimed at exploring feasibility or estimating therapeutic effect or toxicity in a single treatment arm, usually as a preliminary to a comparative study.
- Locate **previous studies** that report this endpoint in a clinical setting close to the one you are considering
- Identify estimates of the **variability** of the specific endpoint in the population to be studied. This is not trivial! Previous studies will help. If the endpoint is a duration (e.g. time to disease progression) or a binary category (responded), this estimate is implied by the treatment difference; for a continuous outcome (e.g. systolic blood pressure), the variability has to be estimated separately. A “change from baseline in a measure” has its own variability that may not be the same as the variability in the measure at baseline.
- Estimate how many patients are **available** to consent and be accrued in a reasonable period (say 2 years) and what is the maximum sample size you think you could manage?
- Email or fax **background** material to the statistician as soon as possible before the consultation to allow time for review to spctrm_biostat@lists.stanford.edu or F/650-725-6951. If you have preliminary data that might help, bring it along.
- Please do not email files that contain **HIPAA**-sensitive material without consulting the statistician.
- We *strongly encourage* the investigator’s **mentor** to participate in at least the first few meetings between a junior investigator and the statistician.

At the present time SPCTRM provides statistical services leading up to a grant application. It may not be possible to provide statistical analyses of preliminary data.

Post award statistical services will be provided at a later date.