

How large a sample do I need?

What your statistician will ask.

Research Governance and Ethics Committees usually require sample size estimates. These are ball-park figures for the numbers of subjects your study needs to stand a good chance of detecting a difference, effect or association where one really exists. Sample size estimates are entirely dependent on the assumptions made about the data and the method of analysis and so they can only be as good as the information *you* supply for them. Your statistician will therefore need to know the following:-

- The **background** to your research.
- The **objectives** of your research.
- Your **primary outcome measure** or measures
- Your **secondary outcome** measures, if any?
- How **exactly do you intend to measure** these?
- **Findings from previous studies** on the likely range/variability of these measures.

For instance, have any previous studies used your measure(s) on a comparable group of patients and if so, is anything known about a) the **'shape'** of its distribution (is it symmetrical or skewed, is it normally distributed) b) its **'spread'**, as measured by its standard deviation or variance, or failing that, the likely **maximum and minimum** values?

Or, if the outcome measure has **several distinct categories**, how many are there? Is there any natural ordering of categories e.g. low medium high, very unsatisfactory, unsatisfactory, adequate, good, very good? Could some categories be merged if necessary?

If your study entails comparing **groups** of subjects, how are they defined? For instance are they intervention and control groups, or defined by some characteristic like age, gender, stage of disease?

What is the anticipated average or median change or **difference between the groups** which you believe exists?

Sample sizes are usually calculated so that your study has an 80% chance (this is the *power*) of detecting a between group difference of this size. Smaller differences than this will have less chance of being detected by the study.

What sample sizes are practical? How many eligible subjects are likely to be willing to participate during the time period of the study?

It is our expectation that the studies we work on are protocol-driven and have sought or are seeking approval from the Ethics and Research Governance committees.