

**Malabar Cancer Centre (Post Graduate Institute of Oncology
Sciences and Research) [MCC-PGIOSR], Thalassery**

What is Statistical Consultation?

In a statistical consultation, you seek the help of a statistician to select and use the best methods for obtaining and analyzing data for some data-related objective. Usually the objective is to answer a question. The subject area could be almost anything, such as business management, government, agriculture, health, economics, or a science.

Do you need a statistical consultant?

A statistical consultant has technical expertise and experience in areas such as planning studies, measurement and sampling methods, data quality management, and statistical analysis and interpretation. A statistical consultant is a problem solver. The statistician's specialized knowledge can supplement your own expertise to enhance the integrity and validity of your study.

A statistician is especially helpful when

- You know what you would like to find out and want help to design a study that will answer your questions. You want help determining how large a study to perform or how many different groups to compare.
- A study involves methods and/or responses that may be different from those to which you are accustomed. Different types of data are analyzed in different ways, and a statistician can determine appropriate methods of analysis for each type.
- A planned study takes an unexpected twist. Rather than improvise and hope for the best, consult a statistician who can help to weigh the merits and drawbacks of different possible actions.
- The size of the study results in a volume of data that is more than you are prepared to handle yourself. A statistician can navigate through large data sets to arrive at specific answers to your questions.
- The analytic method appropriate for your data is complex or difficult to use successfully and requires more applied experience than you have.
- You have done similar projects but would like to get a new point of view and/or take advantage of the latest methods of design and analysis.
- You simply prefer to rely on a professional statistician for advice and support on all methodological aspects of your project.

A statistician can also help to interpret the results of an analysis that you have or another person has performed and can evaluate whether a study design or an analysis is appropriate for addressing the problem at hand.

How to Involve a Statistical Consultant

Prior to Data Collection. The most effective way to work with a statistical consultant is to include her from the very beginning of the project. A statistician who is also knowledgeable in your area of research can be of great value in helping to refine and focus the research effort into an efficient, successful project. An important advantage of consulting a statistician before a study begins is that she can verify that the planned procedures and size of the study will be adequate to address its goals. She can give advice on blinding/masking and randomization, the number and combination of experimental interventions, the timing of measurements or visits, and other important design issues, such as whether it would be better to collect information on a larger sample or on the same sample more times. A statistician can also suggest ways to maximize the efficient use of the available resources. It may seem that using a particular design is sensible, but in fact, the statistician may know a more efficient design. Also, a statistician routinely looks for threats to validity that might ruin a project. The statistician can also contribute relevant expertise in decisions about data management from the earliest stages. Decisions about how to code measures, and what to computerize, directly affect the ease, even the feasibility, of subsequent analyses. If the statistician is consulted before the data management system is established, the items below should be discussed. If the database already exists, the statistician will need to know how all of these aspects of data management were carried out, often in detail.

- Who will be responsible for data management?
- Confidentiality of subject information.
- Data integrity and security.
- Coding guidelines and documentation.
- Computer software and hardware.

Judicious use of a statistical consultant in the early stages of a project can save much time, effort, and aggravation in the later stages. "It is always easier to steer a ship than to raise it off the ocean floor."

After Data Have Been Collected. Although it is best to involve a statistician in the design of a study, a statistical consultant may be brought into a project after the data have been collected. A statistical consultant can help to select and implement data analysis methods that are appropriate and effective for the types of data produced by your study. In order to do this, the statistician needs to have a complete, detailed description of the study design and conduct, as well as a clear exposition of the questions to be addressed. A statistician should know (or may be able to develop) statistically valid ways to obtain answers to your questions. Also, she will examine your data for threats to validity, ranging from missing data to questionable outliers to confounders. If the study procedures did not provide data that could answer the research question, the statistician will not be able to remedy this with statistical methods; however, she may be able to point out what information can be extracted from the data

Once the data are analyzed, the results must be interpreted and conveyed to an audience, such as a regulatory agency, management, a research journal, or a media outlet. A statistician can be valuable at this stage, too, by checking that your conclusions fit the analysis results, by suggesting

the best ways to describe and display the data, and by assuring that you have not made erroneous or incomplete statements about the findings. A statistician who is first consulted at this stage may want to re-analyze the data using methods she considers more appropriate than those already tried.

The First Consulting Session

In your first extended discussion, you and the consultant establish the basis of the consulting relationship. Often there is no charge for this initial, exploratory meeting, but do not assume this. If you have not worked together before then this session is an opportunity to learn about the consultant's qualifications, experience, and way of working with people.

The consultant also learns about you, the problem you need help with, and your way of working with people. You both may be able to decide at this point whether there is potential for a satisfactory consultation.

Introducing the consultant to the problem

Not all the issues described in this section may be resolved at the initial session, but they should be addressed and discussed. Begin by describing the problem clearly. Although you should not expect to cover all the details at this session, you should provide enough information to define the problem and provide a basis for estimating the level of effort. Expect a variety of questions as the statistician seeks to understand your research and your statistical needs. Although you might think some of these questions are not directly relevant to the statistician's role on the project, they often uncover issues with statistical implications.

What materials are needed?

In addition to talking about the project, most statisticians appreciate receiving written summary material. The documents should be readable and organized, and the purpose of each should be identified. You might include the following:

- Background information about the problem, including a description of the project, equipment, or procedures to be evaluated;
- A proposal, protocol, or statement of work, if one exists;
- Schematics, such as diagram or flow-chart, that illustrate important ideas and processes;
- Information about any existing database to be used.

It is not always possible or necessary to have complete information on the problem, and frequently the need for information becomes apparent in the discussion. Nevertheless, starting with legible, organized information gets the process off to a good start, saves time later and enables the consultant to give you a more realistic estimate of the time to complete the deliverables.

Once the statistician has agreed to become involved in your project, it may be worthwhile to provide prior studies, pilot data, tests, published and in-house reports relating to the problem, so that the consultant can become familiar with important issues in your research, and with the state of knowledge related to your question. For example, to estimate the needed sample size, it is crucial to have information about variability as well as an idea of how big is a meaningful effect of

treatment or other experimental manipulation. Previous related research can provide a basis for estimating these.

What do you expect from the statistician?

You may begin the initial session with a clear idea of what you want the statistician to do for you. Alternatively, you may be completely open to suggestions about how to proceed. Usually a researcher is between these two extremes. Even if you begin by thinking you know exactly what the statistician should do, be prepared to consider alternatives. Based on her professional judgment and your goals, a statistical consultant will likely present you with choices among valid alternative statistical approaches that may vary in scope, cost, or precision. She should also explain the ramifications of not taking her advice. Sometimes client and statistician can define their mutual expectations completely at the initial session, other times it may take several discussions, with time between to study and to think more about the problem. At the end of each meeting, you should ask the statistician to state what she understands about the project and you should state your expectations, to assure your mutual understanding. During the discussion of expectations, the deliverables for the project should be specified. Deliverables may include a report of the analysis and results, the datasets created during the analysis, programming code developed to do the analysis, or attendance at meetings.

Financial terms

The consultation fee may be set at a fixed amount for the entire project or may depend on volume of work (including protocol development, questionnaire development, preparation of case recording format, sample size calculation, data cleaning, data analysis and interpretation of results).

Ethics in Statistical Consulting

A statistician should be guided by professional and scientific ethics, which promote the integrity of the data analysis and conclusions. The results of a valid statistical analysis may not conform to the expectations or desires of the client or consultant. However, pressuring a statistical consultant to achieve a predetermined outcome may adversely affect the validity of study results as well as the statistician's credibility. No one can guarantee that the results of an analysis will be exactly what were hoped. An expert with a thorough knowledge and understanding of statistical methods is best equipped to establish and defend valid conclusions from the data and study design, as well as to identify and explain any limitations to the conclusions that can be drawn.

Data Confidentiality and Publication

The confidentiality of the data will be highly maintained. The requestee shall send all the communications through department email id only. Authorship/acknowledgement in the research publication is highly solicited.