

ASA Consulting Section Conference Call
1:00 pm EST, March 8, 2004

Charles S. Davis, Round Table Discussion Leader

Slides were e-mailed to participants to provide additional information.

By introduction, Dr. Davis indicated that he would focus the discussion on consulting with pharmaceutical and biotech companies, as this has been his primary experience. His experience is more relevant to persons doing outside consulting on a part-time basis (rather than full-time).

Referring to the slides, there is more than one model for statistical consulting. He is basing his comments on his experience and on his interests. One should be open to other points of view. Slide 3 refers to the discussion to follow.

Slide 4. When considering consulting, a solid training in statistics is non-negotiable. A graduate degree in statistics or biostatistics is a requirement. To be a consultant, one must have excellent oral and written communication skills, the ability to make and defend recommendations, willing to extend oneself and to meet deadlines, and capable of fulfilling both “basic” and “higher-order” roles of a statistician. Another type of consulting he calls “production consulting” is where you just do what you are told, where the above is not important.

Slide 5-7. Define the “Higher-Order” roles of a biostatistician or statistician: collaborate on conceptualization of the problem, define or redefine the scientific questions of interest, ask the “hard questions” concerning the proposed study design, and initiate and lead discussions concerning analysis and interpretation of results. Dr. Davis gave as an example a paper from Dave DeMets et al, 1994, indicating that it is not enough to provide the correct answer to a design or analysis problem when asked, one must be willing to initiate a conversation, schedule and run a meeting, present new insight, propose a possible revised solution, and negotiate an acceptable approach rather than just provide the correct technical response to inappropriately posed questions.

How to get started in statistical consulting is a difficult topic. A little luck may be involved. Networking is important with statisticians and subject-matter specialists, but it may be more important to network with non-statisticians. One may want to start with working with an established consultant. Take advantage of EVERY opportunity initially, because you never know what it may lead to. After you are established, you can be more selective. Do outstanding work, no matter how small the opportunity seems, as small things may lead to greater opportunities.

Slide 9. What should pharmaceutical and biotech companies be looking for? Due to regulatory constraints on processes and procedures, it may be difficult to prepare routine analyses and prepare reports. When consulting in the regulated industry, you need a lot of infrastructure set up to do work that will be used as part of regulatory

submissions. Companies might be looking for general planning (i.e., drug development plans in general), study design, providing general advice, replicating analyses that others have completed, and reviewing protocols, analysis plans, and study reports.

Slide 10. What might companies be looking for? Sometimes they are looking for someone who will validate decisions that have already been made. Some companies will bring in someone when they are afraid to stand behind their decisions. Dr. Davis does not like this model, and doesn't think it applies that much to statistical consulting. Companies may be looking for someone who will find a 'positive' result from a 'negative' study. There is nothing wrong with hiring a consultant to do some exploratory analyses or do some additional work, but you need to be clear in your reporting exactly how much you are willing to stand behind hypotheses you are generating, rather than hypotheses you are confirming.

Slide 11. How to be maximally satisfied as a consultant. This is very important. Don't be a "hired gun" and don't be a "rubber-stamper". A hired gun is an outsider who is really not involved. They may ask one to provide a couple p-values for someone and then they send you away. In his opinion, striving to become a valued team member and working with people who respect you are most important. This has led Dr. Davis to the position he is currently in at Elan Pharmaceuticals.

Slides 12-16. Covers issues he feels are most important to being a good consultant, but they don't take the place of being a good statistician. As an example, Dr. Davis noted that a former statistics professor at UNC, Dennis Gillings, started a small consulting company that is now the largest contract research organization (CRO) in the world. He is clearly not just a statistician that proves theorems and does statistical work. In his 2000 JSM Presidential Invited Address, Dr. Gillings made some important points: we must deliver information our customers want and need, we must improve decision making, and we must judge ourselves by whether we actually do so, and not be satisfied merely by deriving a new formula. This is a critical distinction. Dr. Davis has worked with people who feel that their PhD dissertation research has to be incorporated in everything they do and this should not be the case.

Slide 13. How do we get there? You need to judge whether you are the type of person who can do these kinds of things.

Slide 14. This slide relates to the "softer" areas of consulting. Can you analyze a situation, define the problem and solve the problem? Leadership and communications skills are, again, essential.

Slide 15. Ron Iman, 1994 ASA President, wrote an article for the Sept 2003 *AmStat News*. He talked about many things in this article, but concluded by commenting on the one skill needed for success in the future: the ability to communicate effectively with our customers with the written and spoken word. With such skills our profession has an unlimited upside and without them we will never achieve our potential. Dr. Davis firmly

agrees this is true for a statistician in general, and particularly for an independent consultant.

General Discussion:

A participant asked to elaborate on “Ask the hard questions”. Dr. Davis explained that often people tell us what they want us to do. Statisticians are well suited to provide an objective viewpoint like: how do you know this will work, do you have the right patient population, if the study succeeds will you be able to sell the drug, where did you get your assumptions, what papers did you refer to. Try to be more than just a statistician, try to be a smart person who can contribute a point of view on the scientific question.

A participant asked about travel and do stat consultants travel to companies, or just communicate by phone or email. Dr. Davis indicated in his experience he did quite a lot of travel years ago. But now you can probably use email and fax for most of your communication. If a company was having a face-to-face meeting, the consultant may need to be present. Many group meetings are now done by teleconference call. Ideally, you may want to be located geographically where there is some local business, so you would have business where travel would not be required, and companies may be more apt to use you because you are local. You could pursue more distant opportunities as well.

A participant asked about ethical disagreements (i.e., not publishing negative results) involved with a contract. Dr. Davis has not worked under contract, but has worked under a confidentiality agreement. He has done only work charging an hourly rate. He has not encountered any ethical issues. Although, he would be persuasive to recommend the company to change their mind if he were in such a situation. But, if a company would not do so, he would probably stop working with them.

A participant asked to explain differences between full-time or on-the side consulting. Dr. Davis said if consulting was your full-time livelihood, there is more pressure. If it was your full-time livelihood, you might accept jobs just because you need the money. But the general principles are basically the same.

A participant asked how do you make your first initial contacts. Dr. Davis suggested attending meetings, workshops, etc., meet people and network. He has been contacted as long as a year after initially meeting with people. In the areas where you want to do consulting, find ways to get yourself exposed to people who might need you. Something that might help, would be attending meetings of the local ASA chapter. Here you can meet with other statisticians and let them know the things you can do; these individuals can pass your name along.

A participant asked how do you screen calls, how do you determine who you work with? Dr. Davis responded that sometimes it's clear they need something you can't do and you need to refer them to someone else. But retain the contact by telling them maybe

you can help them in the future. Another participant noted that he had a set of screening questions to determine whether he could do the work.

A participant had a question about conflict of interests with private consulting while working fulltime for another company. Dr. Davis noted that this is an important issue. One should know or find out if you are permitted to do private consulting. The practice of private consulting may be limited outside of the academic environment. If you are employed by a company in a particular area, it may be difficult to consult with another company in the same area.

A participant asked about how do you charge when traveling? Dr. Davis indicated that he had an hourly rate and a day rate. He used the day rate when traveling. Different people handle this in different ways.

It was asked how do you determine an hourly rate? Dr. Davis said you might find some consultants who will tell you. This may be difficult. In retrospect, he never charged enough. As a rough guideline, \$350/hr is an expensive statistical consultant, and \$75/hr is a pretty cheap one. Monica Clark (ASA representative) noted that there may be some salary surveys on the ASA website. Another participant suggested looking at some GSA (US General Services Administration) schedules that the government uses (that take into account your seniority, experience, and the field you are in) where you can see what the government is willing to pay as a starting point. Dr. Davis concurred that in the past he had done some work for the government and was paid at a fairly low rate.

The conference call concluded and Dr. Davis asked everyone to provide feedback to the Statistical Consulting Section on the usefulness of the call.