

Mission Impossible: The Trials of SAS Support in a Health Care Research Group

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Abstract

The goal of this paper is to share typical problems, challenges and solutions involved in SAS* support in an academic setting. Our department conducts clinical research studies in a teaching hospital, affiliated with Case Western Reserve University. These grant-funded studies are designed by principal investigators who are physician-scientists; they are implemented by the Research Director who oversees the survey research group, the data management group, and the data collection team. As data manager, I oversee at least 7 - 10 studies at any given time.

I used SAS for clinical research in the device industry for 8 years, and have spent 8 years in academia; thus I have insights from both sectors. When I made the transition from industry to academic research, I had to "throw the book away" on data handling practices I believed were immutable, and develop new approaches to ensure appropriate data rigor. I will share what it takes to make it work in this kind of environment successfully: the demands; what it takes to make it work; why I enjoy doing technical support and data management in this setting.

Introduction

At my first SUGI conference, I struck up a conversation with an Information Services support person who was complaining about supporting his users, who were engineers. I listened, and said that most of my users were physicians. He suddenly felt better about his work.

I worked in health care research in a diagnostic device company for eight years before I moved to Cleveland and took a similar position in an upwardly mobile academic research group. If someone had told me six months earlier that I would be working at a hospital, and managing a computer operation for academic research, I would have choked. Four years later, I laughed at the thought that they were actually paying me to do this. The similarities and differences in both kinds of sectors fascinated me, and I have not seen much information about this

topic beyond the usual books about juggling and stress management.

University Hospitals of Cleveland is a 947 bed tertiary care hospital, which is also the primary teaching hospital affiliated with Case Western Reserve University. I am the Data Manager for the Division of General Internal Medicine and Health Care Research, which consists of 13 clinical faculty and 10 physician-scientists who conduct outcomes research in health care. The mission of health care research is to improve the quality and outcomes of medical care, publishing the results in good journals. All research activities support this mission. Data management supports the research.

As Data Manager, I oversee the data collection and information operation for all clinical studies in our group: the randomization process; data entry; data acquisition; data monitoring; assembly of analytic data files for other people to use for analysis; data analysis. All data are collected and managed using SAS software on the hospital's IBM mainframe (OS/MVS); we are also beginning to develop more data management tools on the PC.

The Challenges

SAS support for clinical research in academia is different from supporting clinical trials in the private sector. I worked in industry for 8 years, and have been doing technical support and data management for clinical research here at UH for the past 8 years. When I was first hired, the new research group included a new faculty person, a research assistant, and me. Seven years later, the group has expanded into a health care research organization, consisting of 25 faculty members, (10 of whom are physician-scientists), and a survey research group. The survey research group is headed by a Research Director (also a faculty member), and includes a support staff of 8 full-time and 4 part-time employees. Originally, I was the only data support person; currently, I am part of the survey research group, and have four people who report to me.

In order to provide technical support, one must first develop an understanding of the culture of the organization, the department, and the needs of

users. What kind of a group is Information Services? What are the channels and barriers to information support? What software products are you working with? What is the independence level of the users? What is the balance between standards and independence? If you are lucky, there are already established channels and even policies for facilitating communication and support. In my case, there are no channels and no inclination to have them -- so I just do my best.

I encountered three major challenges working with a research group in a large teaching hospital. The first was the general hospital culture; the second was the behavior of the physician-scientists; the third was the nature of working with soft money (grant-funded projects). I did not have to concern myself directly with Departmental politics.

I realized that there were some things I could change gradually, and some things that would not change. The only thing I could control was my response to the situation I was in, and take ownership of whatever actions I implemented as solutions to any challenges. People needed to make mistakes in order to learn from them. There were only two constants: I could count on myself; I could expect the unexpected.

The Hospital Culture

The hospital culture presented serious challenges because of the lack of user-friendly computer support. Information Services supports hospital based operations, such as financial, laboratory, and patient-based data, which are generally housed as DB/2 tables. SAS is installed on the mainframe for research use; the software is maintained, but not otherwise supported. It is mainly used by two research groups and marketing support. The remaining users who access data use only QMF, an access tool for these DB/2 tables. I attempted to set up an informal users' network for collaborating in areas of mutual concern, however, the other groups were not interested. It was very clear that I was on my own. Over time, I have developed some ties with Information Services, and have developed some "street smarts" to troubleshoot problems. I have also made myself available as a resource for '5 minute consults'; this has worked in our favor.

Health care is in a huge turmoil, which has seriously affected hospitals and the delivery of patient care. In teaching hospitals, such as University Hospitals

of Cleveland, there are effects in terms of maintaining clinical studies in a moving target environment. We must do more with fewer people and less grant money. With the changes in the marketplace and the challenges of managed care, better business planning and accountability are beginning to appear. As a hospital employee, and not just a data manager who cares only about what is happening in our department, I feel a strong obligation to help influence and improve information support. There is tremendous room for improvement and it will have to happen!

Physician-Scientists

Currently, my major role is to provide information support and data management for the collection phase of any survey-based study. This function is very straightforward. I also facilitate data analysis for papers, posters, and presentations. The hospital-based research is headed by a Principal Investigator, who is usually a physician-scientist. Working with physician-scientists presents some interesting challenges: most are phobic about learning to use computers; they often work hard at the expense of working smart; they resist planning ahead; they live to work. To this day, there is strong resistance to setting global goals, expectations, and sticking to targeted deadlines. It can be frustrating to see the wheel reinvented when transportation elsewhere is electronic. There are a few principal investigators who are exceptions, and they are exceptional to work with!

Grant Money and the Research Environment

Research is funded entirely from government and foundation grants. Managing with these limited resources and grant money is a continual challenge. My own salary support is derived from multiple grants; my percent data support commitment to any group of grants always seems to exceed 150%; at any given time, I will be working on 7-10 projects.

What took whole departments to implement in industry is managed by individuals in our setting. For example, data collection forms were managed by a documentation control department. It took me about five years just to implement better data collection forms and some form of document control. The department administrator and I had to use brute force to get a tracking log system into our first major clinical study. Smaller companies probably face similar challenges.

What It Takes to Make It Work

The most important time to demand what you need to be successful is BEFORE you accept this kind of position. Since the research group was in the start-up stage, I was unaware of the nuances of working in academia when I was interviewing; however, I knew what I needed to be successful. I insisted upon professional development time, and empowerment to set up what I felt I needed to manage clinical study data. When I first began working and saw an endless obstacle course, I resolved that just coping would not be an acceptable option. I wanted to see the work evolve and continuously improve as far as I could take it.

Here are some of the major tools I have used successfully to rise above the challenges. Your working style and choices must mesh with the corporate culture and your users. You must understand and invest in the goals of your users and the products of your department and organization.

Empowerment, Attitude, Authority

Being treated as a colleague has helped immensely! It is the first thing I insist on, for it means commanding the respect of others. People, especially physicians, do not think through the long-term data control and access issues. Being taken seriously means getting things done right the first time and having the clout to make sure it happens. If you are a wimp, you will not survive in this environment. It is hard to implement and maintain good data handling principles, and even harder to enforce them.

An Understanding of How People Work

First, I needed to understand the research goals. Principal investigators may be "hands-on" in both the execution of a study and in data analysis, or they may delegate the entire project and be unavailable on a daily basis.

Each study and each principal investigator is unique; I have to respond to the needs of each individual with an appropriate type of data support. I also make sure that communication is clear above and below. Written communication is essential to staying in control. As a support person, I prepare a yearly mission statement to keep the work we do in perspective. It also serves as a vehicle for the discussion of issues and changes.

There is also a need to support the survey research group with information. Our research assistants complete face-to-face survey interviews in the hospital and do follow-up interviews by phone. They complete their data collection forms and rarely see the information afterwards. It is important to understand what the research assistants need to make their work more efficient and less hectic. We have developed better access to patient information by computer and many helpful reports. I also review the data being collected and share information with the research assistants whenever possible. Feedback is important so that people continue to be invested in the research process and the products.

An Understanding of the Nature of the Work

I mentioned earlier that understanding of and investment in the work being done are important. In doing outcomes research and quality of care, our "product line" consists of the dissemination of research findings in journal articles and presentations -- preferably in the prestigious journals and at high profile meetings.

I review a newly-funded grant proposal in advance, and determine what the kinds of data will be gathered, tracked, and managed. A research proposal serves as a clinical protocol, but never functions as an explicit guide for the actual implementation of a study. This is one of the major differences between a clinical study done in academia and one in a private setting. Once I work out the administrative issues of data collection, I need to understand the analytic goals of the investigator. I need to take these into account in order to work out the best way to deliver information for analysis. Therefore, I need to work both forwards and backwards to develop the best kind of data base for the clinical study.

Work Ethic

A strong work ethic has made a real difference. First, I am not a procrastinator. I respond rapidly to problems and keep people informed about the long-term projects I can't get to. Being proactive in a reactive environment is formidable. In the absence of global goal setting, I have defined my own goals and set objectives and review them regularly. I get to work very early, so I can get the "leave-me-alone" tasks out of the way. I can then be available for people during business hours. I

also have a computer connection at home; this enables me to manage a computer-related crisis from home, and telecommute when I need to be left alone to do any deadline-dependent programming. I am a big believer in Continuous Quality Improvement techniques and use them to manage the processes of data control, programming, administration, and delivery of information to any of my users.

Ethical behavior can not be overstated. It is important to know what your principles are and stick to them -- no matter what. In a previous job, I learned that I would not hesitate to resign my position on the basis of personal principles; it was a personal milestone in my career. By taking preventive measures in data management, such as no-nonsense data handling and honest reporting of problems, I have successfully avoided potential problem areas. I also work closely with our Department Administrator regarding interpersonal issues in our operation.

It also helps when ethics is one of the research areas. We have people in high positions in the hospital who are invested in ethical issues and are always available in the event something needs to be addressed.

A Sense of Humor

Stress is a daily fact of life. The major key to my success is having a sense of humor. It helps to minimize stress and keep things in perspective. I can't be driven crazy when I already am. Professional humor is a constructive way of relieving stress, getting an important point across, and helping me keep my perspective. One of my favorite uses of humor is in the comments section in my SAS code documentation. It forces people to read my programming documentation and prevents boredom. Adding interesting comments in strategic areas of my SAS code provides a tool for flagging problems.

Tactics

The most important advice is to be professional and strive for excellence, no matter what the circumstances. Although it sounds trite, this often gets lost in the daily details of work, politics, and interpersonal behavior. It is important to be creative and choose tactics that are appropriate, keeping "win-win" goals. Have fun with some ideas; there are many resources available in

workshops and books. In my current position, I have used various approaches in my working relationships with principal investigators and support staff. The success of using any of these approaches really depends upon using the correct approach at the appropriate time. A "can-do" attitude goes a long way.

Sell Yourself and What You Need to Do

For better or worse, salesmanship is important when you are dealing with people who don't and won't understand the technical nuances of your work. When a new clinical trial is being implemented, I have to convince people to invest in particular data management strategies that they don't want to hear about but that will affect their work. Humor really helps here -- e.g. my "To SAS users and Abusers" and "It's Geek to Me" memos. You have to continually communicate the value of technical knowledge and daily details. This is useful leverage in getting people to work with you.

Never complain about a problem without measuring it first. Always have at least one proposed solution. Be a listener. Learn negotiation skills and use them.

Identify External Resources.

Adopt a statistician. Network within your company. Utilize your professional affiliations and know a few programmers. Be proactive in making and maintaining these contacts. If you are unable to solve a particular problem, you need to be in a position to make referrals.

Empowerment or "Who's Interfering, I'm Taking Over"

You need to learn how to let go when there are problems that are beyond your control. People need to learn from their mistakes. Deciding to let go of a problem can be a very difficult judgment call. On the other hand, you may be better off just taking over a project that you know you could inherit anyway -- especially if you are going to take the blame for problems you never created. This may give you a chance to control the problems -- or, even better -- prevent them from happening in the first place.

For example, I took over and developed data control systems for the chart review sections of our clinical studies. It was far less work for me to oversee the correct requisitioning of charts and develop PC

tracking systems than to clean up the data messes we inherited from some of our less organized principal investigators.

Your Staff

If you have a staff, take good care of them. Make sure they are appreciated. Take them to lunch and do what you can to ensure that they enjoy their work. Push for their professional development. Go out of your way to help when you can.

Use Continuous Quality Improvement Techniques

Continuous Quality Improvement (CQI) will never happen in our group. However, CQI can be used as a personal management tool. It allows me to identify and target problems, and to improve my own personal work. I use it as a technique to develop my programming skills. I even use it to manage my personal life!

Look the Part.

Many people dress very casually in the academic sector. My husband, who is a physics professor, wears cutoff shorts during the summer. While there is no "dress code" in our department, I strongly felt I had to dress in the part in order to be taken seriously. I wear business attire at all times.

Finally, here are ten of my favorite reasons for working in academia...

10. It beats not doing this!

The Cleveland area has limited opportunities for doing clinical trial data management. I often view the daily challenges as job security.

9. Rising to the challenge.

I enjoy finding creative solutions to problems. I like seeing the progress we have made in my eight years with the group.

8. I do not have to hassle with politics.

My previous job in industry included political power struggles -- which I never liked and don't miss.

7. The Academic / Nonprofit Culture.

There are times when I miss the private sector. Overall, however, I have enjoyed working in academia far more than in industry. I find it refreshing to worry only about developing my area and doing my job rather than dealing with politics.

6. The good intentions of the physician researchers.

These are great people who are seriously invested in doing cutting edge research to improve the quality of care and patient outcomes.

5. Independence

I call the shots in data management.

4. Flexibility

I've learned to be a juggler. The academic life allows me to maintain a professional career and balance my family life.

3. The research is interesting and is making a difference in patient care.

Given the nature of medical care, we will be where the action is. It really hit home with me one evening at a social gathering when I met a resident who knows the physicians in our group. She told me about the difference it was making in patient care, specifically in the area of anticoagulation therapy.

2. Feeling needed and appreciated

I am the buffer zone between analytic data integrity and total chaos. I have prevented many disasters and people know it.

1. The survey research group

A sociologist was hired 2-1/2 years ago to be our Research Director. He has been instrumental in pushing for organizational support for the various research projects. It has been refreshing to have others facing challenges with me. Overall, the support staff are great to work with, and I prefer being a team player.

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