PharmaSUG 2013 - Paper IB07

Clinical Trials: If You Can Explain Them to Second Graders, You Can Explain Them to Anyone!

Lara E.H. Guttadauro, inVentiv Health Clinical, Newport, KY

ABSTRACT

We work in a technical field and face complicated challenges daily. Discussing these issues with like-minded colleagues can be difficult at times. Another layer of complexity is added when you need to explain an issue to professionals outside your department. Yet another layer is added when you try explaining your career to friends and family. Now imagine explaining clinical trials to second graders! This is the challenge I faced when asked to participate in career day at my daughter's school. In this paper, I share my career day experience with hopes that you can benefit the next time you have a challenging issue to explain to a diverse audience.

INTRODUCTION

My daughter asked if I would participate in career day at her school. All she knew about my job was that I worked at home and spent a lot of time on the computer. I knew I had some work ahead of me in being able to explain clinical trials and SAS programming to second graders.

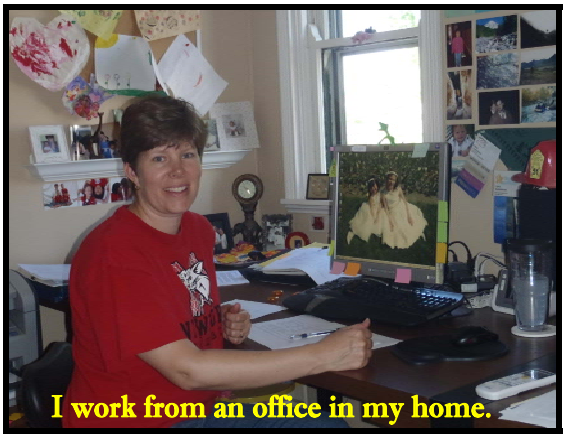
Explaining clinical trials to second graders is an extreme example of meeting your audience at their level. But it's also a wonderful example of keeping your audience in mind when discussing or explaining a challenge that you face. The conversation I can have with a fellow SAS programmer is different than the one I can have with a project manager. Both of these conversations are very different than those I have with my mom or neighbor when discussing my profession. Knowing the background, experience, ability and interest of your audience are all critical when choosing your approach.

Throughout this paper, I use my experience presenting at career day as an extreme example of communicating with your target audience.

WHO AM I? WHAT DO I DO?

I answer these questions very differently depending on who's asking. To my SAS colleagues, I am a senior statistical programmer with 15 years of pharmaceutical industry experience and a passion for validation. To my project manager, I'm the lead programmer who needs to explain why a data issue is causing delays to the timelines and blowing the budget. To my daughter's friends and classmates, I am a mom who happens to works on computers every day.

For the career day presentation, I included a photograph of myself at my desk. My daughter's school is an urban one where most students come from disadvantaged homes. The concept of getting paid to work on a computer in your home is foreign to most of the students. Including a photo of my workspace was a great introduction for my presentation.



Slide 1. A photograph of me at my desk.

WHO DO I WORK WITH?

For many of us, being part of a global project team is a familiar experience. For many non-industry people, this kind of interaction with people from different geographical locations and cultural backgrounds is a rare occurrence which can be both fascinating and intimidating.

For the career day presentation, I introduced the team that I worked with on a particular project through their photographs and a world map. Neha and Samuel are also SAS programmers, Adam is a data manager, Lisa is a statistician and Marianne is a project manager. I asked the students to think about how far away China, India and the UK are and to think about some of the challenges and advantages about working with people from different parts of the world. The global aspect of my position was really interesting to the students.

Slide 2. Photographs of the people on my project team.

SIMPLIFY! SIMPLIFY! SIMPLIFY!

One of the most important lessons I have learned throughout my career is it to keep explanations as simple as possible. This usually translates into providing the least amount of information or explanation needed in order to make your point. An investigator doesn't care which SAS procedure you used to create an output! Your dad probably has no idea what SAS is!

When my mom asks what's on my plate at work, my response might be "I'm working on a challenging vaccine study". She would be immediately lost if I tried to explain a particularly challenging analysis. However if another SAS programmer asked the same question, my response would be much more specific and detailed about the particular challenges I was facing. Keeping your response as simple as possible helps to prevent that glazed-over look most people get when we start talking SAS programming details.

CREATE HYPOTHETICAL EXAMPLES TO EXPLAIN YOUR POINT

I have worked on many types of trials over the years, but explaining any of them to second graders would be a bigger task than I felt comfortable tackling. I chose to create an example that would be something they could all relate to - 'fever sickness' and its treatments. I created a hypothetical, very simplified trial that they could all relate to as my example. This turned out to be a great approach for the students. It also turned out to be a wonderful example for my non-technical family and friends who never fully grasped what it is I do for a living.

While I don't typically create hypothetical trials when discussing challenges with project team members, I often need to think through hypothetical scenarios within existing trials while programming. There are times when I need to communicate these scenarios to others on my team – trying to figure out how processes they have in place would respond to potential situations. These hypothetical scenarios are usually related to raw data and how it will be handled. One memorable example is from an animal health study involving cats – one cat ate the other's study medication – a scenario not often encountered in human trials. This situation led to many other "what if" scenarios that needed to be considered by the study team.

A SIMPLE 'FEVER SICKNESS' HYPOTHETICAL TRIAL

The following hypothetical fever trial is the example I presented to the second graders for my career day presentation.

TRIAL DESCRIPTION

I explained that somebody had made a new medicine to treat fever and they were trying to figure out if it was better than the old medicine which most families were already using to treat fevers. I used our family as an example explaining that my daughter Kierra would receive the old medicine and her sister Lianne would get the new medicine. I asked the students how we would know if the medicine was working and let them come up with the idea of taking temperatures before and after the medicine was given to determine if the medicines were working. I continued by explaining that the person who made the new medicine would need to try it out on more than one family to make sure it was really working. This is data collection!

COLLECT THE DATA

Our Family	Another Family
Kierra: 101.6	Brother: 100.9
- 100.1	- 99.7
1.5	1.2
Lianne: 102.8	Sister: 103.1
- 99.3	- 100.0
3.5	3.1

Slide 3. Data collection for a hypothetical fever trial.

DATA MANAGEMENT

At this point, I explained that the data manager was in charge of turning the data that was collected into a dataset that other people could use. I also described patient privacy here and pointed out that Kierra and Lianne were turned into patients A-1 and A-2 since it was not important for the people like me working with numbers to know the names of the people who had received the new and old medicines.

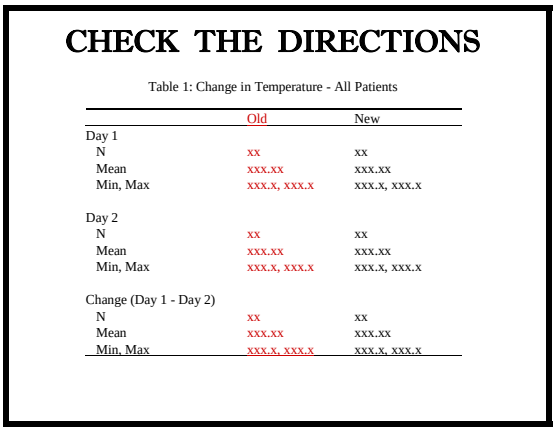
REARRANGE THE DATA

Patient	Medicine	Day	Temp	Change
A-1	Old	1	101.6	
		2	100.1	1.5
A-2	New	1	102.8	
		2	99.3	3.5
B-1	Old	1	100.9	
		2	99.7	1.2
B-2	New	1	103.1	
		2	100.0	3.1

Slide 4. Data management rearranges the data collected.

STATISTICAL MOCK UPS

Next, I explained that the statistician and project manager are in charge of working with the person who had made the new medicine to see what they needed to check if the medicine was working well. I went on to explain that the statistician would create an example of what should be done with the data we collected when the kids were sick. I continued by explaining that these examples are the directions that the programmers need to follow in order to create the needed outputs.



CHECK THE DIRECTIONS

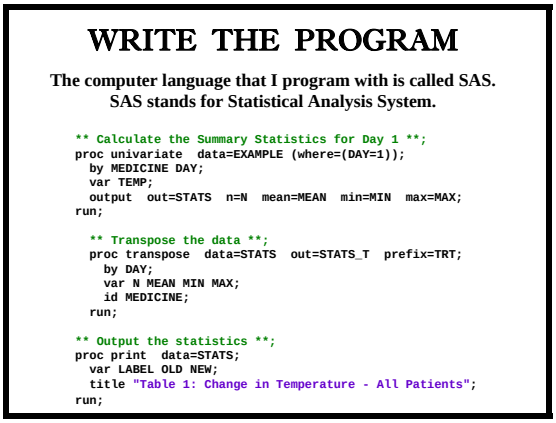
Table 1: Change in Temperature - All Patients

	Old	New
Day 1		
N	xx	xx
Mean	xxx.xx	xxx.xx
Min, Max	xxx.x, xxx.x	xxx.x, xxx.x
Day 2		
N	xx	xx
Mean	xxx.xx	xxx.xx
Min, Max	xxx.x, xxx.x	xxx.x, xxx.x
Change (Day 1 - Day 2)		
N	xx	xx
Mean	xxx.xx	xxx.xx
Min, Max	xxx.x, xxx.x	xxx.x, xxx.x

Slide 5. Statistician's example of what is needed.

SAS PROGRAMMING

Finally, we had gotten to the part of the clinical trial where I do my work! I did not go into any specifics of the logic needed for SAS programming, but I did show a piece of code that could be used to get the data into the format needed for the table output. I explained that by writing the code, I was able to get the computer to do the math and create the output for me. For kids who are just mastering 2 digit addition and subtraction, anything more detailed than this would have sailed right over their heads! I also explained that the other programmers and myself needed to work together to create the needed outputs and then check each other's work through validation.



WRITE THE PROGRAM

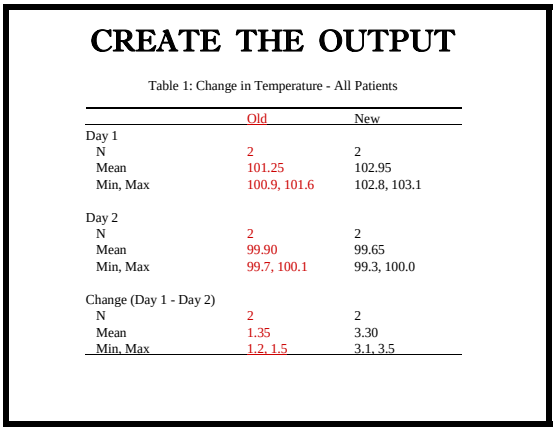
The computer language that I program with is called SAS.
SAS stands for Statistical Analysis System.

```
** Calculate the Summary Statistics for Day 1 **;
proc univariate  data=EXAMPLE (where=(DAY=1));
  by MEDICINE DAY;
  var TEMP;
  output  out=STATS  n=N  mean=MEAN  min=MIN  max=MAX;
run;

  ** Transpose the data **;
  proc transpose  data=STATS  out=STATS_T  prefix=TRT;
    by DAY;
    var N MEAN MIN MAX;
    id MEDICINE;
  run;

** Output the statistics **;
proc print  data=STATS;
  var LABEL OLD NEW;
  title "Table 1: Change in Temperature - All Patients";
run;
```

Slide 6. A SAS program.



CREATE THE OUTPUT

Table 1: Change in Temperature - All Patients

	Old	New
Day 1		
N	2	2
Mean	101.25	102.95
Min, Max	100.9, 101.6	102.8, 103.1
Day 2		
N	2	2
Mean	99.90	99.65
Min, Max	99.7, 100.1	99.3, 100.0
Change (Day 1 - Day 2)		
N	2	2
Mean	1.35	3.30
Min, Max	1.2, 1.5	3.1, 3.5

Slide 7. The output created.

ADDITIONAL CAREER DAY MATERIAL

Once I had explained the clinical trial process, I ended my career day presentation by talking about what makes my job fun, what I studied in school and taking questions.

My job is fun because SAS programming is puzzle solving – you are given an example and some data, then you have to figure out how to get the data to look like what's in the example. I enjoy that challenge! I also enjoy working with so many different people from all over the world. I like how people who are good at different things can work together like the pieces of a puzzle fitting together to create the final output.

The question "what did I study in school" was easy to answer. Math, math, math! I asked the students if they liked math. Then I shared that I LOVE math! That it was always my favorite subject in school and that it was pretty easy for me. I also shared that spelling and social studies were not my favorite subjects, but that it's ok for different people to like different things since there are lots of different jobs and they are all important.

I ended my presentation with questions from the students. Most had nothing to do with programming. Several were about the logistics of working with people around the world and about working from my home. I have found this to be true with adults as well. Most people do not have relationships with people different from themselves and are curious to learn about other people and cultures.

CONCLUSION

I had a fun time participating in career day at my daughter's school. I enjoyed the challenge of simplifying the clinical trial process so that it could be understood by second graders. An audience of second graders is an extreme example, but it's a great reminder that keeping your audience's background, experience, ability and interest in mind is critical in clinical trials communications.

ACKNOWLEDGMENTS

Thank you to my inVentiv Health Clinical colleagues Lisa, Marianne, Adam, Neha and Samuel for providing me with photographs of themselves. Additional thanks to Colleen and Nancy for their support and review of this paper.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Name: Lara Guttadauro
Enterprise: inVentiv Health Clinical
Address: 529 East Fourth Street
City, State ZIP: Newport, KY 41071
Work Phone: 859-291-8228
E-mail: lara.guttadauro@inventivhealth.com