Development of a Clinical SAS University Training Program in Eastern Europe

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ABSTRACT

Many specialized positions require training above and beyond standard University degree programs for even entry-level work. We are starting to see various industries turning to Universities for specialized training to develop their workforce.

To build on the success of our programming team in Eastern Europe and establish a pool of resources for the future, we have developed and implemented a Clinical SAS training program at a University local to our offshore office.

The program enrolled students in the Mathematics graduate program. Curriculum was developed to include SAS, Statistics, Clinical Development, English, and Clinical SAS programming - culminating in SAS certification, Internship opportunities, and client placement. A varied approach was utilized for instruction including traditional text and classroom instruction but also overseas interactive web-ex presentations, optional Hot Topic sessions, social media groups, and senior team members as mentors.

This presentation will take the audience through the process and sometimes creative solutions we took to make this program a reality - from the collaboration with the University and recruitment/selection of students, to the outcome for the inaugural class. We believe this type of training program could be successfully utilized anywhere but that strong partners and collaboration are critical.

This topic is thought to be of interest to those in management as well as programming and Biostatistics with no particular level of skill or background required.

INTRODUCTION

The Programming and Analysis divisions of Pharmaceutical, Biotechnology, and Clinical Research entities are increasingly seeking cost-effective solutions to their growing need for high quality Clinical SAS programmers. US-based resources are becoming scarce and given the prevalence of cross-functional, global teams in the industry, the opportunity for highly skilled programmers in lower-cost regions around the world is great – offering both time zone and cost advantages. Eastern Europe is a prime location. The GMT/UTC + 2 time zone allows for 6-hr and 4-hr work day overlap with most of Europe and North America, respectively. The area also has a rich history of mathematic, science, and technology excellence with a high concentration of universities. Clinical SAS programming however, is a relatively new area of focus and the pool of experienced resources is limited.

We have had a team of highly skilled clinical resources in place in Eastern Europe for over two years. In order to grow a pool of known, well-trained resources, we developed a University training program and subsequent Internship providing Clinical SAS training and the opportunity for Internship and a career in the Pharmaceutical Industry. A multi-year commitment was key for credibility in order to attract and retain motivated students. The first graduating class has been successfully placed and are contributing to their project teams. Our second class of students will be graduating in June of 2015.

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CURRICULUM DEVELOPMENT

In order to achieve the goal of the program – graduates capable of joining a clinical project team and contributing immediately at a junior level – proper training and education was critical. The first semester was spent creating a solid foundation to prepare students for the hands-on work that would come in the second semester. A list of the courses and their descriptions are provided below.

First Semester

Base SAS = (3 lectures + 2 labs) × 15 weeks = 45 lectures + 30 labs
English for Pharma Industry = 2 lectures × 15 weeks = 30 lectures
Introduction to Databases = 10 lectures
Advanced Statistics = 20 lectures
Introduction to Clinical trials = 10 lectures

Second Semester

Clinical SAS Programming = 5 classes per week × 15 weeks = 75 classes
Clinical Data Interpretation = 10 lectures
English for Pharma Industry = (2 lectures + 1 speaking club)× 15 weeks = 45 classes
Base SAS Certification Preparation = 10 lectures
Advanced Statistics = 10 lectures

- Base SAS

    The students coming into the program had varying degrees of exposure to SAS. We had 2 professors that worked together to teach the SAS curriculum. The goal of the Base SAS course was to prepare students for the hands-on programming in the second semester and to prepare them for the SAS Certification exam at the end of the school year. An SAS Academic Partnership was established and the University officially became part of the SAS Institute Global Academic Program. This was a two-semester course.

- English for Pharma Industry

    Our programmers work in a model where they are integrated into their study teams participating in teleconference and WebEx meetings as well as communicating through email and messaging. Therefore, each of them must be very comfortable communicating in English. As a part of this class, students also started to become familiar with common terminology used within clinical development and the Pharmaceutical industry. This was a two-semester course.

- Advanced Statistics

    The Statistics course was taught by a professor from the University with input from our team leader to focus the content on statistical topics encountered in clinical development and clinical SAS programming. This was a two-semester course. A sample of the objectives of the course is listed below.

    o Understand the appropriateness of different methods of data collection, particularly ways of

    o Interpret differences in data distributions via visual displays

    o Calculate and interpret confidence intervals for population means and proportions

    o Interpret and explain a p-value

    o Perform a two-sample t-test and interpret the results; calculate a 95% confidence interval for the difference in population means

    o Understand and interpret results from Analysis of Variance (ANOVA)

    o Understand and interpret relative risks and odds ratios when comparing two populations

    o Understand why survival (timed to event) data requires its own type of analysis techniques

    o Construct a Kaplan-Meier estimate of the survival function that describes the "survival experience" of a cohort of subjects

- Base SAS Certification Preparation

    This course (second semester only) was designed to prepare students for taking the Base SAS Programming for SAS 9 examination. The course provided the students information about SAS certification and the advantages of obtaining certification. The course also covered the typical challenges students would encounter during the exam, an overview of the technical aspects, and practical experience of mock tests.

- Introduction to Clinical Trials

This was a very popular course with the students and was offered during the first semester only. The professor for this course was on staff in the Internal Medicine Department of the University and had 10 years of experience in Clinical Research trial management. The objectives of this course were for the students to:

- o Know the basic concepts of clinical research design and analysis
- o Understand the process of new drug development
- o Be familiar with terminology used by clinical research professionals
- o Understand stages of new drug approval process
- o Be able to analyze medical protocols, guidelines and other documents
- o Know how to interpret clinical research data

- Introduction to Databases

  This course (first semester only) provides the foundations of database systems, focusing on basics such as relational algebra and data modeling, schema normalization, query optimization, and transactions. The algebraic query language that forms the formal foundations of SQL as well as SQL advanced features were also covered.

- English Speaking Club/Hot Topics

  These were both optional offerings, provided once per week on alternating weeks through both semesters. There was a native English speaker from the University who attended English Speaking Club and offered the students more time to practice their English skills in a casual environment with no agenda other than stretching their English skills. The Hot Topics were presentations by senior members from our local team, our US-based team, or from the client and covered topics that relevant to the industry in general or programming specifically.

- Computer Lab

  The computer lab was open and available to students during each semester. Students could use this time to work on and get assistance with classroom and programming assignments. Instructors and Mentors were available in the room.

- Clinical SAS Programming

  During the second semester, the students were broken into teams to work on a mock project. They were given a real-world anonymized clinical project and tools (documentation, specifications, output, and tracking logs) for hands-on project team simulation. Each team was assigned a mentor to provide oversight and guidance. The mentors were senior programmers from our local team who volunteered to commit their time to be available to the students both during their class time and to answer questions via a closed Facebook group. The general structure of the course was organized so that the students went through the process of clinical programming once, then repeated it a couple of times so that they have 3 times to learn each step. These 'cycles' included different data domains (eg. Demographics and AE's vs. efficacy and labs), and resulted in different reporting events (e.g. Patient Profiles vs. CSR). Each cycle was approximately 4 weeks, which left 3 weeks for the teams to finalize their programs, prepare for unblinding, run and check their final deliverable, and present their results.

- Clinical Data Interpretation

  The is a second-semester only course that was added based on feedback from our inaugural graduating class to teach students how to interpret clinical data and the outputs generated during the Clinical SAS Programming module. It is designed to help students who have no background in life sciences prepare for data interpretation assessments in clinical practice. The course explores a number of key topics in medicine and each topic is set around an image or investigation, such as vital signs, an X-ray, CT scan, or laboratory results and interpretation of the data generated.

- • Team-building Events

  There was one team-building fun activity per semester (high-ropes course and scavenger hunt) that engaged the students outside of the classroom and allowed them to build relationships with each other and our current local team.

All classes were held onsite at the University and planned around the regular university curriculum schedules. To ensure success on the program and that learning opportunities are maximized, students had to dedicate at least 15-18 hours a week to participate in the program.

STUDENT RECRUITMENT AND RETENTION

The initial meeting on campus to recruit prospective students was in early June prior to the Fall 2013 program launch. Flyers, emails to Mathematics Graduate students, and social media announcements preceded this initial meeting to generate interest. Just under 100 students were present and 10 immediately signed-up. Two more information/recruiting sessions were held resulting in a total of 38 Graduate student applications. The selection process was rigorous. Of the 38 applicants, 26 were approved by the University and all 26 took the entrance examinations comprising Statistics, Databases/Programming, and English.

Twenty-four students were chosen for interviews based on their GPA, University records, and entrance examination results. These are highly motivated students as the Clinical SAS courses are in addition to their major curriculum (Applied Mathematics, Statistics, or Information Science). The face to face interviews were conducted with our local team leader, HR Manager, and a representative from the University Admissions. Areas of assessment were:

- • Students' records (GPA, attendance history)
- • Interest in biostatistics
- • Desire to learn something new
- • Availability to study evenings
- • Body language and behavioral assessment
- • Communication skills

The top reasons given by the students for applying were: a strong desire to apply learned math skills; humanity (saving people's lives); and jobs in internationally recognized companies. Eighteen students were accepted into the program, 16 completed both semesters, and 12 were recommended to take the SAS Certification exam. Of these 12, 8 were selected for Summer Internships.

INTERNSHIPS

Eight students were given internship opportunities and were split into 2 groups. We had client commitment for 4 interns to work "in shadow" with current team members providing mentorship and oversight so that they could learn the client systems and be evaluated for permanent hire. Toward the end of the Internship, several of them were productively contributing to project work and all were eventually added to the client team as permanent hires.

The other 4 interns were paired with US-based senior programmers from various other client projects. In order to prepare them as much as possible for future client work, these 4 interns were given an anonymized project that was converted to CDISC standards for this purpose, and assigned project work (creating and validating CDISC datasets and TLGs from specifications) as they would be had they been assigned to an actual client project. The interns utilized study and tracking documents (Protocol, SAP, Tracking sheet, Issue Log, QC Findings and Resolution documents) to give them further exposure to a study team working environment.

The mentors and interns met as a group and individually 2 times per week (on average). The interns also communicated with mentors through issue logs, Skype, and email. The data and specifications were not completely clean and this gave the interns further "real-world" experience and allowed them to find issues on their own, apply reasoning, and ask questions. At the end of the internship, the interns presented their deliverables, learnings, and feedback for future program improvement. Wonderful relationships were established through this program and we are happy to say the interaction between mentors and interns has continued long after the program has ended. Some of these interns were also hired by the client above and all are currently engaged on client project work.

Current former intern engagement = 100%!

KEY SUCCESS COMPONENTS

There were many variables and effort by multiple people that have been critical to the success of this program. A few of the major ones are highlighted below.

Commitment from our Client

Based on the success of support provided by our established team, our client committed to a minimum number of Interns and subsequent permanent hires. This was critical to secure the investment of time, financing, and resources from both companies that were and are required for an undertaking of this size. They have also provided some web-ex presentations to supplement the classroom curriculum and give the students exposure to the technology and interaction with working professionals in other countries.

Relationship with the University

Without the interaction with the University and their willingness to partner across all aspects of the program, we would not have had the access to students, facilities, or credibility to make this program viable. As a part of its commitment, the University has established an academic partnership with the SAS Institute that provides a unique opportunity for our program to incorporate best-in-class software solutions.

Technical Leadership

This encompasses multiple items. We were able to provide the students with the same training and materials that have proven so successful with our current teams of programmers as well as access to our trainers and technical managers. In addition, the students benefited by interacting regularly with senior team members who served as mentors and established strong relationships. This commitment from current senior team members – both in the US and Europe - to volunteer their time was critical.

The ability to find competent and engaged instructors was also a key component of technical leadership. The instructors were all very flexible regarding input from our team so that the course curriculum was customized to provide the students with the information they needed to be successful Clinical SAS programmers.

Incentives

It is understandable, that given the amount of time, effort, and cost for this program, retention of students was a major point of focus. The hot topics and team building activities were fun and engaging opportunities for the students to get to know each other and our local team. This offered them something different and conveyed the value and commitment we were putting into them.

The cost of the SAS certification exam was covered for those who were recommended by their instructors and mentors. Whether or not they were immediately placed on teams, this was an opportunity for the training and certification to make them more marketable SAS candidates. Internally, the opportunity for internship and placement with global clients offered career potential.

CONCLUSION

The philosophy of our program is to support open communication and collaboration between students and industry leaders, as well as to provide our students with a unique niche-oriented educational opportunity. The curriculum takes advantage of our established Best Practices, hands-on real-world study team simulation, close ties with current team members, and the relationships developed with US-based mentors. All of these components work together with the aim of preparing the graduates to help meet the growing needs of leading CROs and pharmaceutical companies for global statistical programming support.

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