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Outcome of a Clinical SAS University training program in Eastern Europe

How are graduates performing in a real work environment?

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ABSTRACT

We introduced our Clinical SAS University training program at PharmaSUG 2015 - presenting the impetus for the program as well as the structure, development, obstacles, and keys for success. Our first class of graduates now have over a year of work experience, our second class has just gotten started with client work, and our third class of students are over half-way through their school year. The education provided in the program is valuable only if it translates to preparing a work force. Therefore, this presentation will provide updates on how our graduates are performing now that they've been assigned to client teams.

As presented previously, the interns were split into 2 groups – one group shadowing client work and the other group working with US-based mentors. Regardless of where they started, all of the students that were accepted into the internship program are currently engaged in client work. Topics covered in this presentation include: what type/complexity of work graduates are doing, the processes, new programs, tools, and support structure we have implemented to support their success.

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

Last year, at the 2015 PharmaSUG Annual Conference, we presented the Clinical SAS University program we developed in Eastern Europe. We have had a team of highly skilled clinical resources in place in Eastern Europe since 2012. This area is a prime location offering 6-hr and 4-hr work day overlap with most of Europe and North America, respectively. They also have a rich history of mathematics, 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. Therefore, in order to grow that team, the University program was developed to provide a pipeline of resources to support our cost-effective, global solution to our clients' growing need for high quality Clinical SAS programmers.

Our first two classes of graduates and subsequent interns have now been in the work force supporting client teams for a period of time ranging from 4 months to a year and a half. They are performing a wide range of tasks and supporting client teams in both Europe and North America. The University and intern program, as well as the support structure put in place for them has evolved since this program was first presented. Our third class of students will graduate in June 2016.

OVERVIEW OF THE CLINICAL SAS UNIVERSITY AND INTERNSHIP PROGRAMS

The University program comprises 2 semesters of course work. The students are enrolled in Graduate programs within the School of Mathematics and the Clinical SAS program is in addition to their degree courses – so these are highly motivated students. The goal of our program is to produce resources capable of joining a clinical project team and contributing immediately at a junior level. In addition to the courses listed below, guest speakers from the US and Europe provide Web-ex presentations on various industry topics giving the students an opportunity to interact and ask questions. The courses were:

- Base SAS
- Database Essentials
- Introduction to Clinical Trials
- Advanced Statistics,
- English for the Pharmaceutical Industry
- Clinical SAS programming
- SAS Certification preparation

For the Clinical SAS Programming course, the students are divided into “clinical study teams” and a mentor (an experienced current team member) is assigned to each team. The students work to produce output using study documentation, assignment trackers, specifications, and requirements from an anonymized study just as they would if they were on a client team. Students who receive recommendation from their professors and mentors take the SAS Certification exam. The top students are chosen for internships.

Interns were split between those shadowing current Eastern Europe team members and those who were paired with US-based senior programmers from various other client projects. Interns working in shadow were provided mentorship and oversight so they could learn the client systems and be evaluated for permanent hire. Interns paired with US-based mentors were given an anonymized project that was converted to CDISC standards for this purpose, and assigned project work as they would be had they been assigned to an actual client project.

PROGRAM STATUS AND PROGRESSION

The Clinical SAS University program is now in its third year and the program has undergone some changes since its inception based on lessons learned and student feedback.

Thus far, our students have expressed extreme interest in team work assignments which involved mentorship from our senior programmers. Therefore, for this school-year, we split the group into teams starting from the first semester, rather than waiting until the second semester as was done in the initial 2 years of the program. We also decided to introduce remote team work, where mentors were assigned to the teams of students located in another city. This gave us the ability to simulate a real-world work environment in which team members such as study leads, Clinical SAS programmers, project managers, and others are not co-located.

Our main goal with remote mentorship was to give students an opportunity to learn how to organize themselves, how to structure communication within the team and with the mentors, plan with consideration to their individual class schedules, and to evaluate responsibility for team work and the results each team was to produce This also allowed them to improve their time management skills.

Handling remote mentorship could have not been possible without introducing a number of communication tools most of our students never used before. Video-conferencing, project assignment tracking logs, and team communication and collaboration tools all became essential parts of our program enhancements this year.

In addition to the introduction of the team-work approach in the first semester and remote mentorship, we also aligned the assignments from the Statistics, Database, and SAS courses to give our students the opportunity to see how data may migrate from different sources. For instance, some assignments included database manipulation using SQL-queries, followed by statistical exploration using SAS and the result was presented as a number of charts and diagrams in Excel.

As a result of these improvements we have achieved a lower student turnover after the first semester compared with the previous two years. Participation in our program requires up to 20 hours per week in addition to their existing curriculum and this year we had only 1 student out of 15 who dropped-out after the first semester.

PAST STUDENT STATUS

Class of 2014

Six of the first class of interns were hired by the client as soon as their internships were completed. This included all four who were shadowing client work in addition to two who were working with US-based mentors. Of the four shadowing client work, 2 of them were already contributing to project teams during their internships. The remaining 2 interns working with US-based mentors worked on short-term project work for a couple of US-based clients before being hired as long-term, full-time resources.

These junior resources have now been contributing to client teams for roughly 16 months; half of them are supporting North America and half supporting Europe. The tasks they have been assigned routinely include tables, listings, and graph (TLGs) and value-added datasets (VADs) programming and QC from specs - both safety and efficacy. They have also contributed to Interim Analyses, Summary of Clinical Safety (SCS), and Clinical Efficacy (SCE), and data mapping.

This first group has made quite an impression on their client teams. A first assignment for one of them was to QC efficacy datasets which she did successfully. This particular ex-Intern was subsequently recognized as the top contingent resource after just a year of programming experience! The variety of programming tasks they have been

given and the level of complexity is extraordinary given the normal path of a new programmer (ie, straight safety QC) and is serving to advance their value and experience at a rapid rate.

Examples of advanced tasks this group has taken are:

- Single programming contact for a dead-drug study. There was quite a bit of work need to close the project and this class of 2014 graduate was solely responsible for any ad-hocs, changes etc.
- Complex tasks for a survival analysis

Class of 2015

The class of 2014 set the bar pretty high but all of those involved with the University program in both of the first two years remarked that this second class was even sharper than the first. The University program was adjusted after the first year as described above and that likely was a contributing factor to this perception as the students were engaged in hands-on programming work from the beginning rather than just the second semester.

The timing of hiring of this class was a bit more staggered than then first so their "real work" experience ranges from two to six months. Two of four who were shadowing current team members were hired immediately following the internship; the other two were hired two months later. During this two-month hiring gap however, we continued their client system access and allowed them to keep programming and learning in the background. When the client was ready to bring them on, they had gained two more months of experience and there was no ramp-up or training time required.

For the four interns who were working with US-based mentors, their internship was extended an additional two months with some intensive CDISC training as described below. At the end of that extended training, we also obtained client access for them so they could shadow program and learn client systems. All but one intern from this class has been hired.

Since starting project work, the class of 2015 has also caught the attention of their client teams with the level of work they are providing given their lack of experience. For example, one of them caught an incorrect conditional code error in a senior programmer's while working on a similar table. Additional errors caught by this class within 2 months of starting programming work supporting the client include:

- Wrong sign on summary statistic (difference in means)
- Incorrect confidence interval level (should have been 90% CI and not 95% CI)
- Incorrect selection criteria for input data

Identifying this level of errors is remarkable enough but additionally, the class of 2015 graduates acted independently in clearly communicating their findings to the senior first-line programmers who were from another vendor or the FTE of the client.

Addition of North American Programming Support from Eastern Europe

Previously, the entire team was supporting only client work based in Europe where our teams enjoy a 6-hr work day overlap. However, this past July, a subset of the team started supporting West Coast client work where there is a 10-hr time zone gap. The majority of this team is comprised of our graduates from both classes. Any initial trepidation regarding time zones and level of experience on the client-end has been erased given the team's performance, quality, and efficiency. Our graduates are mainly working through their local lead as well as US-based Experis liaisons, but also interacting directly with their client teams. Working globally and across 10 time zones has been great experience for them! Their communication skills, expanded task opportunities, and use of tools such as project logs have served to accelerate their learning curve and capabilities.

DEVELOPMENT PROGRAM AND SUPPORT

There has been quite a bit of effort and structure put in-place to support the students as they work their way through the University program, SAS Certification, internship, and hiring. Those programs and structure are described below.

Vetting process

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

- Interest in biostatistics
- Desire to learn something new
- Availability to study evenings
- Body language and behavioral assessment
- Communication skills

Mentors – remote and local

During the first two years of the University program, the school-year mentors were all local and present in-class during scheduled times for both the first and second semesters. This year, non-local members of our Eastern European team were selected as first-semester mentors. This was done with the intention of giving the students the experience of communicating with remote team members - to mimic global teams in the industry. For the second semester project team simulation, local mentors were again assigned in order to be hands-on to guide and mentor the students. In addition to the mentors, technical managers and senior programmers based in North America contribute to the curriculum, conduct web-ex learning sessions, serve as mentors during the internship, and provide continuous support to the Eastern European team.

Pharma project team simulation

The focus of the second semester is the pharma project team simulation in which students are broken into teams to work on a mock project. They are given a real-world anonymized clinical project and tools (documentation, specifications, output, and tracking logs) for hands-on project team simulation. Each team is assigned a mentor (senior programmers from our local team) to provide oversight and guidance. The students go through each clinical programming 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). Before the conclusion of the semester, the teams finalize their programs, prepare for unblinding, run and check their final deliverable, and present their results.

Technology to support collaboration and communication

In addition to SAS On-Demand that was available to our students as a result of academic partnership that we helped establish between the University and SAS Institute, our student used a number of technologies through almost every step of the program. The remote mentorship and guest speakers' involvement utilized a number of video-conferencing tools, such as Web-Ex and Team Viewer. Project-specific activities, including task distribution and progress reporting were handled by Trello which became an essential tool for offline communication between students and mentors. We also made heavy use of social media groups for idea-sharing and hot topics discussions; the incorporation of social media was highly appreciated by all participants – the students, teachers, and mentors.

e-Learning, guest speakers, and English-speaking club

Focusing on extra-curricular activities helped our program create a positive environment which distinguished our education process from the experience students were having while pursuing their main degree at the University. For that reason, every second week we have guest speakers sharing some industry insights with the students either face to face or via web-conferencing tools. We invite volunteers from our offices in Eastern Europe and the United States as well as from our clients' offices in the United States and Europe, to participate in Hot Topics discussions. Another extra-curricular activity is optional student participation in a number of online courses provided by leading Universities through Coursera and other online resources. Our students have shown an interest in more intensive learning (above and beyond the courses in our program) in regards to additional statistics and clinical trials courses to gain insights that will help them pursue careers in Life Sciences.

Taking into account that English is not the native language for our students and that success in their future careers will also depend on developed English skills, as an extra-curricular activity we have a weekly English Speaking Club. During informal sessions with native English teachers our students have a chance to discuss recent news from the Pharmaceutical industry as well as develop interpersonal communication skills and confidence interacting in English.

EXTENDED INTERN TRAINING

In order to further enhance the marketable skills of our interns, our in-house CDISC expert developed material to provide them with more intensive CDISC knowledge. This training comprised:

- Creation of blankcrf.pdf
- Creating SDTM specifications
- Annotating TLG shells
- Developing ADaM specifications

Issue logs can be critical tools when working and communicating within global teams. Therefore, an issue log was utilized for tracking questions and communication so our interns gained more experience working effectively across time zones.

Creating the SDTM specifications was a large portion of the CDISC exercises. Examples of topics items that were checked during the SDTM work are:

- Ensuring they identified which domains were missing and in one case, what data were missing from an existing domain.
- Ensuring correct variables were included for each domain and that they were the correct type (ie, Char or Num)
- Correctly creating a codelist on the codelist tab if the Controlled Terminology column (CTLIST) is populated
- If the ValueLevelMetadata Flag (VLM) = 'Y' then there should be a record for that DATASET and VARIALBE combination for each unique set of conditional variable and value. For example, if a DATASET / VARIABLE combination had an algorithm that was based on another variable when it was a specific value then a record in the VLM worksheet should exist for that condition. In some cases there could be two or three sets of conditions and so a record must exist for each unique combination of conditions. CONDITIONAL_VARIABLE1, CONDITIONAL_VALUE1, CONDITIONAL_VARIABLE2, etc. combination.CONDITIONAL_VARIABLE1, CONDITIONAL_VALUE1, CONDITIONAL_VARIABLE2, etc. combination.
- DATASETS tab – ensuring all domains were listed and the have the necessary information such as label, data structure, key variables that make the record unique, type of data set, dependency, and source of each domain.
- DATASET and VARIABLE names no longer than 8 characters; DATASET and VARIABLE labels no longer than 40 characters; Variable LENGTH no larger than 200

CONCLUSION

The original philosophy of our program was 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 end goal was to prepare the graduates to help meet the growing needs of leading pharmaceutical companies and for global statistical programming support. The program and the enhancements made over the three years of its existence, along with the support structure for the graduates have resulted in success meeting the goal and exceeding expectations of the contributions the graduates would be able to make to their client teams in such a short period of time.

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