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Managing Programmers across the Great Divide: An Odyssey in managing CRO's, in Big and Small Pharma, Biotech and Pharma and in NJ, CA and Boston

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ABSTRACT

Managing SAS programmers has always been difficult, given the somewhat paradoxical nature of having to possess the technical nature of SAS programming, and at the same time as a Manager having to understand and, most importantly, communicate in assisting and overcoming the difficult technical challenges posed to SAS programmers in the pharmaceutical industry. For example, a recent trend has been to analyze elevated Liver Function Tests [LFTs] administered on the same day, when there can be multiple tests on the same day, etc.. In addition, managers of SAS programmers routinely have to present to a variety of peers and stakeholders within their own companies (not to mention at industry conferences!). Moreover, the recent trend in offshoring has added at least two major new difficulties in effectively managing SAS programmers: (1) having to deal with different time zones (which at times has meant trying to get a team to work all 24 hours of the day), and (2) an even bigger challenge to communicate effectively.

INTRODUCTION

This presentation will present one manager's experience in laying the groundwork for understanding the technical nature of programming. Subsequently, it will detail the travel, challenges and successes over the course of managing SAS programmers in biotech and pharmaceutical, small and large pharma and in New Jersey (home of traditional 'Big Pharma'), San Francisco (home of 'hot biotech start-ups') and now in Boston, home of all of the before mentioned industries. It will also give suggestions and real-life experiences that have led to being able to translate managerial style across these 'different' industries and regions. In sum, the goal of this presentation is to facilitate discussion regarding managing SAS programmers in different work environments and locales.

STEP 1, LAYING THE TECHNICAL GROUNDWORK

As mentioned above, it's imperative that a manager of SAS Programmers not only understand SAS and it's many functions, steps and calls (and learning another language, that of the macro user), but also understanding the nature of programming in the pharmaceutical industry (e.g., knowing the 'standard' safety analysis, knowing which therapeutic area you are working in, getting exposure to multiple therapeutic areas, understanding very complicated primary, secondary and tertiary endpoints, analyzing 'messy' diary data and knowing the intricacies of PK/PK, Lab and Biomarker data, just to name a few). I got this experience first working for a very large epidemiological trial (determining whether women who developed gestational diabetes had longer term side effects for either themselves or their infants) at Northwestern University Medical School in Chicago, IL where I worked for both a single Professor as well as a single Database Designer. My 'Statistical Analysis Plan' was largely determined by what ad-hoc analysis the physician in charge of the study asked to see on a routine basis (I would later come to see these as Data Monitoring Committees in Biotech and Pharma). It was later solidified at Forest Laboratories in New York City (where I moved shortly before 9/11) and later moved to Jersey City. While at Forest I was primarily involved in Phase III clinical trials, and worked on many submissions (since the business plan at that time was to in-license products or partner with companies who had products in late stage and bring them to market). This is where I learned to understand in detail the 'standard' AE, CM, LB, MH, EX, PD safety domains but, in my mind, even more importantly was to carefully read the Statistical Analysis Plans, deliberately understand the endpoints, and figure out the best way to set up the Analysis Datasets (AD's) in a way that most efficiently could generate the often-complicated statistical analysis. Needless to say, this is also where I learned my basic communication skills – all by working with statisticians who often did not have a lot of patience for questions from SAS Programmers (or who had not always put a lot of thought into how complicated it is to make analyzing data appear 'easy!').

STEP 2, TAKING THE LEAP/MANAGING CROS

After I laid the 'groundwork' described above, I felt I needed to work on communication skills to bring them to a level that was on par with my technical skills. After being at Forest for a little over 4.5 years, I decided to 'head west, young man' and, after interviewing for several companies (and at that time when the economy was still hot receiving several offers), I landed a position at Genentech in South San Francisco, CA. In this capacity, I was involved in all kinds of Quality Control (QC) activities, including validation methodology. At that time at Genentech, almost all QC

was performed by a small CRO on the East Coast (3 hours ahead of us in CA), and I was involved in overseeing the QC of all 'non-Oncology' projects and another very large project – bringing the QC software (used to track outputs, note which kind of mistakes were made, how long it took to complete outputs, etc.) from a vendor to having it managed, updated and up-versioned in-house at Genentech, which meant working with many different groups, primarily IT. As IT had their own acronyms, language and agenda (and I did too), this involved many meetings and close collaboration with our IT partners. Back to the QC of 'non-oncology' deliverables, I also had to closely monitor the QC process, meet with key programming stakeholders on a routine basis, obtain feedback on both QC Programmers as well as the QC Software, and also not only talk about issues but compile that feedback and update the QC Software (three versions during my 1.7 years there) and make adjustments to the QC team as well (often substituting QC programmers from one project or another or in some cases, when they just weren't working out, removing them from project). As mentioned many times already, communication is critical to managing at any level, and part of communication is being able to relay both good and bad news to programmers who possess all kinds of different skill sets and abilities. This was my lesson in both CRO and Stakeholder management.

STEP 3, TAKING THE LEAP/MANAGING CROS

After obtaining the critical amount of SAS programming abilities, nature of SAS programming in the Pharmaceutical/Biotech field and gaining experience in CRO and Stakeholder management I decided I wanted to get involved more deeply in a single project again and it was clear to me that I wanted to remain managing people and projects. Since I didn't want to leave Genentech unless I got the exact opportunity I wanted (and the economy had started to turn sour), it took me several phone interviews and discussions with peers that I knew and trusted before I found an opportunity to both lead a challenging drug compound for a somewhat unique indication (transplantation) and manage programmers (both at the line and dotted-line levels). I chose to head back to New Jersey, this time to 'Big Pharma'! Managing is never easy, and the only way to get better is keep managing, talking to employees, opening up the lines of communication and ensuring they stay open and, perhaps most critically, addressing issues and concerns in a timely way (e.g., not pointing out a mistake during the middle of a filing when programmers may have worked until 2 or 3 a.m. the night before!). A new lesson I learned during this time was managing programmers on the 'dotted-line' level, meaning they did not report into me directly but they did work on my project. In general, these programmers may not be as heavily invested in the project as they are with the respective managers, and their managers may also be asking them to perform activities that are not always related to the project they were assigned to (my transplant project). So I went back to some training materials from a class I took at Genentech (and would recommend to anyone) – 'Managing without Influence', which meant that a manager needed the right set of tools to motivate programmers who would not be receiving their year-end evaluations from you. In the end of almost four years at BMS, I was satisfied that I had continued to grow as a Manager, secured myself in Phase III work, and ultimately we got a successful Advisory Committee for the compound I was working on.

STEP 4, TAKING THE DEEP DIVE AND BECOMING A MANAGER OF VERY ADVANCED SAS PROGRAMMERS

After working so deeply and long on a single project, leading it from Phase II to the pivotal Phase IIIs and to a successful Advisory Committee vote, I was ready and clear about what I wanted to do next – lead multiple drug compounds and manage more programmers. This time either the job market had rebounded or my experience was paying off, because I had three interviews and ended up with four job offers, so I was in the position I wanted to be in! In the end, I did receive a job offer as Associate Director, overseeing drug compounds in Phase III development. And it also meant that I had an opportunity to hire both multiple programmers and contractors (an opportunity that does not come along very often!). So, not only did I have stake in building my team, but I also inherited a group of very skilled and advanced programmers working in Phase III. So I'm currently adjusting to life in Boston and continuing to manage programmers, oversee programming efforts for projects in Phase III and work on initiatives (something that, while I'm not naïve to, it's not something I did on a routine basis in my past). This story is still being told....

CONCLUSION

In sum, this paper hopes to present ideas to think about and share with other managers. The point of the paper is not that it's necessary to try different environments, but that there is no single path to becoming an effective manager.

CONTACT INFORMATION

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