Working experience for the filing resubmission from supporting Statistical Programming Analysis (SPA) perspective

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ABSTRACT

The purpose of this presentation is to share my experience of working for the filing submission at Genentech from supporting Statistical Programming Analysis (SPA) perspective.

The submission was the effort of years of committed work from the filing team, patients and physicians. As the deadline was approaching, the team faced challenges like multiple databases, delays, changing resources, pressure and attention, as the product is of a crucial importance for hundreds of thousands of cancer suffering patients worldwide.

In March 2007 I was assigned 65% of my time to help the study submission as the deadline for this filing was three months away. Since I was employed only for five months in Genentech Inc. (having 10 years experience in SAS® programming), the stake was very high. The team demanded that supporting SPA must learn quickly by himself the current project status, his roles and responsibilities, what the team needs and how to meet their needs. I had the great opportunity to learn about filing, adapt to and communicate with a new team, contribute to the big project and shift the roles, from being responsive to being responsible.

The presentation will underline details about improving the collaboration among the study statistician, Quality Control Programmers and SPA, the lesson learned during the filing and the personal experience accumulated during this big project.

INTRODUCTION

Working on the filing team to complete the submission could be both challenging and rewarding. It was even more challenging when being assigned to replace someone else as Supporting Statistical Programmer Analyst (SPA) three months before the filing was expected to be completed. It was challenging because there were so much to learn within a few days. It was rewarding because the supporting SPA had the chance to not only gain filing experiences but also contribute to a drug that can help and revolution the lives of hundreds of thousands of cancer patients.

THE CHALLENGES

Two IRF (Independent Review Facility) analysis datasets (IRFPAT and IRFMSPAT) were assigned, each contained over 100 variables and more than 10,000 observations. The changes to definitions or add more variables from biostatistics were expected to be completed and QCed within two business days. In many situations, the task had to be done within one business day. The algorithm to create variables was very complex. It took the study statistician up to three hours to explain the intent of creating a new set of variables and its algorithm. The stake was very high; time was extremely precious; demanding to turn things around was extremely quick; stress was increasing every day. Since the other team members were busy with their own work, one had to respect his/her colleague time and ask for their help only when it was absolutely necessary.

There were great motivations and rewards included: the SPA had the opportunity to work with the brightest staffs in the department and to complete a task which might have impact on so many
people, making the drugs available for those who critically need them. Being a valued member of a cancer-fighting team was one of the best rewards possible.

It was crucial to identify the major challenges a supporting SPA could encounter. There were four major problems every SPA had to face: know where to find information, understanding complicated derived datasets within very short period time, learn to work with your team, and learn to cope with stress.

THE INFORMATION

As a new SPA, I need to find where the information was, from the locations of the derived dataset programs, input and output datasets, CRF, macros, specifications, etc. I also needed to identify and assume my roles and responsibilities. I needed to learn the names of the study statisticians, lead programmer, data managers, clinical scientists, their e-mail and phone contacts, the dates and times they could be reached, the time it normally took to respond to my request. Memorizing / prioritizing all the information (and not searching for it) really saved a lot of time. As the result of this, time can be wisely spent on the task required to complete the work.

THE DERIVATIONS

It can be frustrating for a SPA to spend time writing the specification, define the algorithms of each variable and documenting every single issue that affects the datasets. However, this saved a huge amount of time and effort for a new SPA assigned to take over the task. The document provided clear guidelines to understand what the dataset intent to create, how many variables and observations in the datasets, how the variables were derived, what kind of data issues SPA needed to be aware of, when the changes were made and what the reasons were for the changes. The faster understanding of the specification of the databases helped the ability of performing the programming support. Your predecessor SPA had gone through painful experience to create new datasets. While her/his memory about the study was still fresh, s/he could help you understand the complicated dataset within a very short period of time. When you review the specification, wrote the summary of what you did not understand and request her / him to explain about it. You will earn a lot of respects when you could explain clearly to the study team your in-depth knowledge about the datasets.

THE TEAM

Before learning to work with the team, it is important to know who is in the team. If you are a supporting SPA, three important team members you work with on the regular basis are: Statistician, Lead SPA, and Quality Controller (QCer). Also it is crucial to have regular contacts to identify what the team needs and to be able to provide what they need to complete the task.

Statistician’s needs might include all of the following: to be consulted about the issues which prevent SPA from the wrong doing moving forward; to hear SPA opinion on how to resolve the issues; to be updated if there are any pending issues.

The role of a Lead SPA is to oversee the overall study programming activities. This includes what have been done and what have not been done, and when the clinical results could be delivered. Therefore, it is very important that the supporting SPA informs the project leader about his daily activities at the end of the day.

The role of a QCer is to verify that the clinical results are high quality, accurate, and promptly delivered. Therefore, they need a clear and non-ambiguous specification, reasonable estimated QC duration interval. They also want their comments are responded promptly. The SPA needs to be informed if the QC due date needs to be extended, and if any specs or program code change has been made since their last verification.
STRESS MANAGEMENT

Working with the filing team could be very stressful. However, managing the project well could minimize the stress. There were few magical communication tools that helped reducing the stress: understanding the small picture versus the big picture; keeping up with constant changes by attending meetings and teleconferences; communicating closely with the team; identifying the issues that may prevent the project from moving forward; asking for help whenever needed; and (not to be ignored) making sure that you have enough time to sleep.

CONCLUSION

Working with the filing team to complete the submission could be both challenging and rewarding. Four major challenges every supporting SPA has to face: know where to find information, understanding complicated derived datasets within very short period time, learn to work with your team, and learn to cope with stress. Direct communication, understanding and feed-back among Supporting SPA, Study Statisticians, Quality Control Programmer and Lead SPA are crucial for the success of the filing submission.