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Combining quality of productivity and efficiency under highly pressure of lacking time – discussion by view of first-time quality

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ABSTRACT

The field of clinical trial is a hallowed and special work, and highly related to human health, how to provide correct data and results for investigation is a critical issue. Therefore, enhancing quality in programming and increasing productivity are always important topics, especially working on Contract Research Organization (CRO). We aware that low-class quality in programming will cause extra time while implement, and even destroy the company's reputation as well. We realize there are many articles mentioned about time saving by efficient programming skills, and keeping good quality of deliverables via quality control (QC) or third-party viewer; however, they rarely to focus on the first-time quality in programming. Here, this paper would like to focus on discussing improvement of process while playing the originator role to get expected quality and efficiency.

Generating plenty of deliverables in tight timeline and limiting to use specified macros in programming are current trend in pharmaceutical companies and CRO, under this situation, the quality issues increased accordingly. The main reasons cause the quality issues including unfamiliar with study design, programming without deeply thinking and improper way to use the specified macros. This paper would like to provide some useful suggestions and solutions in fist-time quality, as well as functional process to promote quality and productive, such as ensuring programmers understand what they supposed to do, engaging thinking about the meaning for their responsibilities, and reducing repeated trainings across different clients and so on. Hopefully these could help programmers to complete tasks smoothly under compact and frequent deliveries.

INTRODUCTION

Clinical trial, which includes many processes of development, data collection and analysis, is highly related to human health, apparently, all of them are crucial topics in clinical trial filed. Thus, people who work in clinical trial filed such as statistical programmers and statisticians should take responsibilities to produce correct results and accurate reports, at the end, help to develop new medication and new medical technology to improve health level for human.

Nevertheless, the procedure of data analysis and generating the clinical outputs are really complicated, it includes collecting data, designing the statistical analysis plan, programming and reviewing output. Additionally, many different roles need to be involved in it, so, manpower arrangement and quality control become a challenge as well besides professional skill, in the industries that are in charge of these tasks. A bad quality control, for example, incorrect data or reports may mislead final result in development process, increase cost, and even lead to failure of program.

Nowadays, in order to reduce human error and improve quality, many companies set plenty standard operating procedures (SOP) collocating with some common methods. For instance, using check list to ensure that everything is following SOP; grouping by the features of task, it makes team members focusing on specified tasks and familiar with those tasks deeply. Using validated macros from clients or incorporations to generate datasets or outputs in programming, a high quality and efficiency of processing could be expected, it may avoid programming issues and saving time to produce tasks. Moreover, providing training focusing on "how members deal with data analysis well" is also a common way; but similar trainings from different clients should be avoided to make the programmers could have more time to focus on the projects. Those are good ways to keep high quality and efficiency; however, the author believes that the effect of those common methods will be better if programmers have good first-time quality. (Note: The definition of first-time quality is: The quality of all finished items after programmers completed their responsibilities and before the items go to the next step to quality check.); reciprocally, if bad first-time quality appears at the beginning, the level of entire quality will be lower than expected. Furthermore, generally speaking, these procedures and common methods will take more time to accomplish and increase cost.

Fast developing of medications and huge competition among medical industries are continue rolling, due to medical technology advances and demands increase of human health. As a result, more and more clinical trial projects need to be accomplished under tight schedule and manpower limitation. Especially in CRO industry, a lot of quality issues appear because of this circumstance. Here, this paper would like to focus on programming period, and how to improve quality and time saving. Although quality management is related to personal behavior, the author believes that the quality in programming could be improved by good first-time quality, common methods to QC and process from incorporation. This paper also provides a scale measurement to assess programmers' first-time quality, and assumes that it could help to arrange resource then combining quality and efficiency to finish tasks. Additionally, this paper shares the experiences of quality management from senior programmers and statisticians, hopefully, it will be useful and be considered as methods and strategies.

QC PLAN

During programming period, in order to guarantee the accuracy of the results, the programming team in the incorporations always establish a QC plan before the matters which are related to programming begin. Generally, there are some templates from SOP which could be found in incorporation, and then the programming lead will adjust them based on the features or requests from projects. The QC plan usually includes some programming processes as Figure 1 shows, such as the tasks will be done, when do each task need to be finished and how to perform the activities for QC. For example, double programming, code review or manual review.

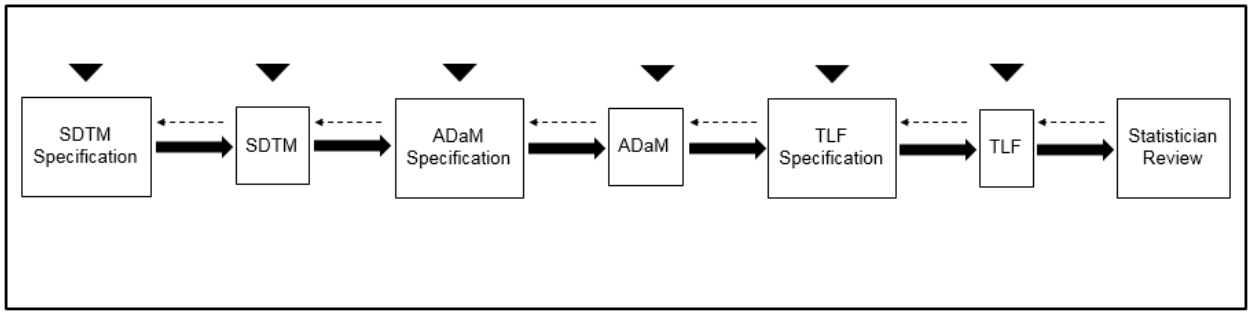

Figure 1. Programming process

In Figure 1, all possible tasks in programming process may perform the QC procedure where triangles are marked, whatever programming part or specifications review. The programming part may contain SDTM (Study Data Tabulation Model) datasets, ADaM (Analysis Data Model) datasets and TLFs (Tables, Listings and Figures), and all the specifications of them may need to be reviewed independently. In most cases, double programming is chosen to QC, it means that two programmers make the programs independently for the same datasets and outputs. However, there is no necessary to do double programming for some tasks in specified projects, such as figures or listings, it should be considered in QC plan. According to the QC plan, when the QC is completed, it will proceed to the next stage. For instance, programmers could start to program for ADaM datasets after ADaM specifications are generated and pass the QC procedure; however, if some problems are found in the QC stage, programmers may go back to recheck the last stage, as the dotted line showed in Figure 1.

The whole QC plan plays an important role while checking the quality in programming period, it takes a lot of resources and time, thus, when programming team is planning the timeline, the QC plan is always a significant consideration. If the team members could be assigned well into the projects by their level of first-time quality, it may perform QC plan efficiently and reduce time cost to modify programs or specifications repeatedly. On the contrary, if programmers are unfamiliar with the projects, or they do not achieve the assignments well, it will take too much time to accomplish the QC plan and may cause the delays of timeline.

THE FACTORS TO AFFECT QUALITY

While exploring the content of this paper, the author interviewed some experienced programmers and statisticians and discussed the topics related to programming quality with them. The main topics were explored in the interview are displayed as Appendix. It aims to understand what kind of issues will be met in the practice and what are the point of views of the interviewees about the purpose of this paper.

There is no doubt that keeping high quality is an important matter during the programming process, and all interviewees are desiring to generate outputs accurately. Therefore, companies always command some strategies to improve the level of quality, the common approaches including, first, grouping by the features of task, such as ADaM team of which member only do matters related to ADaM and TLFs, for this approach, it also may group by ADaM domains. Second, the clients or the companies command to use some validated macros. Lastly, take specified trainings before starting to projects. Most of the interviewees think that these common approaches are useful to increase the level of quality and efficiency. Nevertheless, the foundational factors of programming quality are ensuring the programmers understand the meaning of their tasks, the requirements from clients and confirming the completion of self-responsible part. If these matters could be completed by the programmers themselves, then collocates with common methods as what the author mentioned earlier, the effect to improve the quality will be outstanding, and all of these are associated with personal first-time quality.

According to the discussion with interviewees, there are some factors would lead to bad quality, including the programmers are unfamiliar with the project design, low completion rate for self-responsible part, time pressure, personal experience and complicated requests from clients and so on, as Figure 2 shows. This paper focus on discuss if the first two situations could be decreased via controlling the first-time quality, and then more time could be saved and could reduce the time pressure. However, they also believe that personal experience and negotiating the

scope with clients are important parts as well.

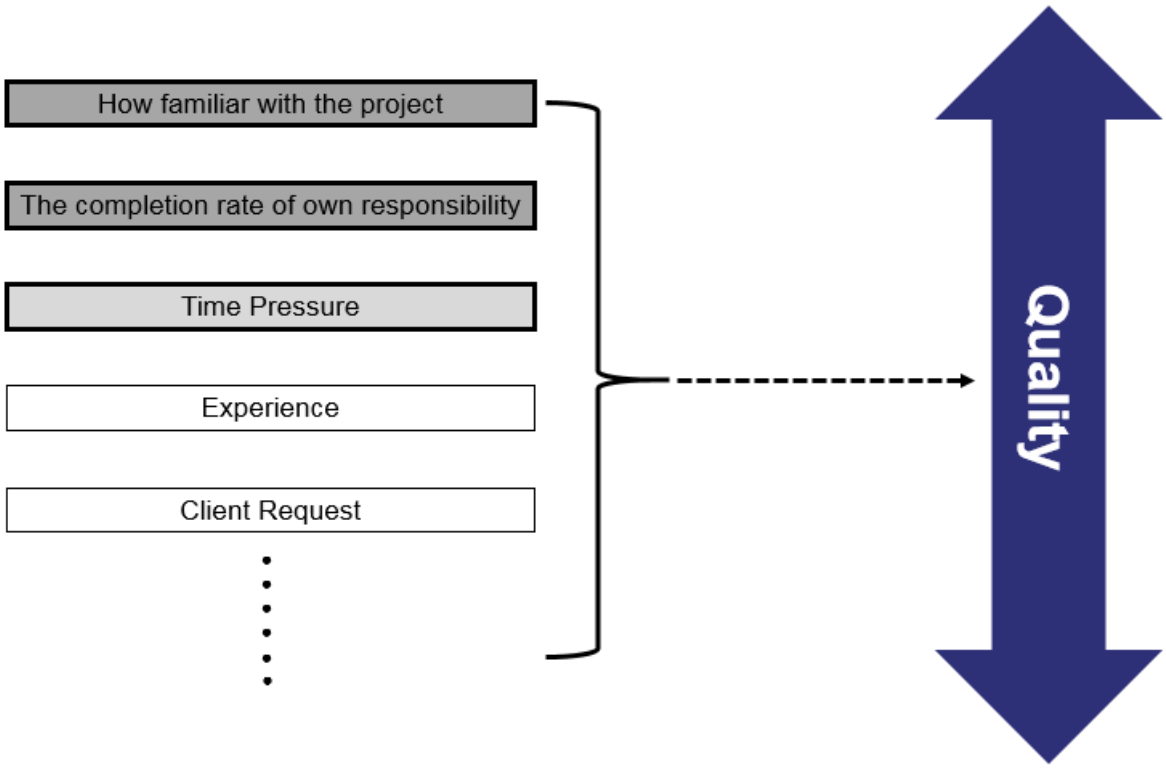

Figure 2. Factors to affect quality

FIRST-TIME QUALITY

In this paper, the author thinks that improving personal first-time quality is essential and important while considering entire programming quality. When doing QC procedure, particularly double programming, if both programmers have good first-time quality, it does not only expect to get correct results but also spends less time for QC procedure. Otherwise, if both programmers generate programs or documents with bad first-time quality, it will take too much time to accomplish the QC procedure.

The quality of project is usually assessed by the situation of QC procedure, client comments and client satisfactions. Here, this paper would provide the concept scale to evaluate the level of first-time quality for each programmer as Figure 3 shows. In this scale, there are three dimensions, including QC comment (a), Client comment (b) and Client satisfaction (c). All dimensions have corresponding scores, from 1 to 5, the higher score means better first-time quality, moreover, it also contains the total score, sum of scores for those three dimensions.

The programming lead and programmers who participated the projects need to fill out the scale. For part (a) and (b), the main consideration is the situation of generating the low-class issues from QC / client comments. Regarding to the low-class issue, it means some obvious mistakes are found, such as the wrong layout format, typo and so on, under the situation that related documents and requirements for those findings are already given, and these all could be avoided easily. About the part (c), it could be realized that client satisfaction may be a comprehensive indicator which made by client, but the author thinks that the quality of deliverables is a key factor to affect satisfaction from client, thus, the client satisfaction still be put into this scale.

Through the result of this scale, while a programmer get more than 4 points for each dimension and the total score is higher than 12 points, then this programmer could be thought as a person with high first-time quality. As the author mentioned, the projects could get both great quality and efficiency in programming process if it has better first-time quality. Therefore, it is suggested that programmers could be assigned into specified project team depend on the result of first-time quality scale in the past records. For instance, it is better to assign more programmers who with high first-time quality if there is a project need to be completed with tight timeline. Nevertheless, it should be understood that this first-time quality scale is a conceptual scale, the companies could take this scale as a template, and then adjust it based on the feature of clients / projects to obtain the level of first-time quality for each programmer.

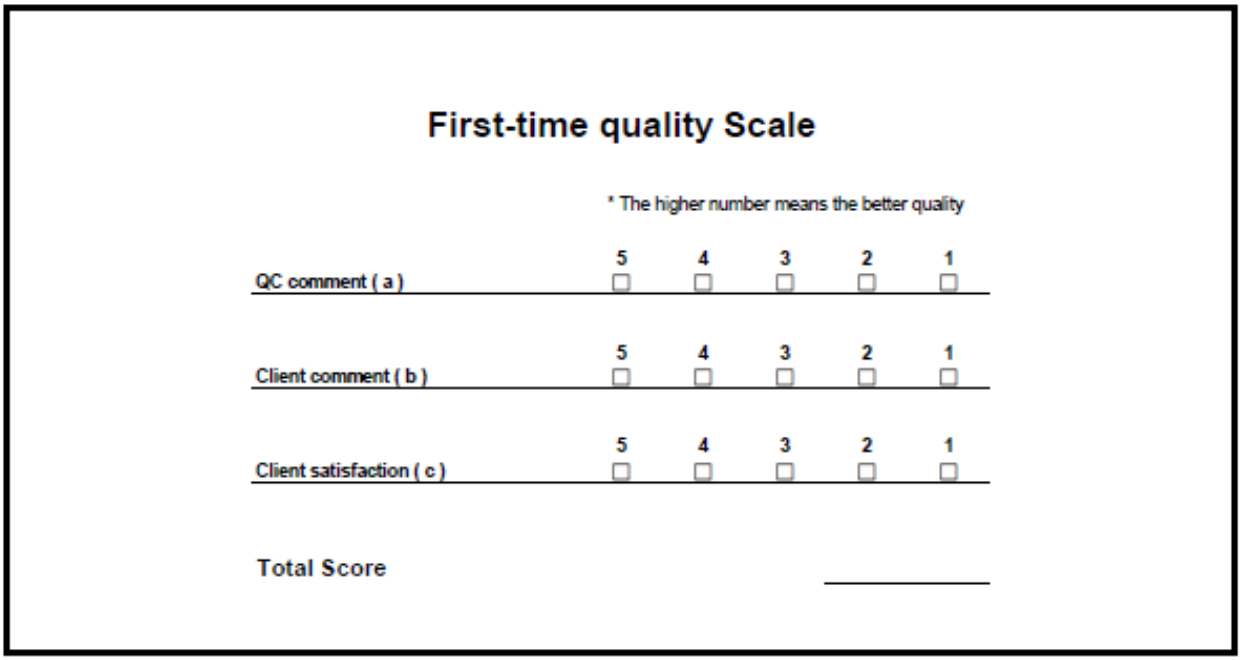

Figure 3. First-time quality Scale

CONCLUSION

The circumstance is that programmers have to accomplish high quality deliverables within tight schedule, so, how to finish those deliverables, at the same time, with efficiency becomes an important topic. Nowadays, many companies catch up this main-trend by some approaches from programming procedures and methods. On the other hand, most of employees believe that maintaining high quality deliverables is necessary, moreover, good quality also helping to reduce time while processing projects. Therefore, the author aims to help to improve both quality and efficiency by the views of this paper.

It is easy to know what first-time quality is, and it means that everyone should check everything in their responsibility by themselves and keep all the deliverables with high quality, then programmers could decrease a lot of time in modifying programs or documents. The most important is the dual manpower could be saved when the modification could be omitted, because, normally, the approach of double programming will be chosen while programming in most tasks. If these costs could be avoided, the incorporations could have more time to ensure the correct result and keep high quality, even could do more projects to increase the company profits.

Here, the author introduced the "First-time quality Scale", which is considered by some dimensions that could identify the level of first-time quality, including QC comment, client comment and client satisfaction. And, "First-time quality Scale" is provided to assess the level of first-time quality for every member at each period. Depending on the results of assessment, managers could assign members into different projects by different time-demand. This sort of arrangement in project team will be easier to accomplish tasks with both high quality of productivity and high efficiency.

APPENDIX – PERSPECTIVE OF QUALITY WHILE PROCESSING CLINICAL DATA

All the responses below are based on the structure of open discussion and all the interviewees could express their perspective freely.

Note:

The definition of first-time quality here is: The quality of all finished items after the programmers completed their responsibilities and before the items go to the next step to quality check.

- How long have you been a programmer / statistician in CRO / Pharmaceutical company?
- When you are judging the completion of a project, what is the priority of quality as the assessment criteria?

- In your opinion, is there any factor is more important than quality? If yes, for example, timeline? efficiency? others?
- According to your experience, what kind of factor will cause bad quality? For example, the experience of the programmer / statistician? timeline? client's request?
- From your point of view, what kind of standard will you use to evaluate the project's quality? For example, the result of quality control (QC)? client's feedback?
- Do you think keep the project with high quality during the process of programming will take more time than you expected at the beginning?
- From your viewpoint, how can a programmer / statistician do the first-time quality well?
- In your opinion, will the first-time quality be the most important part of the process of QC? Why?
- From your perspective, what kind of factor of method could improve the quality effectively?
- Generally, the methods are using to improve the quality that including using validated macro, specified training for programmer / statistician, grouping by the features of the task. How about the effect? Regarding to the methods mentioned above, what kind of problem will be caused while using these methods?
- Do you think the Efficiency and the quality will create conflict for time? For example, in order the keep the project with high quality will lead to lower efficiency? Or you think these two factors can be complementary?

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