

## Clinical Programming is More Than Programming

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### ABSTRACT

With the rapid development of biotechnology and ever-changing clinical trial environment, being a qualified clinical programmer encounter more challenges than ever.

Actually, the medical industry has unified the CDISC (Clinical Data Interchange Standards Consortium) standard, and SAS (Statistical Analysis System) Institute is still launching new programming products as well.

However, in many newcomers' view, clinical programmer is considered to be the job that just doing programming, so there are some topics and questions we would discuss:

What is a clinical programmer's responsibility?

What is the challenge for clinical programmers?

What is the future of clinical programmers?

### INTRODUCTION

Previously, the work of clinical programmers was to complete statistical analysis report by using SAS from the macroscopic point of view. At present, a clinical programmer should have ability in finishing multiple tasks efficiently with high quality.

As a relatively backward part of the clinical trial line, clinical programmers are also required to have strong abilities of collaboration, communication, and the concept of standardization. Even so, every clinical programmer is expected to be an excellent manager who can supervise varieties of projects. In this paper, we will view the retrospect and the prospect of clinical programming.

### THE QUALIFICATION OF CLINICAL PROGRAMMER

1. Basic knowledge of statistics. Be able to understand protocol and statistical methods.
2. Ability to explore, query and analyze various data sets. High level of attention to detail, particularly in data entry and quality check.
3. As a general analysis tool in clinical trial, SAS is stepping stone for entry-level technology for clinical programmers.
4. Strong process, problem solving and analytical skills.
5. Strong oral and written communication and interpersonal skills. Teamwork is necessary and play an important role.
6. Awareness and talent of presentation. Don't just focus on doing, know how to summary.
7. A sense of management. Arrange the time properly and well done in documentation.

### THE RESPONSIBILITY OF CLINICAL PROGRAMMER

#### PREPARATION

When a clinical programmer is assigned to a new study, it is necessary to read protocol and SAP (Statistical Analysis Plan) carefully and understand the study design and some important statistical methods. Especially, the lead programmers should get a full picture of the whole study and have a detailed plan about how to carry out, including the organization of participation programmers and assignment of tasks, the prediction of key and difficult points, etc...

Apart from the communication among programmers—lead programmer and participation programmers, meeting with staff involved in the same study from other departments, like DM (Data Manager) or statistician, is necessary. Programmers should confirm the key milestones timelines through the study meeting or emails. (For example, the timeline for database lock and the timelines for deliveries.)

## **DOCUMENTATION**

After preparations, programmers should arrange time properly. After all, programmers should deal with several studies at the same time. Reasonable arrangement is conducive to improving efficiency and ensuring the quality of delivery.

Clinical programmers need to make some issues clear, 'how many data and tables are needed?', 'what is the requirement?', 'how to achieve the expected results effectively?'. Preparing draft documents is a good habit when a lead programmer is ready in a certain study, such as a listing of all tables, the assignment of work, a decision or issue log which containing confirmation from DM and statistician, a document recorded with QC (Quality Check) findings, etc.... A lot of programmers wonder why I have to do documentation, and they may think documentation is a waste of time. However, this step is really effective, not only to make our work clearer and more organized, but also to protect our work from being queried. If you work in a clinical trial with a long period, these detail and tedious work may avoid troubles.

## **STANDARD**

Before programmers start to coding, SDTM (Study Data Tabulation Model) and Adam (Analysis Data Model) specifications should be completed.

CDISC unified the standard in the medical industry. CDISC has both rigid and flexible parts and it is constantly updated. Clinical programmers as members of clinical team, also need to abide by CDISC standard for the rigid requirements. For the flexible section, there are different solutions or algorithm in each company.

In general, clinical programmers need to create their own templates to enrich standards and make work more uniform and effective in different company. Even in CRO, templates and unification are necessary as well. When we have uniform standards, we can have uniform programs and even develop our own systems. The effectiveness would be greatly improved and the cost would be reduced significantly.

## **PROGRAMMING**

Recently, a programmer posted a question, 'now we already have a unified standard, and a set of standard programs. Would programmer be unemployed if the interface operation is advanced?'

The ideal condition for industry is to build an advanced system and golden standard while it is difficult for every industry. Why? The reason is that data quality and study design are usually different. Although there is CDASH (Clinical Data Acquisition Standards Harmonization) standard, it is necessary to check data indeed. Especially for China, the CDISC standard is not widely used and the data quality level is not consistent. Many problems of data quality come from the source caused by different operations from different site. It is not easy to directly use the data in the database. Moreover, the scheme changes over time, indirectly leads to the constantly updated standardization. Programmers usually create new codes that do not meet the standard when they cannot find corresponding standards. In addition, the work of updating and maintenance for standard is still necessary.

In summary, without a doubt, programming is still a programmer's main daily work.

## **STRONG PROCESS, PROBLEM SOLVING**

Due to long-lasting process of clinical trials, programmer sometimes should finish their work in a very short time.

Programmers are supposed to do their assignment after upstream divisions are done with finishing the data clearing and SAP. However, due to the modifications beyond the plan, they spend much repeated time following these changes and correct corresponding mistakes happened with every rerun for several

projects at same time. To ensure to accomplish tasks, programmers should arrange time reasonably and be confident solving emergency problems.

## **COMMUNICATION**

Job of clinical programmers can also be regarded as services, serve for data and for statistical methods. Therefore, programmers, DM and statisticians maintain close contact in the form of telephone, email and meetings. In fact, interpersonal communication skills are applicable to all aspects. Tone of voice should be neither too arrogant nor too humble, when we have a talk with other members in the team. Teamwork is inevitable in the clinical field. Every programmer should think about the way of how to work with others in harmony, which benefits the development of project. Good communication skills will make everything twice as effective.

## **PRESENTATION**

Finally, when a study come to end, is the clinical programmer's job finished? What else do we need to do?

Summary and presentation!

Why are summary and presentation necessary for clinical programmers?

Actually, presentation is one of the elements needed in all kinds of work, just like communication skills. Most of people pay more attention to finish assignments rather than present their results, share experience in public to make more progress. Presentation makes programmers review the whole study again and summarize the achievement. Programmers need to share their experience and let others know what they contribute in a study.

## **SUMMARY**

Look, who says programmers are just coding every day? Clinical programming is more than programming. I am not clear about how programmers work in other industries, at least our clinical programmers are definitely all-powerful.

## **LOOK FORWARD TO THE CAREER DEVELOPMENT**

### **TECHNICAL CLINICAL PROGRAMMERS**

Technical clinical programmer is generally considered as the one who is excellent at applying SAS to studies. Excellent technique is the foundation in this field. For the technical part, what can be improved?

#### ***Tools***

As an ancient says, if a workman wants to do his work well, he must first sharpen his tools. In fact, for the sake of unity and convenience of management, various tools have been widely used in the daily work of clinical programmers in many companies, such as Microsoft office (word, excel, outlook), Unix, FTP (File Transfer Protocol Server), UE (UltraEdit), and of course SAS. Every software we often use is updated regularly to make progress and improve skills. Why? In order not to be eliminated by the market. So, should clinical programmers accept new biostatistics products and maintain updating? Of course, we should and have to. For example, what can we do if SAS is not used and replaced one day?

Clinical programmer is a kind of programmers. Can we cooperate with other programmers from other fields? And clinical programmers also need to pay attention to teamwork. In a team, roles can be divided, such as study management, programming technique or technology, statistics knowledge, and DM. So, let's try adding another responsibly in the clinical programmer's team. New roles can provide us with new ideas, such as Java. Maybe new members can develop clinical programmers' own tools in combination with SAS.

The advantages:

1. Cost saving

Tools used now are all copyrighted. If clinical programmers can develop tools by themselves instead of purchasing, then cost saving can be accomplished.

2. Customizable

Create own tools according to one's own requirements due to different industry and even different national conditions.

3. Stronger team

If fresh blood is added to the team of clinical programmers, the team will become more reliable like doing the program patching.

## MANAGERIAL CLINICAL PROGRAMMERS

Managerial clinical programmer is the same as meaning for the leader of the programmer's team. Soft skills are the source of development. Capable managers should have the talent of communication, leadership and innovation. Managers always need to stand a higher level to give the guidelines for the programmer's team. In addition to having technical foundation, managers also should have a certain sensitivity to discover able people and put them at suitable position.

## OTHER - COMBINATION

At present, clinical programmers in China generally fall into 2 categories due to various reasons, one is inclined to DM, the other is inclined to statistician. Will this be a trend for future programmers? In short, there would be more advantages to study related knowledge.

## CONCLUSION

Recently I interviewed a guy who is interested in clinical programming. I asked him 'why do you want to be a clinical programmer?'. He said 'because this job is very hot now. When I am searching in the job search website, there are many opportunities. Luckily, I am capable of using SAS, maybe I can try, that is the reason I am eager to join clinical programming'.

All right, pharmaceutical industry is indeed thriving and demand of clinical programmers grows fast in the job market, but I wonder how long this boom and prosperous marketing in clinical programmers can last. As we all know, too much water drowned the miller. What are challenges would be occurred in next years?

I hope not only that every clinical programmer can better understand his work through this paper, but also that we should think about the future. If there are shortcomings, please improve them. If there are advantages, please keep up them.

In the end, let's work harder together to keep up with the rapid development of The Times. After all, we can't change the world or the environment, we can only change ourselves.

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## RECOMMENDED READING

- *Careers in Biostatistics and Clinical SAS® Programming: An Overview for the Uninitiated* Justina M. Flavin, Independent Consultant, San Diego, CA  
<https://support.sas.com/resources/papers/proceedings16/7940-2016.pdf>
- *Changing Careers to Become a SAS Programmer in the Biotech / Pharmaceutical Industry* Sy Truong, Meta - Xceed, Inc, Milpitas, CA [http://www.meta-x.com/changing\\_careers.pdf](http://www.meta-x.com/changing_careers.pdf)

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