

Team Management and Staff Career Development of Statistical Programming in FSP Model

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ABSTRACT

With the development of life science area, nowadays Functional Service Partnership (FSP) is one of the mainstream outsourcing strategy. Thereinto, client cooperation, cost saving, team quality and staff career development etc. are the key pillars. FSP model has been existing for many years globally and is steadily mature, however, searching for a path of the best benefit to achieve 'Win-Win' solution in ever-changing pharmaceutical and biotech industries is still a key subject that we are keeping thinking about, especially on today's demand exceeding supply and fierce competition of talent market.

This paper will focus on team management and staff career development of statistical programming in FSP model from provider manager's perspective. Team management part includes two topics: one is how to build up high-quality embedded-team adapting client's environment, structure and expectations; the other is cost saving. Staff career development part includes introducing the '6 essential skills' for statistical programmer, how to establish statistical programmer's system of knowledge, promotion path and the type of talents we need in our industry.

Keywords: FSP; Team Management; Career Development;

INTRODUCTION

Nowadays Functional Service Partnership (FSP) has been used in pharmaceutical and biotech industries for many years as one of the mainstream outsourcing strategy. Searching for a path of the best benefit to achieve 'Win-Win' solution of FSP model between provider and pharma/biotech company to optimize drug development time and cost is a key subject that we are keeping thinking about. This paper will focus on team management and staff career development of statistical programming in FSP model from provider manager's perspective and provide solutions on how to achieve benefits. Team management part includes two topics: one is how to build up high-quality embedded-team adapting client's environment, structure and expectations; the other is cost saving. Staff career development part includes introducing the '6 essential skills' of statistical programmer, how to establish statistical programmer's system of knowledge, promotion path and the type of talents we need in our industry.

TEAM MANAGEMENT OF STATISTICAL PROGRAMMING IN FSP MODEL

BUILDING UP HIGH-QUALITY EMBEDDED-TEAM ADAPTING CLIENT'S ENVIRONMENT, STRUCTURE AND EXPECTATIONS

In FSP model, the relationship between provider and client is partnership. The FSP staff's work responsibilities are same as client employees. Generally client not only care about FSP team's work quality, performance and retention etc., but care about FSP team's adapting and integration under client's environment. FSP staff, as embedded partnership team, working with client usually use client work system and follow client SOPs in project work. The work location is client office, provider office or home-based based on different situations. Below are some topics on how to build up high-quality embedded-team adapting client's environment, structure and expectations from provider manager's perspective.

Building Good Sense of Belonging to FSP Team

In FSP model, sense of belonging is a common issue that management team need to pay attention to, especially for the FSP members based client office or remote home-based. Thus, it is one of FSP manager's key responsibilities.

Here are some tips:

- Regularly organize team /group activities to enhance team bonding and cohesion.
- Provider manager has close communication with FSP members and support staff if they need any help.
- Provider manager has close communication with client manager to follow up anything related to FSP team timely.
- Make FSP staff be aware that in FSP model, they can get double resource and care from both their own company and client.

Partnership-Based Cooperation Between Provider and Client

The key cooperation characteristic of FSP model is partnership-based. The common target of both provider and client is to build better cooperation and make FSP staff adapt and integrate client’s environment to deliver high-quality work. Below are some points of how to achieve the target.

- **Talents Identification and Development**



Figure 1. flowchart of talents identification and development

- **Organize Co-Workshop**

The co-workshop is organized by both provider and client. Members from both FSP team and client are office-based or home-based in different locations and they are hard to meet face-to-face together at daily work. Thus, organizing co-workshop activities is a good way of facilitating team cooperation. Usually the co-workshop could be held in a selected location and the agenda includes review past, look into the future, knowledge sharing and team building.

Training

Besides traditional professional trainings like SAS or R programming, CDISC, essential soft skills etc., This paper highlights some kinds of trainings special for FSP model:

- **Gap and Bridge Training**

Case Scenario 1: In recruitment stage, one candidate completed Client Meeting & Greet. Client thought this candidate mostly met their requirement, however, he still had some gap on CDISC knowledge. Since the fierce competition of talent market, provider manager and client manager achieved the agreement to accept this candidate and it's provider manager to give gap and bridge training to make him make up the gap of the CDISC knowledge in a short period after onboarding.

Case Scenario 2: During the regular 1:1 between provider manager and client manager, they found that this year a lot of FSP staff start to take lead role in project. However, most of them are new to project management and need to receive some trainings. After discussion, the agreement is provider manager to give project management training to FSP members based on client work process and environment.

Case Scenario 3: Client required provider manager to give R training to FSP staff since client had plan to complete a proportion of projects using R programming within the future 3 years.

In conclusion, the gap and bridge training given by provider manager is to facilitate recruitment, project work and individual development. It is based on both individual needs and client requirements for various special purposes.

- **Onboarding Training**

It's provider's side to cover the responsibilities of making new FSP staff complete the onboarding training of client system, process and SOPs etc. The train-to-trainer and mentorship SME group models are introduced to implement this.

New FSP staff will be assigned 1:1 mentor from FSP team, mentor needs to receive train-to trainer orientation in advance and will accompany new FSP staff during the onboarding training period to support them be familiar with client system, environment and work process etc. The mechanism is made of provider manger, 1:1 mentor, client manager and mentorship SME group to work together, and they are not independent but interactional. The mentorship SME group is built up by some of mentors with strong professional techniques and mentorship capability. Their primary responsibilities are centralizing and optimizing training materials per needs and creating operational demo videos or files as project task goal orientation.

Among these the responsibilities of provider manger are:

- Provide train-to-trainer orientation to mentor.
- Regular touch base with new FSP staff, mentor and client manager to check the status and provide solution if necessary.
- Work with mentorship SME group and provide support on consistently gathering needs and feedback from all stakeholders, summarizing FAQ, optimizing training materials as an ongoing basis etc.

COST SAVING

With today's demand exceeding supply and fierce competition of talent market, the cost is getting higher every year, especially in tier 1 cities. Clients have been thinking for the way of balancing the cost, quality and team stability and want to get the best solution from their providers. In FSP model, this paper introduces some solutions from provider's perspective.

- **Experienced Talent Recruitment in All Cities of China**

Recruiting experienced talents in tier 1 cities are always very competitive, especially in recent years. Giving the working mode of statistical programming and more often working from home due to pandemic situation, recruiting experienced talents beyond tier 1 cities will be the alternative solution in terms of delivery quality and team stability.

- **Campus Recruitment and Academy Training**

As the industry continues to develop, the talent demand is far exceeding supply. There is urgent needs to cultivate new fresh member for whatever way. It is also feasible to launch campus recruitment and academy training through the cooperation of provider and client in FSP model. The benefits are decreasing the cost and cultivating good talents adapting client's environment and meeting client expectations.

Here are some highlights below for implementation:

- Provider and client work together to launch campus recruitment. Besides provider interview, client interview is also included for each candidate.
- It's provider to give academy training and client to final evaluate training quality. During the academy training, new fresh member also spends some time on client project work. If new fresh member doesn't pass client's final evaluation after academy training period is completed, he/she is unable to join the FSP team for this client.
- The cost is much decreased. Provider and client can discuss and achieve the agreement on how to set up the start date of billing and how to charge fees based on different periods.

STAFF CAREER DEVELOPMENT OF STATISTICAL PROGRAMMING IN FSP MODEL

6 ESSENTIAL PROFESSIONAL SKILLS

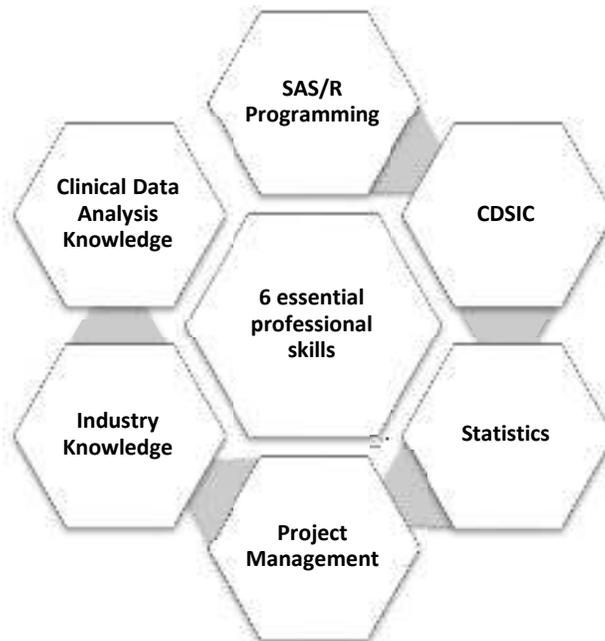


Figure 2. 6 essential professional skills

HOW TO ESTABLISH STATISTICAL PROGRAMMER'S SYSTEM OF KNOWLEDGE

Many statistical programmers may fall in the same situation that every day they are occupied by project work and there are limited time to be allowed on self-learning and skill improvement. Thus, finding a feasible way and thinking to establish strong statistical programmer's system of knowledge is an important subject. This paper raises an idea of 'learning from real project work' and also introduce how to learn from project work and improve 6 essential professional skills.

SAS/R Programming

Good programming practice guideline has described the conduct of statistical programming in detail that each programmer has to comply with. Besides it, to what extent does SAS/R programming skill need to be achieved to meet the requirements? There are 3 main points.

SAS programming two characteristics: applicability and repeatability.

Firstly, for applicability, you need to apply the programming language you learned into your projects. And think about three questions:

- Does your program strictly follow Good Programming Practice and SOPs?
- Find out the methods as many as possible to implement one algorithm and then do comparison.
- Do you take all circumstances into consideration?

Secondly, for repeatability, you need to draw inference from one instance, and accumulate, refer and leverage all assets around to improve work efficacy.

Thirdly, in most time programmers are reviewing the results of data analysis, modifying and updating program, so you need to have ability to identify and solve problems quickly.

CDISC

In recent years, here has been an increased focus on CDISC, with IG and other official guidelines being updated with increasing frequency. How to use official documentation efficiently is important to CDISC learning. Below are the tips:

- Learn to use, don't learn by rote. Find connections, commonalities and rules between domains.
- Don't be lazy. Develop good study habits and practice methods.
- Organize interactive workshop to discuss how to deal with various cases encountered in specific projects.

Case Scenario 1:

The manager organized a workshop of deep learning an integrated case study.

In SDTM part, members were required to describe how to map from raw data to each SDTM domain variable, and then make deep discussion about some key points combined with IG.

In ADaM and TLF parts, there were 2 steps:

Firstly, required members to find the corresponding clues and descriptions in protocol and SAP for each ADaM domain and each TLF.

Secondly, discussed the derivation of each ADaM domain variable combined with study documents and CDISC documents.

During the workshop, the manager led the whole discussion and helped members summarize and extract the key points, and analyze various situations encountered in multiple projects.

Organizing such workshop is to help members develop good learning habits and methods. The whole process is a qualitative leap. It is important to absorb good experience and lesson from past project and apply them into future real project work.

Statistics

With the increasing demand of statistical programmer in our industry, the division between statistician and statistical programmer becomes much clearer. More and more members whose major qualifications are not statistics direction become statistical programmer. From the perspective of the current situation, what level of statistical knowledge statistical programmer should achieve to meet the most basic project needs? There are three aspects:

- Know how to apply SAS/R program into each statistical analysis model.
- Know the purpose and usage of statistical analysis models.
- Ability to read statistical analysis report and understand the meaning of results.

Case Scenario 1:

Invited biostatistician to give statistics series lecture to statistical programmer. The topics are about above three items and the basic concepts and knowledge of statistics in clinical trial.

Clinical Data Analysis Knowledge

From statistical programming perspective, clinical data analysis knowledge runs through the footprints from study set up to final delivery including understanding CRF, raw data, protocol and SAP etc., how to implement study documents into programming activities and review results etc. It is integrated, comprehensive, systematic body of knowledge and also a map that connect all of parts. Here are some tips on how to learn it efficiently:

- Build a map, not a pile of scattered knowledge points when you read study documents or review results.
- Don't think of yourself as a programmer, think of yourself as a data scientist. Mining the significance of clinical data analysis is important.

Case Scenario 1:

The manager organized a workshop of intensive reading study documents including CRF, protocol and SAP etc. of a case study.

The purpose of intensive reading is to understand the structure and focus of the documents, find the links and connections between the study documents, divide the ADaM domains according to Protocol, SAP and table shell, and think over all valuable details. During the discussion, the manager asked questions, and made suggestions and supplementary summaries.

Case Scenario 2:

The manager organized a brainstorming series of ADaM and TLF review. The main topics include ADaM spec and dataset review, ADaM programming QC, TLF QC and review etc. During the brainstorming, the manager was acting as leader to control and introduce the discussion on track.

In each brainstorming, one member was assigned as recorder to summarize key points and ideas and make a mind map.

Project Management (Acting as Lead Role)

Taking lead role is an important turning point in statistical programmer's career, which is not only a change of project role, but also a change of way of thinking. Many people may have some inadaptability and misunderstanding. Project management, as a general capability, is a very important skill. Usually at this time, the manager's support and help are needed.

A leader of SP study team is generally required to coordinate and direct the team to run towards the target normally and efficiently. The leader is taking comprehensive roles as:

- Resource Integrator
- Information Communicator
- Atmosphere Creator
- Decision Maker
- Study Team Leader

Case Scenario 1:

The manager provided project management series training to FSP staff. The series training are made of theory courses and workshop combing with PMP knowledge hierarchy, general concepts of project management for biometrics and related client work process and SOPs. The purpose is to give FSP members a whole picture of project management knowledge and make them be familiar with the process knowing what they should do and shouldn't do when acting as lead role.

Industry Knowledge

A junior statistical programmer may only focus on specific tasks like how to generate a table or how to write an ADaM domain specification etc. However, with the career development of statistical programming, member should open the vision not only caring about things in the statistical programming field, but also expanding to a larger scope. The accumulation of industry knowledge is an essential part to help towards the road to be a mature statistical programmer.

Usually, we encourage team members to broaden their horizons through subscribing to magazines, participating in industry exchange meetings, sharing hot articles of website, recommending some books, and organizing cross-functional exchange.

In a word, industry knowledge gives a more comprehensive system of knowledge which can help statistical programmer adapt to the rapid development of the industry, embrace changes and cultivate an overall view.

PROMOTION PATH



Figure 3. promotion path (technology direction)

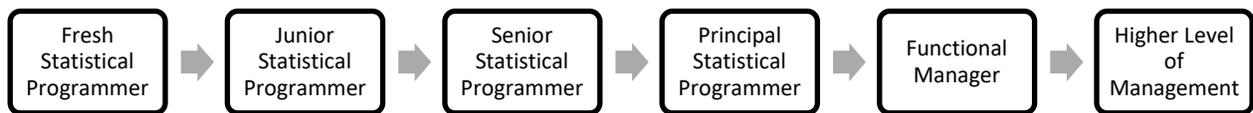


Figure 4. promotion path (management direction)

TYPE OF TALENTS WE NEED IN OUR INDUSTRY

- Have a comprehensive and systematic way of thinking.
- Strong ability to summarize and learn.
- Strong resilience and positive attitude to solve problems.
- The ability not only to make yourself be better, but to make others be better.

CONCLUSION

This paper introduces team management and staff career development of statistical programming in FSP model to help deeply understand FSP model (or embedded model). The sprits of FSP is to provide the customized strategic solution to release the workload of clients from recruitment, all the trainings (including onboarding, technical skill gap training and soft skill training etc.) and resource management rather than simple staffing like staffing agency. Hope it gives peers a little help and reference. In ever-changing pharmaceutical and biotech industries, the future is still a long haul ahead. As management and R&D people in this industry, we keep on going and working.

REFERENCES

None.

RECOMMENDED READING

- *第五项修炼 学习型组织的艺术与实践*

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