Practice Makes Perfect

Sunil Gupta and Mandyam Srirama at Quintiles offer some guidelines on making the most of training for statistical programmers

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For the past few years, pharmaceutical and biotech industries have enjoyed healthy growth that has created a unique opportunity for SAS programmers. Not only did the industry demand an increase in numbers of these skilled personnel, there were also new requirements for more advanced statistical programming skills for tasks such as the identification of difficult study-related data issues, and the programming and validation of more complex tables, lists and graphs.

With a severe shortage of SAS programmers with clinical knowledge and experience and an abundance of skilled SAS programmers from other fields, pharmaceutical companies and CROs needed to reevaluate their staff orientation and training programmes to better meet the needs of the new environment. To address these changing conditions and requirements, an effective best practices training programme was recently developed for new statistical programmers, with special emphasis on servicing the needs of their clients. The goal was that by the completion of a four-week best practices training programme, statistical programmers would be more empowered to channel their interest and motivation, while utilising their analytical programming skills to address clinical study reporting challenges.

THE CLIENT REQUIREMENTS

A client wants to be assured that the statistical programmers on their teams not only have the technical skills but also the training and experience required to carry out the programming tasks expertly and efficiently by following the client's procedures. Clients have a strong need for statistical programmers who can complete tasks with minimum instructions and supervision. Clients need to know that statistical programmers are not only effective in debugging SAS programmes, but that they also thoroughly understand the clinical trials data. Finally, clients need to feel comfortable that statistical programmers working on project teams follow their SOPs across all aspects.

The training programme is designed to provide that knowledge and expertise to give the client an additional level of assurance. The best practices training programme is very important to ensure consistency in the execution of SOPs. Since client requirements may change over time, it is always useful to update the training programme with the latest technologies to reflect current procedures and techniques. CRO programming staff find themselves working directly on a client's system and using client SOPs. As a result, the CRO programming staff are considered an insource extension of the client since there may only be a difference in the physical location of the team members (see Table 1).

With years of experience in bringing new staff on board, a new training programme was customised to address the current and future needs at a client as well as an individual level. The first step was to identify the types of tasks requested by the client's team. From that, the deliverables were defined along with the process flow to create these deliverables. Finally, the skills needed to complete the tasks were identified – such as working in a Unix environment, or clinical knowledge and understanding. A training programme was developed to ensure that statistical programmers

Table 1: Division of client requirements and client teams

Client requirements	Client teams
• Mastery of SAS programming • Understanding of clinical trials data • Programme using data definition tables and programme index • Programme using table shells	• Client statistical programmers • Insource extension of client: – CRO programming staff – CRO management

Table 2: Training programme meets client requirements

Comprehensive training programme addresses each client needs
• Set-up instructions for client account access
• Training programme needs to be consistent with the client's in order to understand and apply client's SOPs
• Three to four weeks of an individualised programme that is intense, self-paced with instructor interaction
• Hands-on exercises using real clinical data sets and specifications
• Monitor, evaluate and provide feedback on deliverables through code reviews
• Comprehensive resource to answer most questions, especially during the first three months on the client's team
• Monthly mentor to answer questions from new team tasks
• Uses any existing client presentation material where available
• Enhances client's standard macro user guides with annotated outputs of macro parameters and options

Table 3: Two main components of training programme

Best practices training programme	Mastery of SAS programming	Understanding of clinical trials data
Key objective	• Learn to apply advanced techniques and macros to create reports and graphs • Learn effective debugging and validation methods • Learn effective testing and documentation methods	• Address complex clinical data issues • Apply correctly primary and secondary endpoints • Understand drug development process
Selected resources (books, SAS papers)	• Sharpening Your SAS Skills • SAS Application Guide • ODS: The Basics • The Complete Guide to the Macro Language and Proc Report	• SAS Programming in the Pharmaceutical Industry • Sample Clinical Study
Sample hands-on exercises	• Create rtf files using ODS • Validate tables, lists and graphs	• Data edit checks • Create CRTs • Create tables and lists

were trained in a detailed and consistent manner which met the client's requirements at their satisfaction levels.

Specifically, a best practices training programme was developed to include specialised sections such as the regulatory processes (the FDA, validation strategies), the use of technology (ODS, Metadata, SAS Version 9, Enterprise Guide, Version Control Software) and solutions based on experience (programme index, data acceptance tests, clinical data issues). When possible, actual client team documentation or guidelines are used as part of the training programme (see Table 2).

A BEST PRACTICES TRAINING PROGRAMME

A well-structured best practices training programme meets the needs of all three groups: client, CRO programming staff and CRO management. The two main components of the training programme are SAS programming skills and understanding clinical trials data. It is very important for the statistical programmers to have excellent SAS programming and debugging skills as well as exposure to the challenges of understanding the summary and analysis of clinical trials data (see Table 3).

The training programme is an intense three-to four-week training period that is hands-on and practical with multiple interactive sessions to engage the programming staff. The clinical study data sets used for training purposes are real legacy study data so that real-world experience can be gained. After the initial day-to-day training programme, monthly training meetings are scheduled for continuous improvement.

For each training section, key questions are asked of the CRO programming staff to confirm comprehension. In addition, actual SAS programming is required to complete the training. This enables staff to gain real-world experience in a controlled, learning environment. Since the programming staff will use production macros to create and validate their tables, lists and graphs, CRO programming staff will learn how to apply and debug the client macros.

Finally, because it is often geared for global clients, the best practices training programme needs to be portable, standardised and centralised so that each statistical programmer receives the same instructions and materials. In addition, all CRO programming staff need to have access to the same set of key clinical and technical references for when CRO programming staff need more details on any given topic.

THE CRO PROGRAMMING STAFF RESOURCE

CRO programming staff have a strong need to understand the motivation behind client requests. They need to be able to get a feel for the clinical trials data to build their confidence. By encouraging the exchange of ideas across various client teams and reviewing new software options, for example, all CRO programming staff benefit during monthly training sessions. Any time spent on mentoring and guiding CRO programming staff is always well worth the initial investment, since they are the single most important resource for completion of the project.

For external training, CRO programming staff are ideally encouraged to attend regional or internal SAS conferences to learn about other approaches to common issues or specific workshops to discover new techniques and SAS procedures.

THE CRO MANAGEMENT EXPERIENCE

CRO management needs to keep client and CRO programming staff satisfied, with a proper balance of training time and production time. CRO management realises that without the required training, CRO programming staff can not complete vital tasks in a clinical study report submission. CRO management needs to have experienced instructors to create and maintain a thorough training programme to address the client demands and communicate this to the CRO programming staff in a user-friendly environment. Trainers can share with CRO programming staff their extensive experience in multiple successful FDA submissions. With the training programme and on-the-job experience over a period of few months, staff can rapidly be brought to the level of an experienced statistical programmer. In addition, on-going monthly training sessions also provide continuing education for existing staff. An up-to-date training programme along with many years of FDA submission experience provides numerous benefits for the pharmaceutical industry. ◆

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