

WORK.STAFF

Using Contract Research Organizations for SAS® Programming

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ABSTRACT

More and more programming in the pharmaceutical industry is being done by contract research organizations (CRO's). This paper will discuss a year-long project in which contract programmers were used extensively and describe how contractors were managed effectively to meet management goals.

Our experience with CRO's has been varied. We have worked with off-site and in-house contractors on large complex projects and on smaller routine assignments. Over the past year we worked with two CRO's to develop an integrated database of safety information and summarize and report information from that database to the Food and Drug Administration (FDA).

Phase 1 of the project involved taking many different studies from a clinical trials program and integrating the safety data into one large database. Phase 2 was the table generation stage. Approximately 130 table programs were written to list raw data, summarize data or generate descriptive statistics on the integrated data. Phase 3 occurred after the submission of the data to the FDA, when additional studies not included in the original submission were integrated, and the table programs were re-run and re-verified on the updated data. Phase 4, which ran concurrently with the other three phases involved routine

programming such as patient data listings and tabulations.

In Phase 1 of the project, all CRO work was conducted off-site. The CRO was issued an account on our computer system to provide access by modem and to transfer data electronically. Documentation of the file structures was delivered by overnight mail, with supporting memos sent by e-mail or fax.

One CRO started building databases with a staff of about 7 programmers for an anticipated 10 week period. As time approached the deadline, the number of programmers reached 15 including a group that worked a night shift. Contact between the project leader and the CRO was made multiple times daily, with constant feedback on work received. The CRO project team had one spokesperson, who acted as customer contact and project manager for the group. The CRO project manager distributed work to the group and maintained data transfer to and from the group. Since we were dealing

with many individual, non-standard studies, notebooks were kept at the CRO which contained all of the documentation for each study. Copies of memos and hard copies of e-mails were filed with each study, and queries to Boots were maintained on forms kept in those notebooks. As queries were answered, the responses were filed with the queries, keeping documentation readily available.

Two meetings were held at the CRO's site, to answer any outstanding queries and explain broad assumptions to make when building the databases. These meetings were invaluable and we should have had more. Phone calls and e-mails could not have replaced the face-to-face contact and write-on-wipe-off board sessions. These meetings included all of the programmers working on the project at the CRO and gave us a new 'team' attitude.

We also used this CRO to program most of the summary tables for the project during Phase 2. They used mock-up tables we designed to produce summary statistics for the data they had integrated. This proved to be more of a challenge than originally anticipated because the planning was incomplete and the CRO programmers did not have experience with our standards and assumptions used in reporting. As a result, a large amount of rework was required.

Because of these problems, we used a contractor for 1 month in-house to work on tables. This allowed constant communication between the contractor and the Boots safety group, and involvement in the review of tables

and produced tables of higher quality. During this table generation period, however, we were still building, reviewing and reworking databases.

After the initial stage of the project was complete (the submission of the safety report including tables to the FDA), work on Phase 3 started. This included the additional studies which had not previously been integrated. We continued working with the same CRO to build databases and added one contract programmer in-house. Our strategy changed from getting final data from the CRO, to getting the initial databases from the CRO and modifying as needed in-house. This process went much smoother than work done completely off-site.

A second CRO group worked off-site on Phase 4, producing patient data listings for each individual study. This group had worked with our department over a long period of time and was familiar with our reporting practices. They required less interaction, because of the nature of the work and the long-term working relationship established between Boots and this CRO. Again, they were set up with accounts on our computer system, and dial-in access to transfer data and receive messages. This group was not used to integrate data or program tables, because they did not have the flexibility in staffing required to meet deadlines.

In general, the project was successful. Because of the lack of resource planning in the initial stages and unanticipated problems with the data,

some deadlines were moved and the CRO budget and utilization was much greater than planned. We experienced initial delays because of the 'learning curve' experienced by the contractors. Managing the group and the information transfer was a full-time job most days. It was difficult to convey ideas and assumptions by documentation and telephone only, without interaction from the CRO at planning and development meetings. From this experience, management saw the need for a formal group to develop the safety report, and changed the organization of the programming group. We also decided to use in-house contractors for these types of projects to avoid some of the same difficulties. In addition we experienced difficulty with an entry-level contractor, spending too much time training and coaching when experienced programmers could have been utilized.

Currently, we have 3 in-house contract programmers and 2 permanent programmers working on a similar project with a new drug and there are no plans to work with off-site programmers. We have contractors with more experience than permanent programmers, so, some of them act as project leaders in a particular area. For example, one contractor acts as the lead programmer for table production, with a permanent programmer assisting. We also hold informal seminars for the group, and allow the contractors to teach programming skills the others may not have.

We tend to treat contractors as permanent employees. When we have

SAS or other in-house training, they attend. They work the same hours and get the same holidays. Our original contracts are for a 6 month period, with a 30-day probation period. During this probation period a contractor may be terminated with little notice. After the probationary period, the CRO requests a 30 day notice. This termination policy is valuable if projects are canceled, priorities change or contractor skills are not adequately developed.

Telephone screening of each candidate programmer is a must. If possible, schedule a trip to interview several candidates. You want to carefully question each candidate about the extent and nature of their previous experience as well as how current their programming skills are. Because of the nature of their business, CRO's will emphasize your requirements on a resume, but it is up to you to ensure the candidate is right for the job. Also, ask about their desire for permanent jobs. If jobs come open, will they be interested? This will save many hours of training, because they will already be familiar with the job. Remember, **you** are the customer here, and **your** needs are the most important.

When contractors are off-site, frequent and meaningful communication must occur on a regular basis. Telephone calls, faxes and e-mails should be constant, to avoid misunderstandings. It is helpful to have face-to-face meetings occasionally to be sure that communication is effective and that all questions are answered and understood.

When deciding to send a project out to a CRO, it is important to manage and

monitor the project properly. Someone in-house must remain the project leader of the project to ensure that those inevitable (last-minute) changes can be done. We have had a particularly difficult time 'deciphering' a project that was completely handled by a third CRO, from beginning to end, with minimal company involvement. Determine and establish quality controls on a project early, and assess the progress at project milestones.

CONCLUSION

Our projects using contractors for SAS programming have been successful. In a swiftly-changing industry with profit-influenced deadlines, the flexibility and innovation provided by CRO's assisted me in meeting management goals. CRO's are a valuable human resource to be considered when planning projects that involve SAS programming.

If you have any questions or comments, the author may be contacted at:

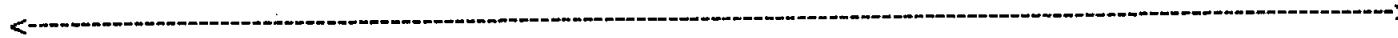
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FACTORS WHEN PLANNING TO USE CONTRACT RESEARCH ORGANIZATIONS

REPETITIVE, STANDARD ASSIGNMENTS

CUSTOMIZED, LONG-RANGE PROJECTS



Small, fixed group

CRO GROUP SIZE

Flexible size staff

Low level explanatory communication

DEGREE OF COMMUNICATION
REQUIRED

High level explanatory
communications and ideas

Well-developed documentation of
standards and examples

TYPES OF COMMUNICATION
NEEDED

Face-to-face meetings and ever-
changing standards
documentation

To check that project meets standards
and is accurate

QUALITY CHECKS NEEDED

To check application of standards
to unusual circumstances and
that basic assumptions are
accurately applied

Off-site may be adequate for long-term
projects, but you may lose consistency
if personnel at the CRO changes

LOCATION OF WORK

Off-site requires additional time-
consuming management and
resources. On-site provides
higher communication opportunity
with the disadvantage of space
and equipment (computer)
constraints