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How to handle decision making in the CRO / sponsor relationship in matters that require expertise

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ABSTRACT

Programming for clinical trials requires an ever-expanding skill set. Many of us are working on trials with team members from both a sponsor company and one or more CROs. In order for these partnerships to be both efficient and successful it is important to assess what expertise exists within each organization and at what level it can be found.

INTRODUCTION

In this presentation I discuss how to handle decision making in the CRO / sponsor relationship in matters that require expertise. The examples I use reflect my experiences as a SAS programmer and an SDTM expert. The solutions I suggest apply to many other situations

I will go over:

Why this is important

How to assess expertise needs and resources in programming teams

How to act on the results of this assessment

WHY THIS IS IMPORTANT

Programming for clinical trials requires an ever-expanding skill set. Many of us are working on trials with team members from both a sponsor company and one or more CROs. In order for these partnerships to be both efficient and successful it is important to assess what expertise exists within each organization and at what level it can be found.

No one individual knows everything needed to program successfully in an environment with complex, interdependent deliverables. Requirements change over time and differ between regulatory authorities. Expert review may be needed, but timelines can be derailed if it is done too late in the process after key decisions have already been made.

In a perfect world our teams would:

- Have members who collectively have expertise on every topic that needs to be addressed
- Agree on who has that expertise and how they will collaborate
- Those members would communicate decisions clearly and in a timely fashion

In our daily work our teams sometimes:

- Do not have an expert on an important topic
- Have an expert who is not communicating decisions clearly or in a timely fashion
- Have multiple experts who are not collaborating well
- Are slow to recognize that this might be a problem

ASSESS NEEDS AND RESOURCES

The first step is to assess the expertise needs for the project and existing resources in programming teams. As the team is deciding what deliverables are needed on a project, consider what skills are needed as well.

For example, studies with a PK component require creation of SDTM PC and PP domains and collaboration with the PK scientists.

When you have identified the skills needed, assess how robust the team's expertise is. Identify team members with expertise about specific items in the team either at the CRO or the sponsor company.

For each individual consider:

- How much experience have they had with that topic?
- Is their experience relevant?
- Are they working for the sponsor, a primary CRO, a secondary CRO?

In the end, decision making rests with the sponsor, but team members from CROs may have more relevant experience

For example, I have a depth of knowledge about SDTM, but not a lot of experience with device domains. I would defer to a team member with experience with those domains.

Identify areas of uncertainty such as:

- Planned submission to a regulatory agency the team has no experience with
- An indication that team members have not worked on before
- Working with a new version of CDISC standards
- Unfamiliar tasks, such as creating BIMO tables

Decide if gaps in expertise should be addressed by the CRO, the sponsor or jointly.

For example, my company is a US subsidiary of a Japanese company. For a drug program that was planning a submission to the PMDA, we arranged to meet monthly with our data science counterparts in the parent company. We recognized that they had far more experience with PMDA submissions than team members from our CROs or our company.

ADDRESS TEAM NEEDS

For issues where the team has expertise, if an expert is easily identified, have them answer related questions for the team. If there are several, consider having them meet separately to make decisions and report back to the team.

For example, I am fortunate to be working with some very knowledgeable SDTM programmers from the CROs working on my current studies. We have been collaborating very efficiently by having ad-hoc meetings with just the leads from the sponsor and CRO companies to address issues raised by the team and then reporting back on our solutions.

Multiple experts may get bogged down if they disagree on an approach. Have them clearly state the alternatives to the team with risks and benefits so the team can decide.

For issues where the team needs additional support, evaluate whether it is available within the CRO or sponsor organization. If yes, arrange to escalate issues to more experienced staff in either organization. This has the added benefits for the expert:

- Recognition of their expertise
- Opportunity to educate
- within and beyond their organization

Experts may be juggling too many tasks and be slow to give feedback. The team needs to share timelines and set clear expectations of when answers are due. The goal is to get answers early enough to avoid having to do time-consuming or costly rework of dependent deliverables.

For example, I have worked on numerous studies in which SDTM was created and ADaM and TLF deliverables were programmed using the SDTM data. Senior review and/or conformance checks were done much later. SDTM was revised based on the review, necessitating revision to production and QC programs and esub components. If this occurs too late in the life of the study, it can be disastrous.

Experts may not communicate clearly. Their feedback needs to be clear enough for non-experts to understand what decision was made and what actions should be taken. I prefer to capture my feedback on my own custom comment log tailored to my skillset. It has pages for each deliverable I am responsible for and columns on each page tailored for that deliverable.

If no experts are available:

- Make sure senior staff outside of the team are aware of the knowledge gap and the risk it carried
- Consider identifying team members to research specific questions

Opportunity to develop expertise

- Hire outside consultants for certain tasks

For example, I worked for a CRO on a project where the sponsor hired a consultant from a different CRO to review submission deliverables being developed by multiple study teams. My company eventually added an option for their clients to address that need. They could request review by senior in-house experts of submission deliverables as part of their contracts

CONCLUSION

We all have great skills, but none of us know everything needed to run successful studies. It is important that we keep this in mind as we plan our work. Considering what topics require expertise and planning how to involve people with the needed expertise is vital to the success of our study teams. My goal is presenting these recommendations is to help teams assess expertise needs and resources and act on the results of that assessment

CONTACT INFORMATION

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