



White Paper
**Clinical Trials: The art of
site management**

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Clinical trials monitoring is often considered as limited to therapeutic area knowledge and monitoring experience, ignoring the vital part of the process - the soft skills, or the ability to work with people. Building proper work relationship with healthcare staff working on clinical trials could affect the project timelines, quality of work and Sponsor Company's image. Therefore, more attention has to be paid on providing guidance and training the monitoring team so they can possess adequate soft skills and be able to face the challenges working with people who do not operate under their authority.

This white paper will discuss practical approaches in building work relationships with healthcare staff based on our company philosophy and experience.

Introduction

“Team work” and “collaboration” are the most common terms used by management teams when it comes to managing people. However, teamwork and collaboration are not easily applied when the Sponsor's representative have to work with healthcare staff who is under resourced, experienced high turnover and not legally obliged to respond to urgent requests. Still the outcome of lack of proper work relationship with healthcare staff could be significant: high turnover, missed deadlines, decline in quality of work, frustration, negative image of the Sponsor Company, etc.

Constantly changing business environment has put extra pressure on work relationships between Sponsor Companies and clinical trial sites. Part of this problem is the reduced monitoring requirements and delegation of more tasks to the under resources and already busy sites. As a result, the work relationship between monitoring team and the sites is getting more and more complicated and challenging. The demand for soft skills and ability to work remotely is more important than ever in order to meet the project goals. And yet many monitoring teams are not prepared and continue operating in the old-fashioned way.

Although in some occasions the approach “do as I say” may work, it is generally inefficient when interacting with people, who are not company employees and under direct supervision. Simple improvements in communication and different approaches could lead to substantial progress in building proper relationship with the sites.

1. Mind your emails

It is a common rule in business email writing to answer the following questions: Who, What, When and Where (if applicable). However, there are 2 other questions, which are often missed in the communication - Why and How.

In the busy corporate environment, we usually forget or we lack time to explain why we are asking something to be done urgently. In reality, even one sentence explaining why the task is important to be finished within the requested deadline could improve compliance. The reason behind is - people are more likely to support you if they understand the rationale behind specific request and in return allows them to prioritize important activities.

Often ignore, How - is another important question that we have to consider when preparing our e-mail. Presuming that people know how to complete the task could lead to miscommunication and delays. The reason behind these issues is - people often do not know how to do something but are concerned that it will be seen as an unprofessional act. As a result, they prefer to take the task for granted. Therefore, providing guidance on how to perform specific task could save lots of time, prevent confusions and further correspondence.

Answering the questions How and Why will not just improve communication but establish a better professional reputation of the monitoring team and help to build the trust of the healthcare staff.

Another important aspect of e-mail writing is, structure. Clear and well-structured e-mails make it easier to follow-up requests. This could be achieved by trying to limit the amount of requests per e-mail and separate them clearly using new paragraphs and bullet points. Often it is better to send 3 separate e-mails instead of lengthy ones. One reason could be - when people are busy they tend to ignore lengthy ones especially if it needs much time to read and understand. Moreover, multiple requests per e-mail could cause confusions and missed follow ups on important tasks.

2. Empathy

While some sites have dedicated clinical trials teams in majority of the cases, clinical research is an extra work to the daily tasks of the healthcare staff. Therefore, the ability to listen and show genuine understanding to their challenges are important part of building proper work relationships. This also allows obtaining knowledge of the current situation at the site and help preparing contingency plan.

Showing understanding and willingness to listen could have long term benefits for the monitoring team as they will obtain important information about the site and will allow them to identify easily if the site needs more support.

3. Offering support

Often monitoring team cannot provide significant extra support to the site, however it is important to show willingness to do so. Healthcare staff is well aware of the support limitations but always welcome the efforts. Discussing site issues and possible resolutions could be beneficial for both parties - site staff and monitoring team.

Proactive approach of the monitoring team and acting as a mediator between different departments could have significant effect on establishing work relationships with the site.

4. Adapt

Living in a global world requires to work with different cultures and in order to be successful we have to take these differences into consideration. Another aspect is the personal differences, for instance, the ability to work under pressure, to learn new technologies, to perform tasks in a timely manner, etc. All of these show the need of individual approach to establish good work relationship with healthcare staff. “One fit all” approach is not adequate in this case.

While constantly chasing deadlines one should not ignore the fact that healthcare staff is already under a lot of stress and the monitoring team should attempt to find efficient way to work with site staff.

5. Appreciation

In the dynamic work environment showing appreciation has become rare and often ignored. Presuming that people do something because it is their job does not eliminate the need of appreciation of their efforts. In reality showing appreciation is directly linked to people’s motivation and not acknowledging their efforts could damage significantly the work relationship with the site.

Always praise people who have been proactive and have gone extra mile to achieve the targets and deadlines.

6. Conflicts management

Working under pressure of constant deadlines could result in tense relationship with healthcare staff. Direct conflicts could significantly jeopardize the relationship with the site. Therefore, it is best interest in all parties involved to find solution to their problems and work together to meet the project timelines. It is easy to allow the pressure to destroy all efforts of building work relationship with the site.

7. Expertise

The knowledge and expertise of the monitoring team is another vital aspect of building good work relationship with the sites. This knowledge should not be limited only to the protocol and therapeutic area but should also include regulatory, country and site-specific requirements. Sites should be able to rely on monitoring team as professional and trusted source of information. As part of the process it is important for monitoring team to acknowledge mistakes and be honest when they do not have the answer to the question.

8. Try walking in my shoes

Another important part of the interaction with healthcare staff is the ability to see their point and the reasons behind their requests. This is especially critical when the requests are related to patient’s’ treatment and standard of living. Monitoring team should not ignore the fact that healthcare staff always act in the interest in the patients and that sometimes specific cases may not be detailed in the study protocol. Monitoring team should adequately present these cases to science team.

Conclusion

Although working with people is a challenging task and these approaches may be seen as time consuming but in reality they can provide basis for a long-term and successful relationship with healthcare staff. A time investment, is worth better.

In contrast lack of engagement with healthcare staff and “do as I say” approach could alienate people and make them less cooperative, which inevitably will have effect on meeting project deadlines and in reality will consume time.