PharmaSUG 2022 - Paper LS-101

How Clear Communication & Expectations Improve the CRO – Sponsor Relationship: the CRO Perspective

Corey Evans, and Samantha Kennedy, LLX Solutions, LLC

ABSTRACT

The Sponsor – CRO relationship is a critical one in the life cycle of clinical trials. Fostering a positive relationship through clear communication as well as clear expectations and timelines is critical in maintaining harmony. A relationship that lacks any one of these key characteristics, whether it is communication, expectations, or no clear timeline can quickly lead to tension and frustration on both sides. Minimizing frustration and tension as much as possible is paramount in preserving a good relationship, which may reduce study team turnover, and will hopefully lead to a long-term relationship between the Sponsor and CRO.

INTRODUCTION

In an ideal world, inter-company relationships would be frictionless and there would never be any speed bumps throughout the course of the relationship. Unfortunately, we do not live in an ideal world. There are always instances of miscommunication, frustration, and mistakes as two businesses work together, especially early in the partnership as both sides learn how to work with each other. This paper will discuss some of those hurdles, which from a CRO perspective, seem to occur frequently. This is not a comprehensive list by any means, only problems that we, or our colleagues, have seen come up while working for a CRO. We hope that you can take some tips from this paper and apply them to your own company's relationships, whether you work on the Sponsor side or on the CRO side. The single most important takeaway from this paper should be to remember that the people on the other side have lives outside of work & these people have feelings. Be kind & considerate as much as possible. Getting the work done in a timely fashion with minimal mistakes is important to the relationship. However, if one side feels like they are getting the short end of the stick, you will never have the ability to work seamlessly together on future projects.

MANAGING TIMELINES

THE PROBLEM

Project teams within CROs, especially smaller CROs, tend to manage multiple projects at any given time. Managing potentially competing timelines can be a headache since the timeline for one client has no bearing on the timeline of another client's project. Timelines can change quickly either from delays within the study (experienced recently due to the Covid-19 pandemic) or the need to accelerate a timeline due to internal pressure within the client company. These shifts are generally unpredictable, but with good planning and communication, alterations to the project timeline can be handled. The scope of the project might change if a client needs to incorporate ad Hoc requests, which can impact timelines. Lastly, delays on either side can have a cascading effect on project timelines; a one-day delay on an item affects the schedule downstream. A single day delay either needs to be made up somewhere or it gets pushed into every subsequent item on the timeline.

THE SOLUTION

All the above problems can be mitigated with clear communication of the project scope, ongoing communication throughout the study, the (tentative) timeline, and how additional work requests or delays will be handled with respect to the project timeline. During the kick-off meeting, all these points should be brought up and discussed. If there is a delay in delivering an item, whether that be on the Sponsor or the CRO side, how will this be handled? Ideally, the timeline of other items would be compressed, and the overall project deadline would not be affected by a delay. However, this may not be possible. Having a clear plan in place for these instances is critical so that one side does not feel rushed or pressured to deal with the consequences of the delay. If there is a request for additional work or ad Hoc requests, what is the lead time that the CRO needs to effectively handle these items? At what point will the scope of the additional work warrant an adjustment to the timeline? The solution will vary for every project and team. Some teams may have the capacity to handle a fair amount of additional work with no timeline adjustments, while another team may only be able to handle a small amount of additional work within a project. If outside pressures force a timeline change, is the CRO consulted on the timeline update to determine if adjustments can be made? Including the CRO in this conversation allows the CRO to feel heard and can reduce the tension brought on by changing the timeline. Bringing these questions up at the start of the project can save both sides from the frustration and confusion that these problems may cause down the road.

SPONSOR FEEDBACK

THE PROBLEM

Over the course of a study, there is time built into the timeline for the Sponsor to review draft versions of datasets, outputs, and other documentation before the final delivery. Some comments can be as general as updating a repeating footnote across many tables or as specific as updating programming logic. Feedback can be provided by the Sponsor in a variety of ways including verbally in a meeting, over email, or in a tracking document. This puts pressure on the CRO to juggle all feedback and incorporate it into the dataset or TLF updates without missing any details. Additionally, it is common that several reviewers provide comments back to the CRO, each with their own comment style, leading to feedback that lacks organization and clarity. There are also times where comments such as “Observation count does not match” or “Cannot match values” may be provided to the CRO that are too vague to figure out what actions are desired. The CRO programmers are left to decipher what is meant by comments that are not robust. If the CRO needs to reach back out to the sponsor for clarification, time is lost during back-and-forth communication to determine a solution for the issue.

THE SOLUTION

Feedback is best received in a detailed, organized way. At the beginning of the study, the Sponsor and CRO should agree on how comments are going to be shared during the duration of the relationship. The most efficient approach is through an excel file communication log or a shared online workspace. This log will serve to track updates. During the review process, pointing out specific observations or subjects is extremely helpful for programmers to focus on when making updates. Including screenshots of mismatched records also allows an issue to be quickly diagnosed. The more details the better! From the sponsor side, all comments should be coalesced into one file with the columns: initials of the reviewer, issue found date, dataset or output name, and specific comment. The excel should be reviewed by the project lead on the sponsor side to check that there are no repeat or contradictory comments and that the wording makes sense. The CRO will then add the programmer’s initials, date addressed, and response or action taken for each line of feedback. The log will be reviewed by the project lead at the CRO to ensure that all comments were addressed before the updated communication log file and deliverables were sent back to the Sponsor. It is suggested that the last column of the excel sheet track whether the comment is “Open” or “Closed” as indicated by the Sponsor. By the final delivery, all comments should be “Closed” indicating that they were reviewed and approved by the Sponsor. Ultimately, the goal is to reduce the number of rounds of review and document all changes.

MAKING MISTAKES

THE PROBLEM

Mistakes on both sides are inevitable. Whether it is a programming mistake, a mistake in review, or mistake in some writing aspect of the project, it is important how each side handles and communicates with each other to resolve the problem. In a perfect world, mistakes are all ironed out during the review process and dry runs leaving the final run as a seamless delivery. Unfortunately, if dry runs are not comprehensive enough, this is not always the case. The following are a few real examples we gathered to illustrate this point:

1. Our team had 3 simultaneous projects that went through several dry runs. All the issues had been ironed out, or so it seemed. During final delivery, the client used their own log check macro on our SAS program logs and they determined that, by their company standards, our logs were not clean. From our company standards and log check macro, they were clean. At the last minute, this discrepancy had to be resolved at the expense of adding additional working hours for our team.
2. During a routine monthly update of SDTM datasets, an oversight by the individual running the programs resulted in a previous extract of data to be used. The Sponsor's programmer noticed the mistake and the CRO promptly resolved the problem within a couple of hours of the notification. Despite the quick fix, the Sponsor's programmer escalated the issue to senior management. Understandably, there was some irritation on both sides - the client did not think this mistake should have happened, and the CRO was frustrated that despite the quick fix, a big deal was made of it.
3. For the first draft of ISS (Integrated Summary of Safety) outputs, our team delivered over 1,000 TLFs and scheduled a meeting to review them. During the meeting, an issue impacting approximately 1/6 of the tables was identified and the solution was to update the programming logic. Our team spent about a week incorporating the changes. The day before delivering the updated outputs, the client presented a new finding that impacted 1/3 of the adverse events outputs. After an extensive discussion, everyone agreed that further updates were needed. The client was very understanding that incorporating these updates would delay the delivery of most of the outputs. The client and CRO compromised that the unaffected outputs would be delivered as scheduled and the impacted outputs would be delivered a few days after.

THE SOLUTION

The solutions to the above examples are simple when looking back at the situations:

1. The dry runs should have included a review of the SAS program logs so that the client could check internally that everything was up to their standards. Additionally, communication from the start of the project about the clients' standards for clean logs would have saved everyone a lot of trouble.
2. To avoid making this mistake, the CRO should proceed carefully when receiving a new data extract to ensure that every detail is checked and accounted for. The sponsor should have evaluated whether this situation warranted being escalated given that it was resolved quickly.
3. These significant issues could have been discovered prior to the first draft delivery if there had been more communication during the creation of the SAP (Statistical Analysis Plan) and TLF shells as well as a more detailed review of the datasets. Despite stress caused by finding the mistake, the overall response from both sides was positive and compromising, allowing everyone to feel okay with the outcome.

It can be difficult to act calmly in the moment when someone makes a mistake that impacts your work, timeline, etc. But in that moment, you need to consider the other side; if you made the exact same mistake, or a different one of equal magnitude, how would you want someone to react? Hopefully, in a calm and understanding manner. Reacting negatively to mistakes may lead to animosity. The mistake maker might be feeling shame and regret. There is no need to pile onto that. Even though the relationship between Sponsor and CRO is a business relationship, at the end of the day we need to remember that the individual on the other side is a person too. We should try to show some understanding of the situation.

PERSONNEL TURNOVER

THE PROBLEM

Given that trials have long-term timelines, the employees working together at the start of the Sponsor/CRO relationship may evolve and change over time. Turnover on either side is expected but may cause tension or confusion if not handled thoughtfully. A new member may propose ideas from their past experience, which may not apply based on previous study decisions made before they joined the team. It can be frustrating to go back over details settled on in the past when those same issues are brought up again.

THE SOLUTION

It is the responsibility of the Sponsor or CRO to update each other when someone leaves or joins their respective team. There should be a formal introduction and a description of the role they will be fulfilling. While the team with the new member is responsible for providing the details about the study to their new coworker, everyone should practice patience when the new member asks questions or provides concern. Ideally, when a new team member is brought on, any questions they have about the project should first be brought up internally, and then can be brought up in inter-company meetings if necessary. Logistically, new email chains and scheduled meetings must be updated for the personnel switch. The goal is to minimize the impact that bringing a new team member on has on the overall project flow.

COMMUNICATION/WORK OUTSIDE BUSINESS HOURS

THE PROBLEM

Communication outside normal business hours is an unavoidable aspect of the pharmaceutical industry. Additionally, the increase in work from home time over the past 2+ years has blurred the lines between work time and family/personal time. Leaving your laptop in the home office is different from leaving your laptop at the company's office for the night. Study unblinding, FDA requests, and various other tasks may need to be completed within small windows. The nature of those tasks may require work/communication outside of the usual business hours. We are becoming increasingly conditioned to expect rapid replies due to the advancement of technology. However, regular communication with the expectation of a same day response, whether by phone or email, outside of business hours should be addressed to be respectful of everyone's time. Can that email you are going to send out at 7pm or later wait until tomorrow morning? And if not, expect not to hear back until the following (workday) morning.

THE SOLUTION

Setting clear expectations and boundaries for appropriate communication/work outside of normal business hours is important to establish from the beginning of the Sponsor/CRO relationship. Yes, some projects may require working over the weekend or on weeknights for certain circumstances. As much as possible, these instances should be laid out within the timeline and agreed on ahead of time by the Sponsor and CRO. Additionally, projects may be transferred to new teams within a CRO, and the boundaries previously set are different from the new team's expectations. In this case, a meeting to discuss/reset those expectations and boundaries is imperative. This exact situation happened to our team: We had a client transfer to our team. Previously, the point of contact for the client would email and call the previous team lead whenever an issue arose, regardless of the time of day. After being transferred to our team, late night contact persisted. Once a meeting invite was sent unexpectedly for 8pm with no advance notice. After some further issues, we called a meeting to discuss communication outside of business hours, especially for items that could absolutely wait until the morning. The meeting was extremely helpful and overall communication with the client improved dramatically.

MEETING ON SHORT NOTICE

THE PROBLEM

There may be a few urgent times when a meeting is needed at short notice. In those instances, the courteous approach is to ask the other side for their short-term availability and meet at a mutually agreed time. It is unprofessional to send meeting invites for a date/time without consulting the members required. It can cause tension in the meeting if the call was forced without considering everyone else's time. Spontaneous meetings do not allow for preparation and often lead to an unproductive conversation.

THE SOLUTION

Before creating a meeting on short notice, it is important to consider two questions: Can this be communicated over email? Is this discussion truly urgent? The response to these questions could help guide you to the next step. Only if the response to the questions above are "No" and "Yes" respectively, should a short notice meeting be considered. In this case, it is recommended that an email be sent to the people needed that explains some details about the issue that needs to be discussed and potential meeting times. Only once a time for the meeting is confirmed by both the Sponsor and CRO can the meeting be created on each other's calendar. Remember that it is important to respect everyone's time, so even if a meeting is called on short notice, it should be quick and run efficiently. Often meetings are called to discuss specific details that require screensharing to view datasets or programs. If the issue were shared over email, the programmers would have time to investigate the issue and prepare an explanation for the meeting rather than attempting to investigate the issue during the meeting. One way to reduce the need for unplanned meetings is to set up a scheduled meeting that brings all members together routinely. Weekly or bi-monthly meetings are useful to put on the calendar so that there is a designated time to discuss the study. As deadlines approach, meetings can be scheduled to occur more frequently as needed. If there is nothing to discuss, a meeting can easily be cancelled.

CONCLUSION

Over the course of the CRO/Sponsor relationship, there will be many circumstances that cause tension. Handling those problems in a positive manner allows both sides to have a favorable outlook on the relationship. The pharmaceutical industry is fast moving, and there always seems to be a bevy of projects to work on. So, whether you work on the Sponsor or on the CRO side, if you find a good company to partner with, do your best to preserve that relationship through open communication and clear expectations. At the end of the day, we all want the same thing; high quality work to be delivered on time and for the project to reach its goal. You are going to come across hurdles along the way, and hopefully this paper has given you some ideas on how to handle those situations. As much as possible, be kind and understanding.

ACKNOWLEDGMENTS

We would like to thank our colleagues at LLX Solutions, LLC for their helpful suggestions on points to include in this paper.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Corey Evans
Corey.Evans@llxsolutions.com