

You down to QC? Yeah! You know me!

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Abstract

The successful delivery of clinical trial-related analysis datasets and outputs are heavily dependent on an efficient and fluid relationship between the Production Programmer, QC Programmer, and Lead Statistician. Given the increasing complexity and rapidity of project delivery, coupled with multiple regulatory standards that must be adhered to; a sound strategy and clear model of communication are paramount to a study's overall quality. Understanding the pressure and stress associated with project deadlines and nuanced sponsor requirements will help navigate around communication shortfalls. Further understanding of each role's subjective nature will help outline a succinct archetype to achieving high-quality results with minimal headaches. The three main barriers of communication between Production Programmer, QC Programmer, and Lead Statistician are vague understanding of client expectations, overall study comprehension and the rarely considered, Ego factor. Tackling these issues can seem insurmountable, however, we have constructed a roadmap to alleviate the friction that may occur during the delivery process. Some of these points include thorough ongoing communication with study leadership, purposeful and engaging meetings to eliminate opacity of overall objectives between team members, and finally, an effective way to universally communicate between any type of team member you may encounter.

Ongoing Communication-

Tools/Resources:

The first form of clear communication, and also highly underrated, is hard documentation. Earnestly adhering to these documents, and pointing out any lack of clarity with the client, develops a deeper understanding of the study requirements. Additional helpful practices include: continuously updating specs for data modifications, tracking clients' desires via shells for output deliveries, and applying traceability to programs via trackers.

All this effort will be in vain unless the changes to documents, such as output shells, dataset specifications, and trackers, have been directly communicated to all affected parties. In whatever manner is most preferred, whether it be emails, messages or calls. A continuous paper trail throughout the study's lifetime keeps everyone on the same page, literally. The flexible nature of a study makes it essential to continuously update and date mark the documents in real-time. This will ensure details aren't left out later, meanwhile, the teams will have roadmap and blueprint of what needs to be done. In a perfect world, there would be no changes to a study after the initial draft is made, but the world isn't perfect, and having the flexibility to change is made easier with clear documentation.

Understanding Client Expectations:

In a successful working relationship, communication is key; and communication is built on trust. Having transparency, a clear voice and defined goals are the pillars to a solid foundation

of a study. Establish trust in the very beginning with kickoff meetings between lead programmers, statisticians, and client's heads. This initiative will help frame the vision of the client and ultimately help patients by increasing productivity and ease of negotiating the many obstacles in this fast-moving and volatile industry. There will be stress. There will be unexpected changes; however, teams are better suited to navigate these tumultuous times if they are equipped with all the needed tools and skills for effective communication.

Standards:

All members should make it a top priority to have a firm understanding of all documents involved in the study outline. These include statistical analysis plans, case report forms, and dataset specifications. Building a comfortable knowledge base when it comes to ICH, CDASH, and CDISC standards. It takes everyone involved in a study to remain vigilant and solve any concerns early on rather than later, where time is short and the damage is great.

Study Comprehension:

Timelines:

A firm grasp of a study starts with the timelines. It is paramount that realistic timelines are constructed, heard and understood. Any possible shift in deadline should be quickly communicated with a real push backdate. Unforeseen events like data issues happen, so having internal and external deadlines help predict for those bumps in the road. The objective must be clear from the client, programmer, and statistical perspectives. All team members actively express concerns in a study's nuanced criteria that will contribute to the overall awareness of any irregularities and outliers that may arise.

Expertise:

Utilizing expertise within the team helps build efficiency. Expertise in particular therapeutic areas will help enhance the quality and validity of study findings and most importantly, assist patients all the sooner. Recognizing and being mindful of data irregularities, anomalies, entry errors will assist in overall study success. We must remember that the correct conduct of a study further contributes to the ensured safety and efficacy of the therapies and medical devices being administered.

Engaging Meetings:

When a meeting can be as effective as an email, it is not a good meeting. Meetings should be pulling everyone in, not just one person talking at a group. Effective by being efficient. Not longer than they need to be, while also not missing important information that needs to be heard. How is that magic equilibrium met? Preparation. Having an outline, especially if there's a lot of topics to be heard. Humans want structure, and a simple outline attached to the meeting invite lets people know what's going to be conveyed and gives all attendees the right mindset going into the meeting. This is a time where unit cohesion is revisited and built upon. Stay on topic and for every problem you bring, come equipped with a solution. This mentality will ensure things are on track and moving forward. When the team is engaged and working in tandem, goals can not only be met, but exceeded. "Careful with teamwork, you just might win."

Implementation:

Removing the Ego:

In the professional realm, there will always be people of varying levels of expertise, skill, and experience. Being able to communicate effectively through these different levels can sometimes be difficult, and friction inevitably happens during a study. It needs to be brought to light on how to use this friction to your advantage. When working with someone of a lower level, automatically assuming you are correct is an easy trap to get into, and can sometimes lower the quality of the finished product, for example, when differences happen between production and validation. A coworker of ours recalls a moment when he was an intern, working on the other side of a highly experienced, and respected programmer. He found an issue with the programmer's output and was nervous to bring it up because he automatically assumed his side must be wrong. While this might be a correct assumption sometimes, bringing up the difference anyway will at least provide a teachable moment, but at the same time ensure the correct final output will be made. Being the experienced person in this situation can also be easy to get stuck in the mentality of “my side is correct, your side is wrong”. Removing the ego while taking on each discrepancy will improve the team, because the output will be at its highest quality, and less experienced team members will be put in a better place to learn.

Navigating Egos:

Understandably, we can only take charge of ourselves. However, there may be those who aren't working from this same perspective of unit cohesion and synergy. Begin to work towards a win-win result. Be of service and see that most are eager to serve, work to only bring solutions and not problems, work from a place of sincere inclusion. At the end of the day, you will see you have found a teammate. If the fear is that the two-way street is more “high way and bike path”, understand it is for the successful delivery of the study, not the current disposition between to coworkers. Work to discuss the differences you all share and get to a working relationship that is productive and efficient.

Delivery of Study Highest Priority:

Having a production and validation side in the studies process requires effective implementation of communication. While this is happening, always inquire within yourself is this contributing to the overall success of the study? Has every possible alternative been attempted? Everyone comes from different backgrounds. Respect, acknowledgment of our shared ownership, and a unified goal of a harmonious workplace will set the tone for timely and successful study delivery. When that shared goal is fresh in mind and the focus is on creating solutions as a contributor that shared value will show itself in the work we do. We differ in the workplace, sure, but what we do share is the vision of producing therapies and new medical discoveries contributing to the greater whole.

Conclusion

In an industry with strict deadlines, precise measurements, and many moving parts, keeping everyone involved is a requirement for a succinct game plan. Ongoing communication between team members makes sure that there are no loose ends. Keeping documents current as the study continues makes sure that there will be no unpleasant surprises at the of the delivery and helps resource management for companies with numerous ongoing studies. Deal with problems as they arise and trust your team to respect your input and intentions. Weekly meetings to discuss timelines, potential data issues, or checking on peoples' workload is a great way to implement these strategies, and remember communication is key. In an industry of introverts, sometimes it can be overwhelming to take over meetings and speak up when problems arise, but sometimes biting the bullet will save more stress than waiting until the end to let someone know of a problem. A professional workplace will respect each team members' questions and concerns, so if you ever feel uncomfortable about addressing issues, always have someone you can go to that may be able to help. Line managers, senior programmers/statisticians are a great resource to have for moments like these. All in all, it takes a certain mindset and a paradigm shift in every project member's perspective to see a successful delivery from start to finish. This requires tenacity, resolve and a genuine pursuit of what is true and valid, meanwhile, if the maxims are kept at the forefront of every endeavor the results will speak for themselves elevating morale and quality to all-time highs.

References

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Hunt, A., Thomas, D. 2000. *The Pragmatic Programmer from Journeyman to Master*. Boston, MA. Addison-Wesley.

Recommended Reading

- *Crucial Conversations*
- *The Pragmatic Programmer*

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