

Optimizing Collaboration and Quality Control in Outsourced Statistical Programming

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Introduction

- Importance of outsourcing statistical programming in clinical trials
 - Enhances efficiency
 - Reduces costs
 - Provides access to specialized skills
- Collaboration between Pharmaceutical companies, CROs/External Vendors is crucial
- Many challenges that's needs to be improved to enhance the collaboration
 - Varying quality standards
 - Communication gaps
 - Differences in operational procedures
- The success of collaboration depends on how well the challenges are navigated
- Objective of the presentation
 - Explore challenges in outsourcing statistical programming
 - A roadmap for efficient and quality-focused partnership with CROs/External Vendors

Challenges in Outsourced Programming

- The pharmaceutical industry outsource the statistical programming tasks to CROs/External Vendors
- Outsourced programming offers various benefits. However, it also presents unique challenges
- The challenges need to be understood and resolved to ensure the success of the clinical trials
- Some examples of challenges are listed below:
 - Communication and coordination
 - Cost and budgeting
 - Vendor selection and dependability
 - Performance measurements
 - Variance in quality standards
- Overcoming these challenges not only streamlines the process but also allows firms to focus on what they do best

Challenges in Outsourced Programming (Continued...)

Communication and Coordination

- ✓ Cultural and language differences
- ✓ Time limitations due to regional or major holidays
- ✓ Time-zone differences

Cost and Budgeting

- ✓ Variability in outsourcing costs and annual hours charged
- ✓ Challenges in negotiating fair rates with vendors

Vendor Selection / Dependability

- ✓ Specialized vendors selection based on their domain expertise
- ✓ Ensure timely delivery
- ✓ Adherence to compliance

Performance Measurements

- ✓ Evaluating quality, timeliness, and adherence to KPIs
- ✓ Vendor's employee retention rate
- ✓ Time taken to hire and replace staff

Variance in Quality Standards

- ✓ Over-dependency on the same resources for multiple tasks
- ✓ Gaps in understanding client systems and processes

Optimizing Collaboration and Process

- The structured approach to managing outsourced projects helps to ensure efficiency, quality, and alignment with business objectives
- It provides a clear framework to promotes efficiency, accountability, and high-quality outcomes in projects
- The 6 key steps approach for optimizing collaboration and process are:
 - Define project requirements
 - Established effective communication channels
 - Quality assurance
 - Performance and feedback
 - Collaborative partnership
 - Process improvements
- Curious on how to implement 6 steps approach? Let's Dive in!

Optimizing Collaboration and Process | Step 1

1

Clearly Define Project Requirements

- The vendor must equip the contractor with a clear understanding of sponsor expectations
- Objectives should specify the purpose of statistical programming tasks, aligning them with the broader goals of the project
- The scope outlines the boundaries of statistical programming efforts, helping avoid miscommunication and potential delays
- Key focus areas for defining scope include data collection, CDISC standards implementation, compliance checks, and deliverables such as tables, listings, and figures (TLFs)
- Clearly outlining objectives and scope sets expectations for the outsourcing partner, minimizing risks related to miscommunication, delays, and budget constraints



Optimizing Collaboration and Process | Step 2

2

Establish Effective Communication Channels

- Effective communication and coordination among multiple teams (data managers, statisticians, programmers, etc.) are crucial for the success of outsourced statistical programming projects
- Regular meetings, whether weekly or milestone-based, are essential for sharing updates, discussing challenges, and confirming project timelines
- Weekly meetings provide a platform for important updates, goal discussions, and planning, while milestone meetings allow for reviewing progress and reevaluating timelines
- It's important to review completed work, discuss lessons learned, and adjust timelines or objectives during these meetings
- Establishing a clear escalation procedure is vital for addressing urgent issues efficiently, minimizing delays, and ensuring timely resolution of critical problems



Optimizing Collaboration and Process | Step 3

3

Quality Assurance

- The quality of statistical programming is vital for maintaining trial integrity and regulatory compliance in clinical trials
- Programmers must be qualified with technical expertise and a solid understanding of relevant regulations, such as ICH-GCP standards. They should periodically review SOPs and regulatory requirements to ensure quality and compliance
- The following quality control measures ensure data integrity, accuracy, and consistency
 - Distribute workloads evenly by allowing the CRO lead to assign tasks received from the client according to each programmer's level of expertise. Establish a timeline for both development and validation.
 - Use manual checks or an internal tool to ensure that all required programs have corresponding validation programs.
 - Have the study lead verify the quality and accuracy of the deliverables.



Optimizing Collaboration and Process | Step 4

4

Performance & Feedback

- Implementing performance metrics and establishing a feedback loop enables effective analysis and constructive feedback
- Helps teams adjust their processes and improve communication
- Identifies areas for enhancement and fosters accountability
- Performance and feedback mechanism leads to increased project efficiency, quality, and trust
- Examples of implementing performance metrics and feedback loops can be explored in the next slide



Optimizing Collaboration and Process | Step 4 (Continued...)

4

Performance & Feedback



- **Define Key Performance Indicators (KPIs)**

- Identify the most critical KPIs that should align with the project's goals
- Example of Key Performance Indicators (KPIs)

1

Task Completion Rate : Helps to identify how quickly tasks are being completed than planned

2

Accuracy & Error Rates : To track the quality of programming work by displaying the error rate and revision requests

3

Turnaround Time for Requests : Measures how quickly outsourced team responds and completes task or requests

4

Milestone Achievement : To assess if the project timelines are on track as per the schedule

5

Communication Responsiveness : Tracks how promptly outsourced team respond to the messages

Optimizing Collaboration and Process | Step 4 (Continued...)

4

Performance & Feedback



- **Feedback and Continuous Improvement**

- Organize review meetings with CROs and vendors to evaluate the engagement and progress
- Have both teams weigh in on matters such as clarity on requirements and communication
- Document the key takeaways and actionable steps from these discussions and focus on minor, easy improvements instead of significant changes
- Make sure to assess how effective these changes are in upcoming meetings as well
- Implementing regular review meetings, soliciting feedback, and documenting actionable steps are essential for the success of any project

Optimizing Collaboration and Process | Step 4 (Continued...)

4

Performance & Feedback



- **Diverse Stakeholder Perspectives**

- Involve a broader range of stakeholders in the feedback loop (e.g., end-users and cross-functional team members)
- Diverse perspectives can uncover unique insights and foster innovation
- Conduct stakeholder surveys to gather valuable feedback on project performance and areas needing improvement

- **Feedback Mechanism Variability**

- Incorporate various forms of feedback mechanisms, such as anonymous surveys, and one-on-one check-ins
- Catering different communication styles may encourage more honest and constructive feedback, thereby enhancing team morale

Optimizing Collaboration and Process | Step 4 (Continued...)

4

Performance & Feedback



- **Training and Development Programs**

- Link the identification of performance gaps to tailored training programs
- Offer continuous education and skills training based on the insights gained from performance reviews to empower team members and enhance their competencies

- **Recognition and Reward Systems**

- Develop a recognition program that celebrates achievements in meeting or exceeding KPIs
- Recognizing individual or team contributions helps to cultivate a positive team culture and motivates members to strive for excellence

Optimizing Collaboration and Process | Step 4 (Continued...)

4

Performance & Feedback



- **Follow-Up Mechanisms**
 - Establish a clear protocol for follow-up actions based on feedback
 - Create an action plan with deadlines for implementing changes that arise from feedback discussions
 - Regularly review the effectiveness of these changes in subsequent meetings to ensure accountability
- **Creating Psychological Safety Environment**
 - Encourage a workplace culture where team members feel safe to express ideas, concerns, and failures without fear of judgment
 - A psychologically safe environment fosters open communication, leading to more effective feedback exchanges and innovative solutions

Optimizing Collaboration and Process | Step 5

5

Collaborative Partnership

- Successful outsourcing partnerships in statistical programming depend on mutual trust and effective communication
- Establishing shared goals is essential for collaboration between teams
- Implementing additional strategies can enhance teamwork and overall productivity
- Fostering an innovative and respectful working environment benefits all stakeholders
- A strong partnership promotes full contribution and shared success among all parties involved



Optimizing Collaboration and Process | Step 5 (Continued...)

5

Collaborative Partnership



- **Effective Onboarding Processes**
 - Initiate a structured onboarding process for both teams to familiarize themselves with each other's organizational culture, tools, and workflows
- **Clearly Defined Roles and Responsibilities**
 - Establish clear roles and responsibilities for team members from both sides
- **Regular Progress Check-ins**
 - Schedule frequent check-in meetings to review project status, share updates, and address any emerging challenges
- **Improving Collaboration Dynamics**
 - Implement formal feedback mechanisms to gather insights from both teams about workflows, processes, and overall partnership dynamics

Optimizing Collaboration and Process | Step 5 (Continued...)

5

Collaborative Partnership



- **Mutual Investment in Professional Development**
 - Encourage shared learning opportunities, such as joint training sessions or workshops that benefit both teams
- **Celebrating Milestones Together**
 - Acknowledge and celebrate key project milestones or achievements as joint successes
- **Long-Term Partnership vs. Project-Based Approach**
 - Both long-term and project-based approaches have distinct advantages, and the right choice depends on the organization's goals
 - Long-term partnerships are helpful to clients who want consistent, high-quality results and a strong, collaborative relationship, especially for ongoing or complex statistical programming
 - On the other hand, project-based outsourcing works better for specific expertise for specialized projects, giving them control over budgets and flexibility

Optimizing Collaboration and Process | Step 5 (Continued...)

5

Collaborative Partnership



- **Navigating Growing Pains and Embracing a ‘One Team’ Mentality**
 - Early-stage partnerships often encounter challenges due to differences in work styles and communication, but patience and understanding can strengthen relationships and build mutual respect
 - Embracing a ‘one team’ mindset fosters collaboration and unity, allowing for the free flow of ideas and knowledge that benefits all parties involved
- **Respecting Cultural Differences**
 - Recognizing and respecting cultural differences is crucial for successful outsourcing partnerships, as it enhances teamwork, avoids misunderstandings, and builds trust
- **The Role of Longevity in Strengthening Partnerships**
 - Long-term relationships enhance collaboration by fostering stability, trust, and understanding, which leads to improved efficiency and higher-quality results

Optimizing Collaboration and Process | Step 6

6

Process Improvements

- Focus on refining workflows in outsourced statistical programming to enhance efficiency
- Analyze feedback, quality data, and metrics to identify and resolve recurring issues
- Aim to streamline processes and improve communication among teams
- Optimize resource usage while maintaining the same resource levels
- Enhance overall output over time, ensuring continuous improvement
- Implement regular training and development programs to improve staff skills and knowledge.
- Foster a culture of collaboration and feedback to encourage innovation and problem-solving.



Optimizing Collaboration and Process | Step 6 (Continued...)

6

Process Improvements



- **Analyzing Performance Data**
 - Analyze performance data from past projects, including timelines, error rates, and team performance, to identify where inefficiencies or quality issues occur
- **Implementing Automation**
 - Where possible, use automation for tasks like data validation, code review, and error-checking
 - Automation reduces manual work, lowers errors, and speeds up repetitive tasks, freeing the team to focus on more complex programming tasks
- **Standardizing Procedures and Templates**
 - Developing standardized templates and coding conventions to improve consistency across projects

Optimizing Collaboration and Process | Step 6 (Continued...)

6

Process Improvements



- **Enhancing Training and Upskilling**
 - Provide training and upskilling workshops on new tools and coding best practices to address any identified gaps or meet new project needs
 - Investing in the team's skills ensures they stay current and capable, enhancing project quality and efficiency
- **Create a Centralized Information Repository**
 - Maintain a shared document or drive where all project related materials, updates and decisions are documented
- **Emphasizing a Culture of Continuous Improvement**
 - Fostering a culture of continuous improvement promotes a mindset of constant learning and adaptability within the team

Conclusion

- Establish clear communication between clients and CROs/External vendors to enhance outsourcing partnerships
- Implement quality control measures to maintain high standards in statistical programming
- Focus on continuous improvement to adapt and evolve processes over time
- Standardize processes to overcome common outsourcing challenges
- Foster a collaborative culture and respect cultural differences among team members
- Emphasize long-term relationships and utilize performance data for better outcomes
- Incorporate automation to improve efficiency and consistency in results
- Provide training and support for team members to enhance their skills and understanding of the latest methodologies
- Encourage feedback loops between clients and CROs to identify areas for improvement and drive innovation

Questions?

