

Single Day Event

Best Practices for Regulatory Submissions

Anagha Gumaste,
ACL Digital



Presentation Agenda: The Path to Successful Regulatory Submissions

- 1. Introduction**
- 2. Key Deliverables**
- 3. Problems and Lessons Learned**
- 4. Cumulative Effect**
- 5. Best Practices**
- 6. Conclusion**



Achieving Successful Regulatory Submissions

The Path to Successful Regulatory Submissions



- Getting a regulatory submission right is all about planning ahead, working together as a team, and sticking to proven best practices.
- We will explore key lessons learned from common pitfalls in the statistical programming process
- By addressing these challenges proactively, we can ensure quality, timeliness, and compliance



Key Deliverables from Statistical Programming

Regulatory Submission Deliverables consists of

- **Electronic Datasets:**
 - **SAS Transport (XPORT) format** for submission.
- **Data Definition Documents:**
 - **define.xml** or **define.pdf** to describe dataset structures.
- **Study Design and Analysis Documentation:**
 - **SDTM Annotated CRF** (Case Report Form).
 - **ADaM Specifications** (Analysis Data Model).
 - **Study Data Reviewer's Guide** (**sdrg.pdf**).
 - **Analysis Data Reviewer's Guide** (**adrg.pdf**).
- **Reporting and Source Code:**
 - **Tables, Listings, and Graphs (TLGs)** in **PDF** format.
 - **Source code** for datasets and displays.



The Critical Need for Proper Training



Problem: The Domino Effect of Untrained Teams

- Lack of foundational skills in statistical software (SAS, R, Python)
- Misunderstanding of clinical trial data analysis requirements
- Resource misallocation, causing delays

Lesson Learned:

Invest in continuous professional development



Upholding Standard Operating Procedures (SOPs)



Problem: Inconsistency and Risk

- Deviating from SOPs compromises data integrity and regulatory compliance
- It introduces inconsistency and risk into the process

Lesson Learned:

Adherence to SOPs is non-negotiable



Bridging the Communication Gap



Problem: Misinterpretation and Rework

- A gap between the biostatistician and SPL can cause significant confusion
- Misinterpretation of the analysis plan leads to incorrect outputs
- Miscommunication between DML and SPL

Lesson Learned:

Establish clear, open lines of communication



The Power of Thorough Documentation



Problem: Inadequate documentation is the Silent Killer

- When programs datasets, and processes are not properly documented, it becomes nearly impossible to reproduce the work
- This makes bug fixing and handovers incredibly difficult and time-consuming

Lesson Learned:

If it isn't documented, it never happened



Embracing Version Control



Problem: Chaos and Overwritten Work

- Without a robust version control system, you can't track changes to programs
- It's easy to accidentally overwrite critical work

Lesson Learned:

Use a version control system for all programming code



Insufficient Validation and Quality Control



Problem: Failing to adequately validate programs and outputs

- Not doing proper validation of programs and outputs is a critical error
- A second programmer independently verifying the code is essential for catching mistakes

Lesson Learned:

Validation is the cornerstone of trust in our data



Timelines Preparation



Problem: The Impact of Poor Planning

- Statistical programming timelines not followed or not planned properly can have a major impact
- Unforeseen delays can jeopardize the entire project

Lesson Learned:

Account for all factors when creating timelines



Reducing Rework and Costly Resubmissions



Problem: Compounding Issues

- The combination of all previous issues leads to significant rework
- Rework can result in costly resubmissions, damaging the company's reputation and delaying market entry

Lesson Learned:

Proactive quality management saves time and money



Successful Regulatory Submission: Best Practices

- **Training & SOPs:** A well-trained team adhering to **Standard Operating Procedures (SOPs)** prevents errors and ensures consistency
- **Communication & Documentation:** Clear communication between statisticians and programmers, along with thorough **documentation**, is vital
- **Validation & Version Control:** Rigorous **validation** using the "four-eyes" principle and robust **version control** systems ensure data accuracy and track all changes
- **Timelines:** Proactive planning with realistic **timelines** and buffer periods minimizes delays and rework

Final Takeaway:

Proactive quality management saves time, money, and protects your reputation



Conclusion

By focusing on these key lessons, we can build a more efficient, compliant, and successful statistical programming team which will contribute to

Achieving Successful Regulatory Submissions

Thank you.



**The Global Healthcare
Data Science Community**

Contact Channels

📞 UK +44 1843 609600
✉ office@phuse.global
🌐 phuse.global

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