

Single Day Event

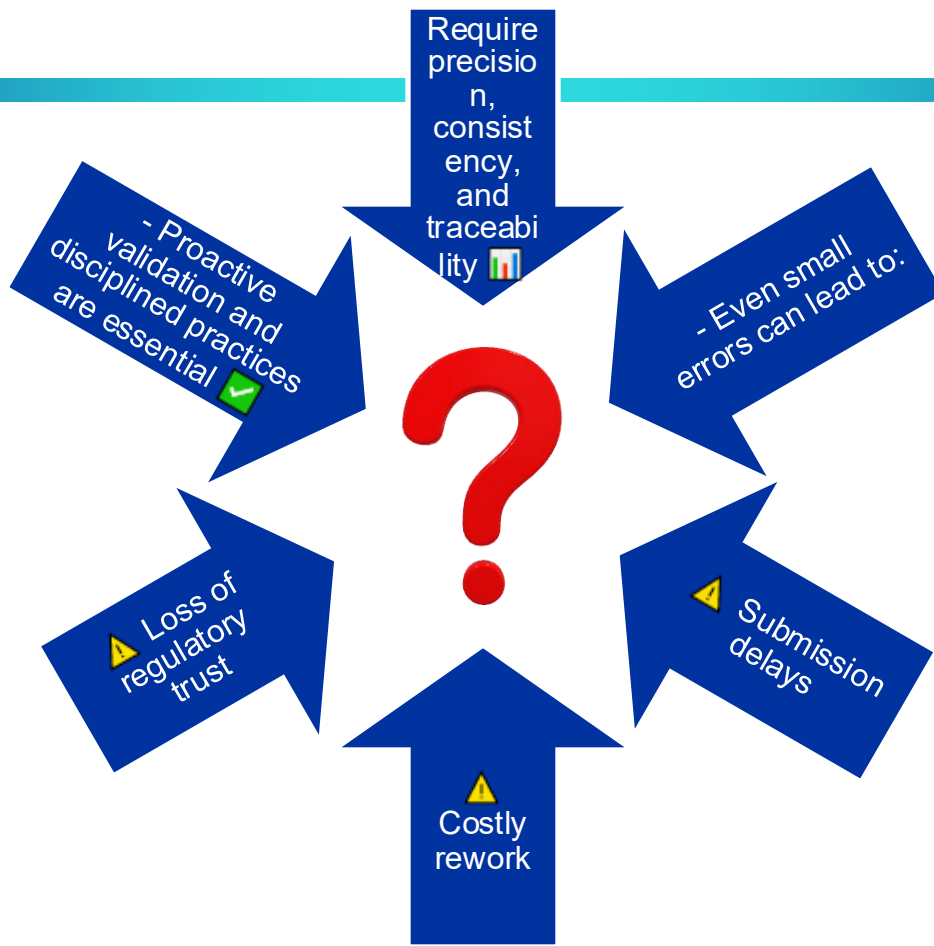
Achieving Successful Regulatory Submission-
Lessons Learned & Best Practices

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Agenda

-  **1** Introduction – Why Regulatory Submissions Fail
-  **2** Common Pitfalls from Experience 
-  **3** Best Practices for Validation & Code Quality 
-  **4** Leveraging Automation & AI Responsibly 
-  **5** Post-Submission Considerations 
-  **6** Key Takeaways 

Why Submissions Fail ?



Lessons Learned – Hard Coding Data Corrections



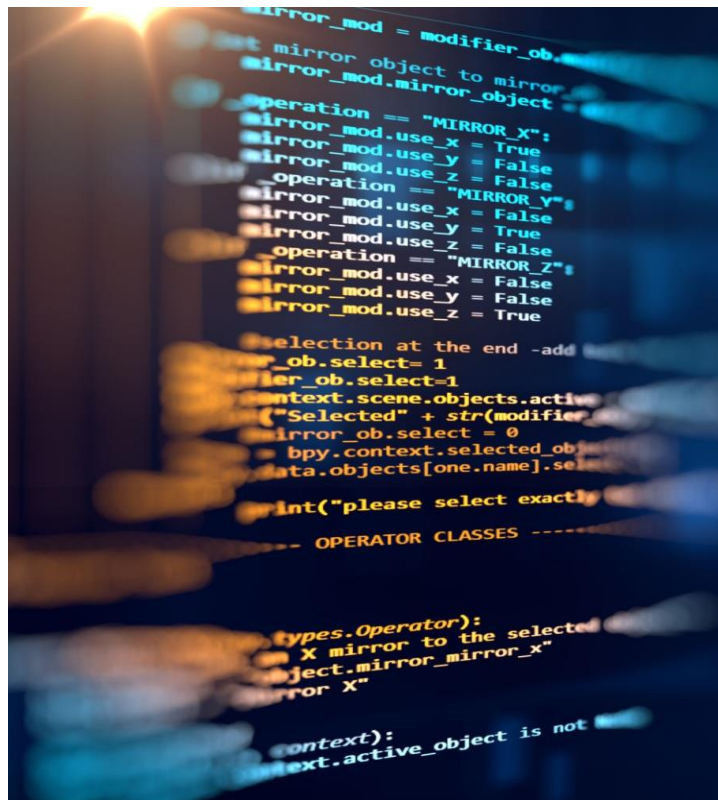
What went wrong:

- Statistician hard-coded correction for patient/timepoint
- Data Manager corrected original value → code caused error

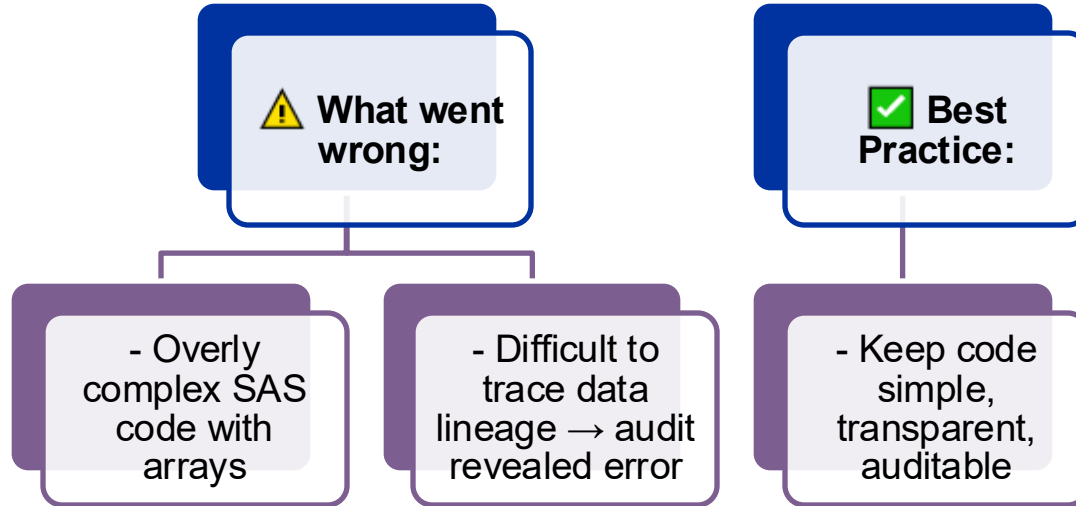


Best Practice:

- Use transaction tables with validation checks
- Never rely on hard coding for data corrections



Lessons Learned – Complex Code



Lessons Learned – Local Data Storage



What went wrong:

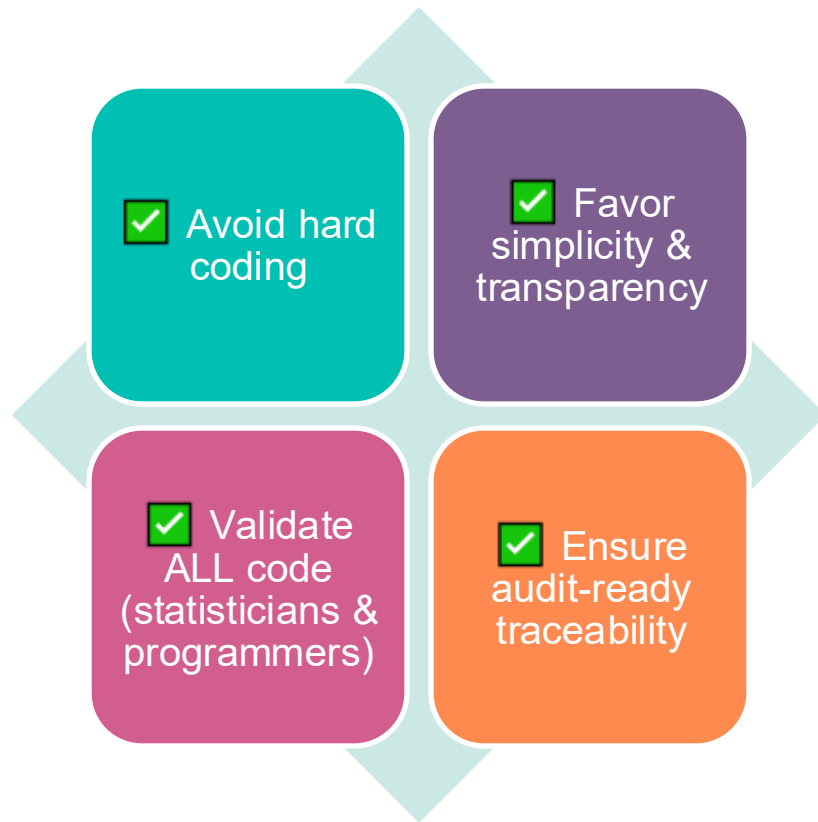
- - Statistician ran analyses on local SAS copy
- - Missed updated dataset → wrong results in tables



Best Practice:

- - Always use controlled, server-based data sources

Best Practices – Code & Validation



Automation – Powerful but Risky



Benefits:

- - Faster assembly, auto-updated TLFs in reports



Risks:

- - Report authors unaware
- - Outdated references in narratives



Best Practice:

- - Notifications & acknowledgment
- - Central TLF lookup table for consistency

Preparing for AI-Driven Use of Data

-  Preparing for AI:
 - - Maintain historic trial data 
 - - Update to latest dictionaries (MedDRA, WHODD, etc.)
 - - Assess accuracy of external data sources 
 - - Assign weights for credibility in AI models

Post-Submission Considerations

Post-Submission:

- Retain and curate historic trial data

Benefits:

-  AI training
-  Answering regulatory queries
-  Supporting medical science teams

Real-world value:

- 20-year-old data answered FDA query
- Historic data avoided costly new trial



Key Take Aways



 Don't hard code corrections – use auditable methods



 Simplicity over complexity in coding



 Never work from local copies – ensure integrity



 Automation aids, but requires oversight



 Historic data is a critical asset

Thank you



**The Global Healthcare
Data Science Community**

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Q&A



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