

The True Cost of Deviations

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Introduction

“There is always time for good study conduct.” This has been an ongoing QA auditor mantra for GLP, clinical, and even non-GLP data. Each auditor strives to ensure that our organizations are fully compliant with established data governance policies. But what happens when data integrity principles are not upheld? There is a monetary cost associated when study excursions occur; however, many scientists, managers, and laboratory staff may not be aware how much deviations from procedures cost. What this poster aims to showcase is the true cost of study deviations. It not only affects internal and external quality programs and regulatory status, but also our organizations’ bottom lines.

Costs to Consider

Tangible Costs

- Costs of laboratory supplies and equipment use for repeating analysis when errors are made
- Costs of addressing corrections and concerns raised by sponsors or outside auditors
- Risks of 483s or warning letters: costs for corrections, assessed fines, criminal liability up to \$250K personal/\$500K corporate, potential close of business

Intangible Costs

- Reputation: poor work will result in reduced opportunities based on word-of-mouth from dissatisfied clients and recommendations from contracted auditors; 483s are publically available through FOIA requests
- Stress: repeated discussions about frequent issues, interdepartmental friction, anxiety about communication with clients, anxiety about upcoming FDA inspections

Case Study: Documentation of a Single Deviation

Reactive Documentation

Documentation produced during review of data



Position	Median Hourly Wage	Approximate Time to Address	Cost
Scientist	\$22.57	2.25 hours	\$50.78
QC	\$26.07	1 hour	\$26.07
QA	\$39.76	1.25 hours	\$49.70
Report Writers	\$38.30	0.5 hours	\$19.15
PI/SD	\$74.36	1.25 hours	\$92.95
TFM	\$96.23	0.25 hours	\$24.06
Total		6.5 hours	\$262.71
Potential Annual Cost			
1 deviation/day, 250 work days		1625 hours	\$65,678

Proactive Documentation

Documentation produced at the time of the event



Position	Median Hourly Wage	Approximate Time to Address	Cost
Scientist	\$22.57	1.25 hours	\$28.22
QA	\$39.76	0.25 hours	\$9.94
Report Writers	\$38.30	0.5 hours	\$19.15
PI/SD	\$74.36	1 hour	\$74.36
TFM	\$96.23	0.25 hours	\$24.06
Total		3.25 hours	\$155.73
Potential Annual Cost			
1 deviation/day, 250 work days		812.5 hours	\$38,933

Tips for Reducing Costs

- Encourage upfront, proactive documentation.
- Periodically re-evaluate methods and systems for the documentation process.
- When using a paper process, minimize the burden to scientific staff by creating concise, straightforward forms; minimize staff needed for review and/or signature.
- When using an electronic process, the workflow should be easy to understand and only necessary personnel should interact with the record.

Conclusion

Consider: would you rather save money or save your reputation? Both are critical for any business venture. Each organization should encourage all areas to be proactive with documentation of excursions. Provide departments with the best tools and best practices to ensure a minimum of deviations occur. Showcasing the real cost of deviations and comparing proactive and reactive documentation makes good business sense. Transparency and accountability through good documentation is great for business by reducing costs, building an excellent reputation in the industry, and maintaining reliability with clients.