



How Much is Enough: A Risk Based Approach to Analysis Verification

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- Introduction
- Prior Verification Process
- Assessment Development
 1. define factors
 2. define levels
 3. define scores
- Impact / Lessons
- Wrap-up / Questions

This is me....



- BBA employee since 2006
- In industry since 1992
- Worked with both drugs and devices
- Database development, SAS Programming, QA Manager, Compliance & Validation
- RAC (2005) and CQA (2004)

- Tables were programmed and independently verified for all types of reports
- Every number in every table for every type of report was confirmed
- Verification typically took longer than the programming
- Did not have process documenting decisions regarding extent of verification

- Quantifying risk of doing less verification based on a score matrix
 - output are scored based on several factors
 - pre-defined scoring levels within these factors
 - score determines extent of verification required

1: Define the Factors



- Define what to assess
 - What impacts verification?
 - When can you do less?
 - When do you have to do more?
- Team approach
 - Programmers, statisticians, writers, regulatory
 - Adhere to SOPs
 - Align with corporate philosophy

Assessment Factors



Programming Complexity (PC)

Intended Use (IU)

Type of Output (TO)

Type of Data (TD)

- Levels assess factors
 - Enough levels so that assessment is meaningful
 - Not so few that everything is in one bucket
 - Not so many that it becomes too granular



Assessment Levels

	Simple	Average	Complex
Factors	Programming Complexity (PC)	Levels	
	Intended Use (IU)		
	Type of Output (TO)		
	Type of Data (TD)		

2: Define the Levels



- What does each level mean for each factor?
- Assign a value to each level

	Simple / 5	Average / 10	Complex / 20
Programming Complexity (PC)	Single dataset, No derived data	Multiple datasets, No derived data	Single/Multiple datasets, Derived data

Score Each Risk Factor

- Assign a level value to each factor and then total

Analysis	Verification Approach				Score
	PC	IU	TO	TD	
Table 1 Accountability	20	20	20	20	80
Table 2 Demographics	5	10	10	20	45
Table 3 Adverse Events	20	10	20	10	60

3. Define Scores



- Decide and document what scores mean
 - What does total score mean?
 - What does it allow you to do/not do?
- Team approach
 - Programmers, statisticians, writers, regulatory
 - Adhere to SOPs
 - Align with corporate philosophy

Complete the tool



- Who completes assessment?
- What is assessed?
- When is assessment completed?
- What do scores mean?

Score	Minimum Verification
< 50	Format review, Statistical review
50 - 75	Format review, Statistical review, Partial verification
> 75	Format review, Statistical review, Full verification

- Definite time savings if defined well
- Amount of verification savings depends on
 - level and score definitions
 - item being assessed
- Be prepared to make changes to definitions after using a few times
- Challenge with comfort in doing less
- Focused verification produces better quality

Questions



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