



Penalties for Not Using Metadata to Generate Reports

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I Have a Dream

- Standardization
- Legacy systems
- Various study designs
- QC, validation, or UAT



Penalties for Life Today

- New chemical entities and flexible designs
- Requires customization
- Each study requires modification
- QC, validation, or UAT



Penalties Not Using Metadata Systems

- Programs have to be modified when the database is changed
- You need defensive coding
 - Messages when expected variables are not available
 - Messages when expected data are not available
 - Variable names must not change from study to study
 - Data elements have to be consistent (e.g. code list 1=Male 2=Female)
 - Expected variables should not be missing
 - Marketing studies do not capture start and stop dates for medications and AEs
 - Need to flag the variables that do not belong otherwise report generates blank variables

Metadata Driven Systems

- Two styles of metadata driven systems
 - Reading of the xml code
 - Utilizing variables in a program
- Misleading output (no data vs no data meeting a condition)
- Customers complaining about blank values in reports



Assumptions

- There has to be some form of global standardization
 - Two different variables can not mean the same thing
 - Active variables vs obsolete
 - Data elements have to be consistent (e.g. code list 1=Male 2=Female)
 - Expected variables should not be missing
 - Key fields can never change (USUBJID)



Conclusion

- A fully functioning metadata reporting system with standards can minimize extra work and maximize productivity
- Time saving, more global reports
- A system that can actually generate output when changes are made to the original database
- I may be a dreamer, but I feel that a metadata driven system can be a reality

Questions?

