
Learnings and Evolutions of Risk Assessment Quality Control within Statistical Programming group

PhUSE October 2014

Tim Barnett



Agenda

- Introduction
- Original Conception
- Learnings
- Business Changes
- Landscape Changes
- The Future
- Conclusion

Introduction

- PhUSE Conference of 2007 - “Validation of Programs developed using SAS”, employing a Risk Management Strategy to the validation approach
- Enabled programmers to assign risk levels to programs
 - level of quality control could be determined
 - appropriate resources (in relation to that risk) could be assigned.
- A journey from ideal scenario beginnings to current version, and beyond!

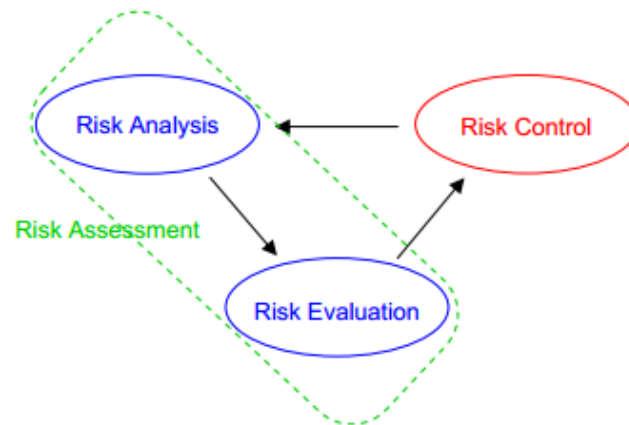
Risk Assessment – Original Conception



Risk Assessment – Original Conception

Risk evaluation –
Reporting event, report
object, program

Full
documentation of
risk level chosen



Factors including intended use, audience,
criticality of data, formality of analyses,
complexity of code and the likelihood of
identifying an error.

Three levels of risk
available – High,
Medium and Low

Risk Assessment - Learnings

- It works!



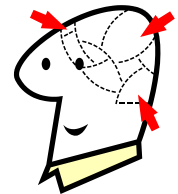
- Adjustment to Risk Levels – Goodbye Medium.



- Revision of concept of low risk – More responsibility on 1st Line



- Help influence culture and mindset to risk – Incorporate a quota



- Simplify determination of risk, and increase transparency of documentation



Risk Assessment - Learnings

Reporting Event

Intended Use

Audience

Criticality

Formality

Programs used

Program Level

Sensitivity

Stability

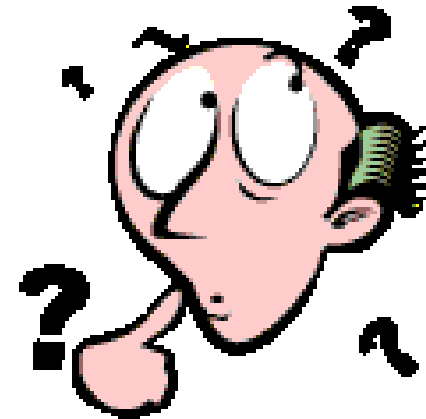
Likelihood of
identifying error

Program
Complexity

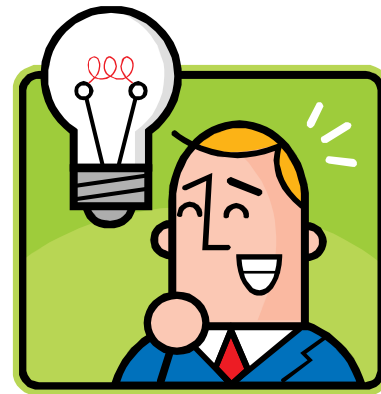
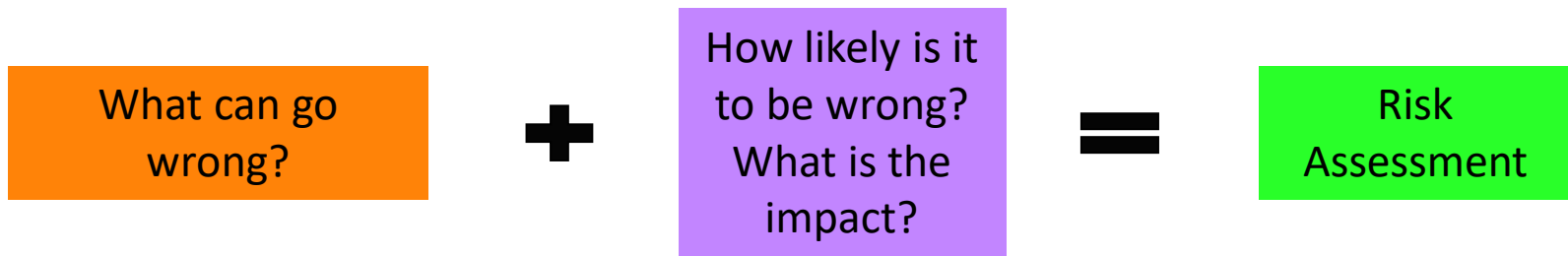
Origin of
program



Risk Assessment



Risk Assessment - Learnings



Risk Assessment – Business Changes

- Smart Risk – A Business Initiative
 - Risk-Based Monitoring
 - Data Quality
- Evolution of the Statistical Programmer
 - More time analyzing, less time programming

Risk Assessment – Landscape Changes

- Data Transparency – increased exposure
- Submissions to Health Authorities where the request for our programs can be made as a deliverable in their own right
- The scrutiny on our work is now increasing as the number of customers to our work increases beyond the recognized stakeholders
- Perception (both internal and external) - can lead to misunderstandings. Communication is critical when discussing Risk Assessment

Risk Assessment – The Future?

- In the Short Term
 - Review of documentation and clarity of our process
 - Stronger guidance documents for consistent risk assessments
 - Incorporate risk assessment capture into standard tools
 - Possible increase in High Risk assignment as we understand the impact of Data Transparency as the evaluation of the impact of an error increases.

Risk Assessment – The Future?

- In the Long Term
 - Increase of standards across data capture, tabulation and analysis should eventually lend itself to a more standard risk assessment
 - High risk programs will be those controlling the meta-data around a standard suite of programs, and thus having quality control incredibly stream-lined.

Conclusions

- Viewed as an asset to the group in assigning resource to the areas of most value, whilst maintaining levels of quality
- Adaptations required, including simplification, more emphasis on the 1st line development, and in helping adjust mindset and set documentation levels for the approach.
- For future of risk assessment
 - more efforts to align risk levels across teams
 - increase of standards allowing more low risk assignments
 - increase of external scrutiny may cause a swing to more higher risk in the short term, but increase in dataset standards and standard reporting tools should balance this out over time.
- As long as risk assessment has clarity and transparency in its use, it is a process to stay for the future.

***Doing now what patients need
next***