Increasing Risk Management Maturity in Lifesciences – taking the journey step by step

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Even the most carefully planned project can run into trouble.

No matter how well you plan, your project can always run into **unexpected problems.** Team members get sick or quit, resources that you were depending on turn out to be unavailable—even the weather can cause problems

BUT the pharma industry has tended to neglect the importance of project risk management. This leads to unnecessary project failures and delays

AGENDA

- Is this a journey we want to take?
  - Research findings & business needs
- Which way do we go?
  - Mapping the journey
- Taking the first steps
  - Walk before you run
- Potential pitfalls
  - Anticipating the banana skins
- Ready for the onward journey?
  - Gaining confidence & seeing results
- Managing risk in our Business
  - Case Studies and Best Practices

Is this a journey we want to take?

*..responding to the **lack of confidence in our ability to deliver** Projects on time and to cost internally and from the **Customer and the City**….the Company has put a much greater focus on…how we manage our Projects and **how we assess the Risks of delivering** the Projects*

Vision:

Improve our project time and cost performance…

Develop our Project Managers' **competency (and confidence!)** in Risk Management…

Demonstrate our professionalism to our customers…

Defining & enabling behaviours, embedding practices and stimulating the right attitudes

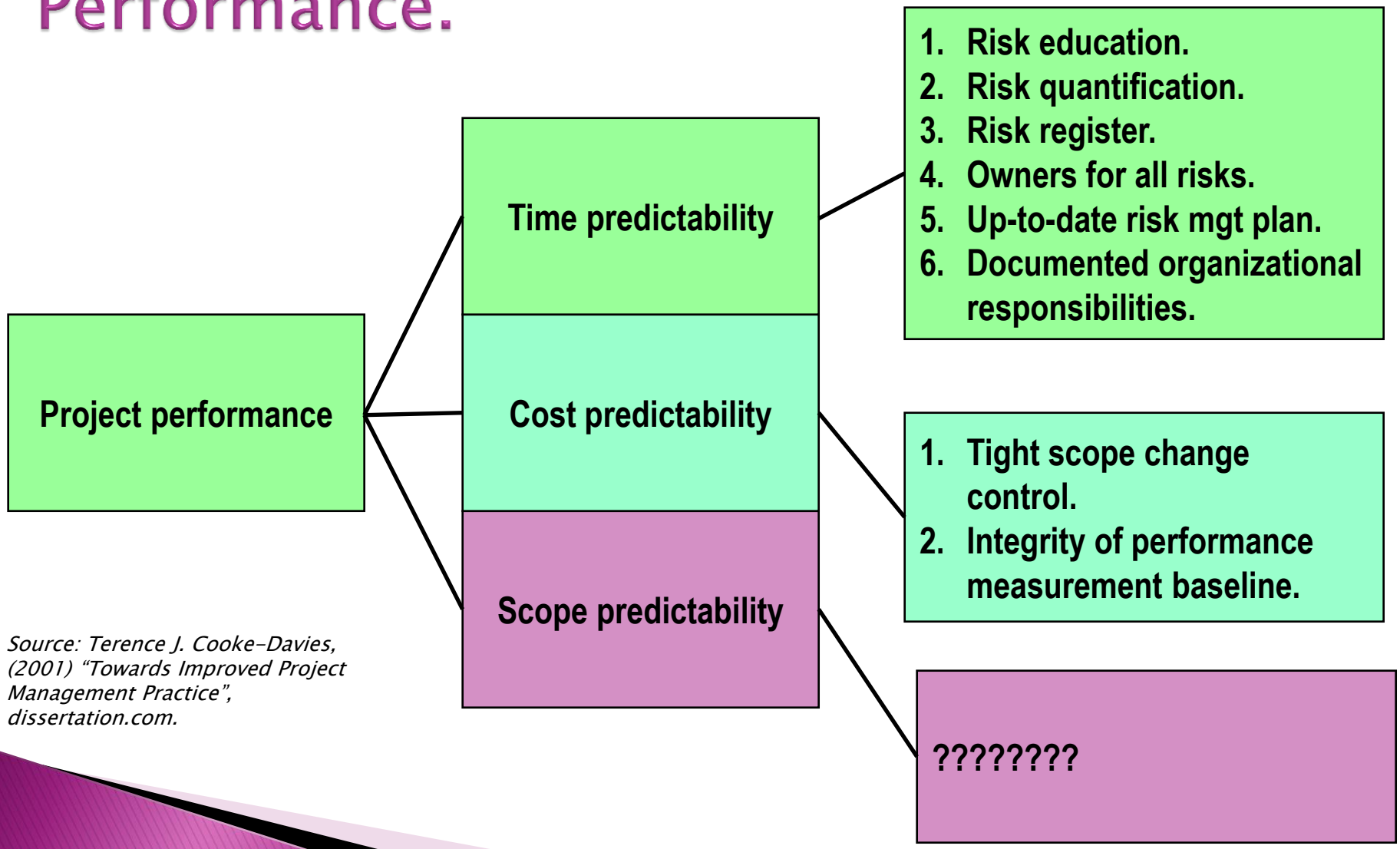
Enabling R&D strategy by focusing on Projects and Portfolios

Enhanced Time, **Risk** & Resource management

The journey for risk management – a need to change

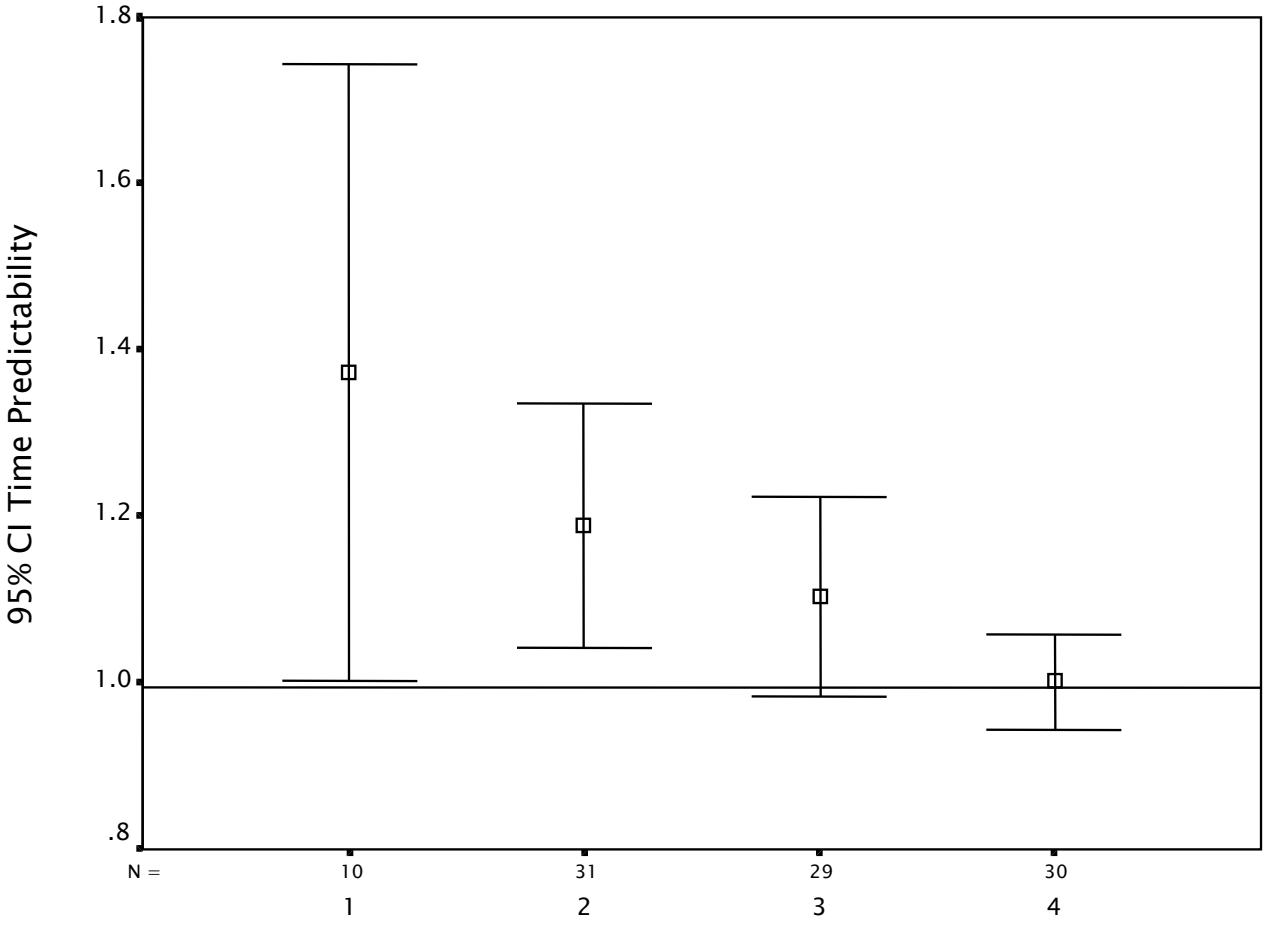
- 2005/6
  - Gap analysis identified need to improve practice
    - Identification but little management of risk
    - Inconsistent reporting
- 2006
  - New R&D Chairman
  - Several late regulatory submissions
    - Lack of confidence in delivery

Research Shows That Different Factors are Critical For Different Measures of Performance.



Source: Terence J. Cooke-Davies, (2001) "Towards Improved Project Management Practice", dissertation.com.

Predictability Improves With Adequacy of Practices.

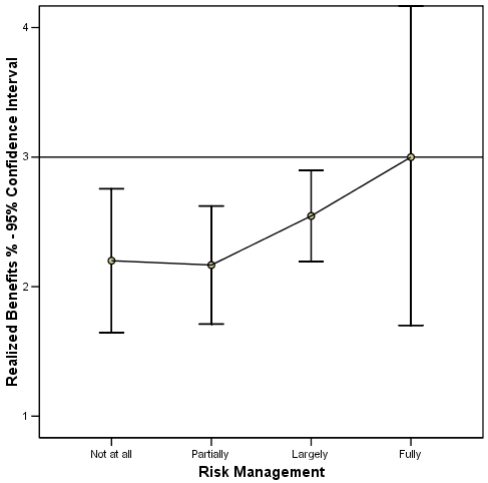


Time predictability

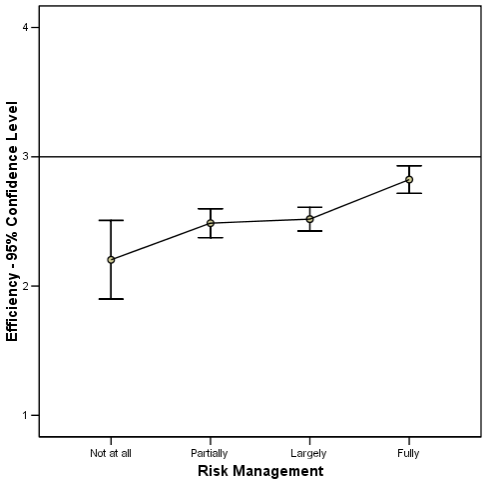
1. Is there company wide education on risk concepts?
2. Is there a visible risk register showing the impact and probability of each risk and other information?
3. Is there a formal process for identifying and quantifying risks?
4. Have all the risks that are to be managed had owners assigned?
5. Is the risk management plan up to date?

.. And Risk Management Impacts Different Aspects of Performance.

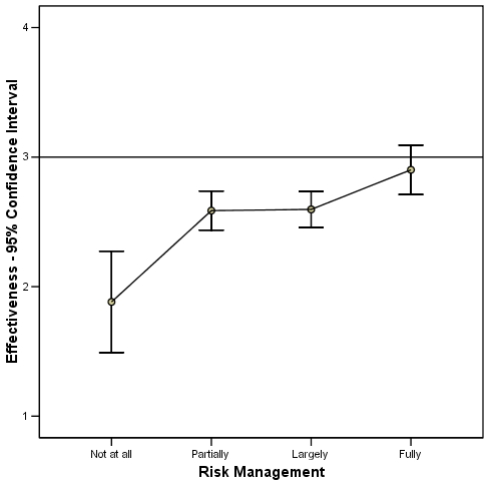
Data taken from an analysis (March 2007) of 339 sets of results in CfS Index, shows that Improved Risk Management correlates to improvements in :-



Benefits Realized. . .



Efficiency. . .



& Effectiveness.

Source 'Capability for Success Index'

So, it's pretty important!

Which way do we go?

- External cultivation or internal growth?
- Focus on training or capability development?
- PMs?
- Project Teams?
- Management?
- Governance?

Training and Developing Project Managers

External Cultivation

- Access to subject experts
- Professional trainers
- Resource 'light'
- PMI accredited – PDUs
- Central coordination (PMO)

- Education not application
- High cost
  - Cancellation fees

Internal Growth

- Relates to company culture
- Integrated with company tools/systems
- Tailored to local vision
- Departmental ownership
- Central coordination (PMO)

- Assumes local expertise
- Resource intensive
  - Faculty

A new company in a new century – externally grown PMs

Training Provision

- Standard project management practice
- Limited Curriculum
  - MS Project
  - Planning
  - Risk Management
- Multiple external providers
- Functional groups selected own providers
- Internal Curriculum
  - Drug Development
  - Conflict, Negotiation, etc

Challenges

- Changing company culture
- No customisation for GSK
- No linkage between courses
- Unclear expectations for PMs
- No PM community across R&D functions inc Clinical
- No central coordination
- Budget challenges in each group

The journey for Risk Management 2002 – 2007

- Principles of Risk Management
- Broad education of principles and methodologies
- All PMs attended (but not clinical PMs)

- No embedding of practice following training
- No tool selected for R&D use
- No clear development expectations for PMs
- No supporting culture
  - No expectations for team members
  - No mandated training across the matrix

Taking the first steps

- Instigate a Change Project & set targets
- Acknowledge time commitment
- Realistic timeframe for adoption
- Develop local experts
- Provide facilitators
- Communicate, communicate, communicate
- Celebrate & reward

The journey for risk management – first steps

- 2007 – 2009
  - Maturity model established
  - Practical workshop launched
    - Simple Excel risk register
    - Education across R&D
    - Central funding for training
  - Clear expectations for PMs, teams and governance

Potential pitfalls

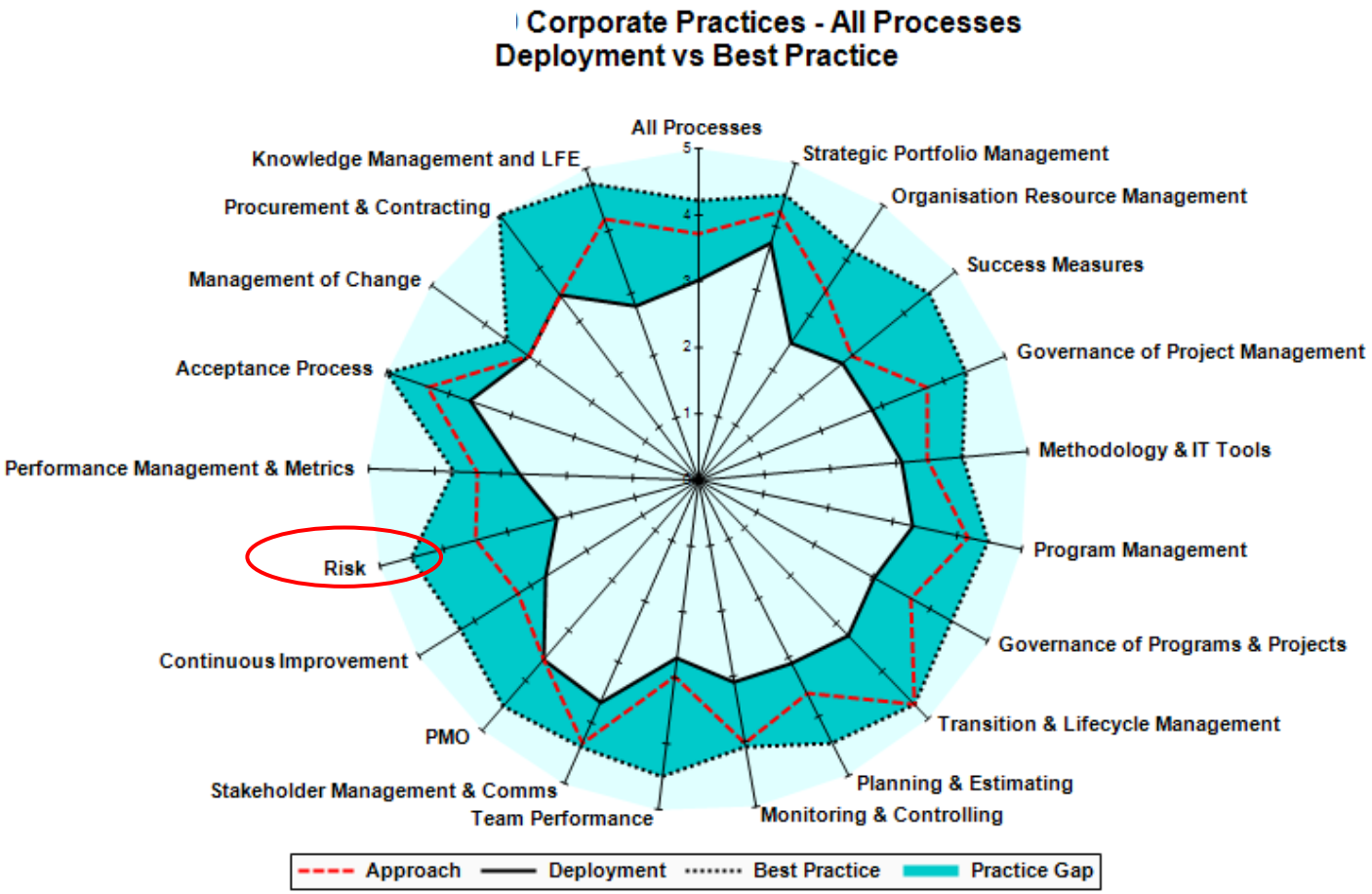
- Excessive organisational change
- Baseline data
- Lack of integration
- Great process but…..
- Governance reinforcement

Complex topic with many linkages

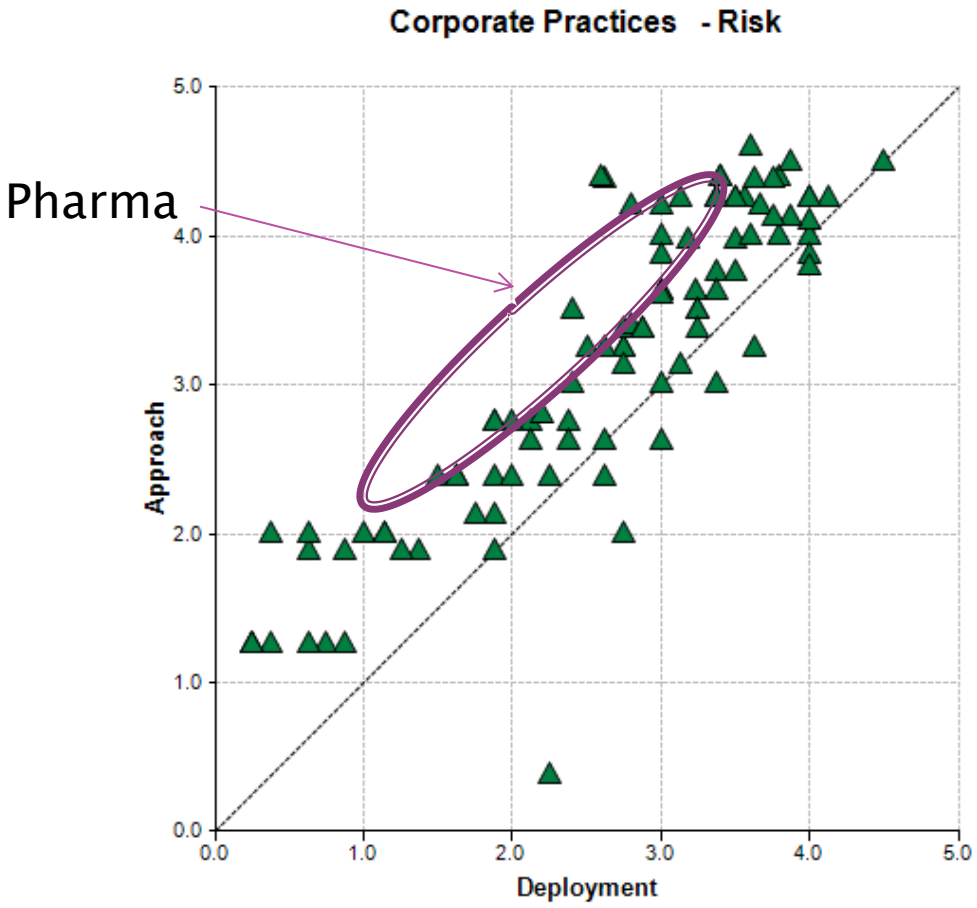
- Masses of models & tools available, yet…
- …Many of the issues are behavioural:
  - Failure to follow well structured process
  - Risks identified but not managed
  - Poor KM – little learning from experience
- …And there is significant risk from failure in other PM disciplines:
  - Poor estimating
  - Failure to control scope
  - Inadequate resourcing

} Poor project management !

Practice gap – Approach rarely matches reality



Risk Management Approach vs. Deployment



Key role for Governance in reinforcement of behaviour

Metrics easily gathered from minutes

- Risk registers logged pre meeting
  - Team *adopting*
- Key risks presented
  - PL/PM *integrating*
- Discussion within the meeting
  - Governance *understanding*

The journey for risk management – continued work with our partners

- 2009-11
  - Integration of maturity model with other practices
  - Updated Excel register to 'match' future Planisware format
  - 3rd Level Kirkpatrick review
  - Training course updated accordingly
  - Expert clinics
  - Project Team Resource centre created

Ready for the onward journey?

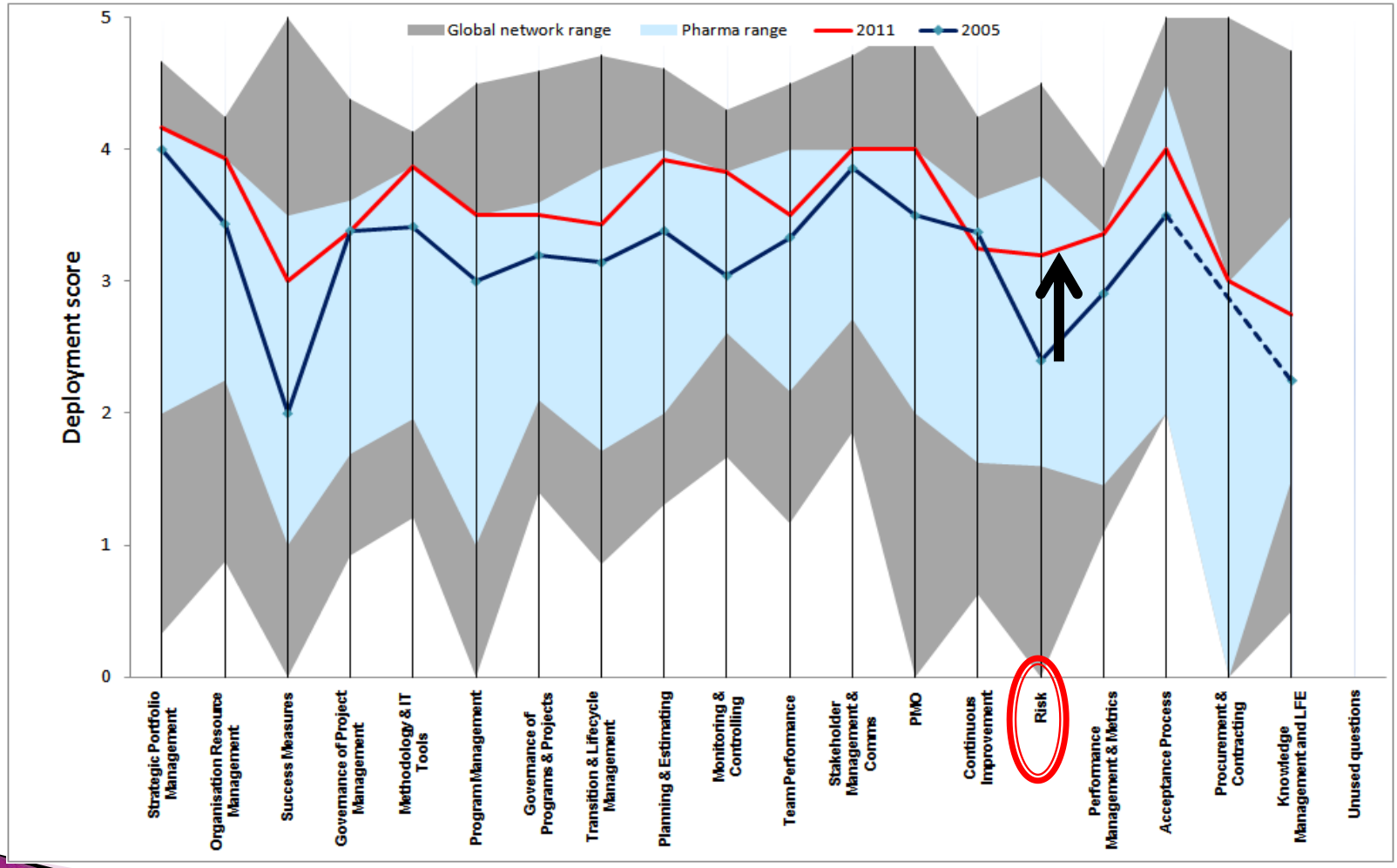
- Was it all sorted? – No
- Essential to maintain your belief & commitment
  - Measure success
- Continuous improvements are vital
  - Integration into other practices
  - Practice development
  - Tool development
  - Training development
  - Support development

The journey for risk management – Business as usual

- 2011 onwards
  - Planisware risk management functionality roll
  - Project Team Resource centre updated
  - Project team health checks
  - Training course adopted into new Academy plans
  - Expert clinics continued
  - Closure of Change Programme in 2012

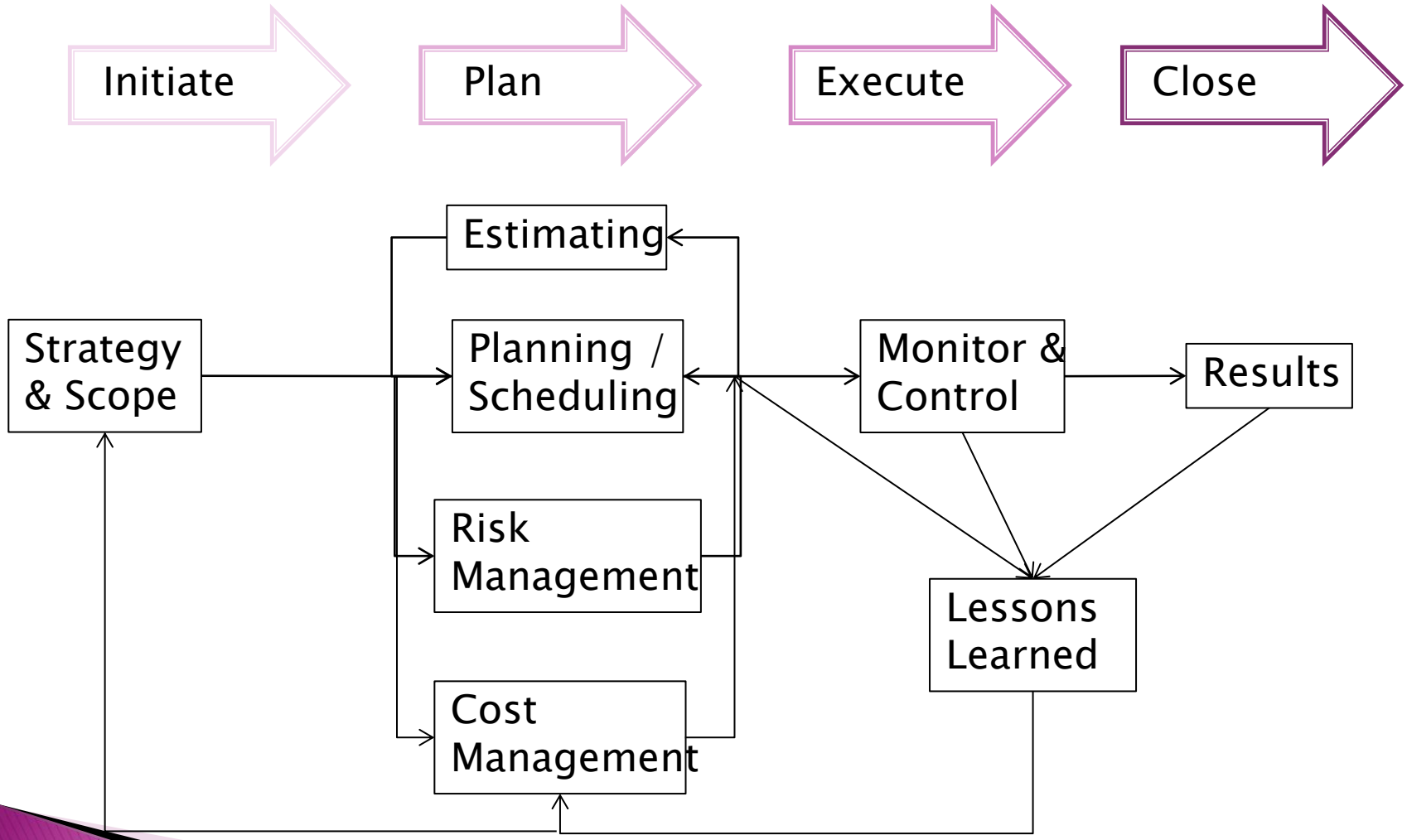
'Risk management has become part of the way we work, which means increased confidence in our project plans'

Project Capability Benchmarking

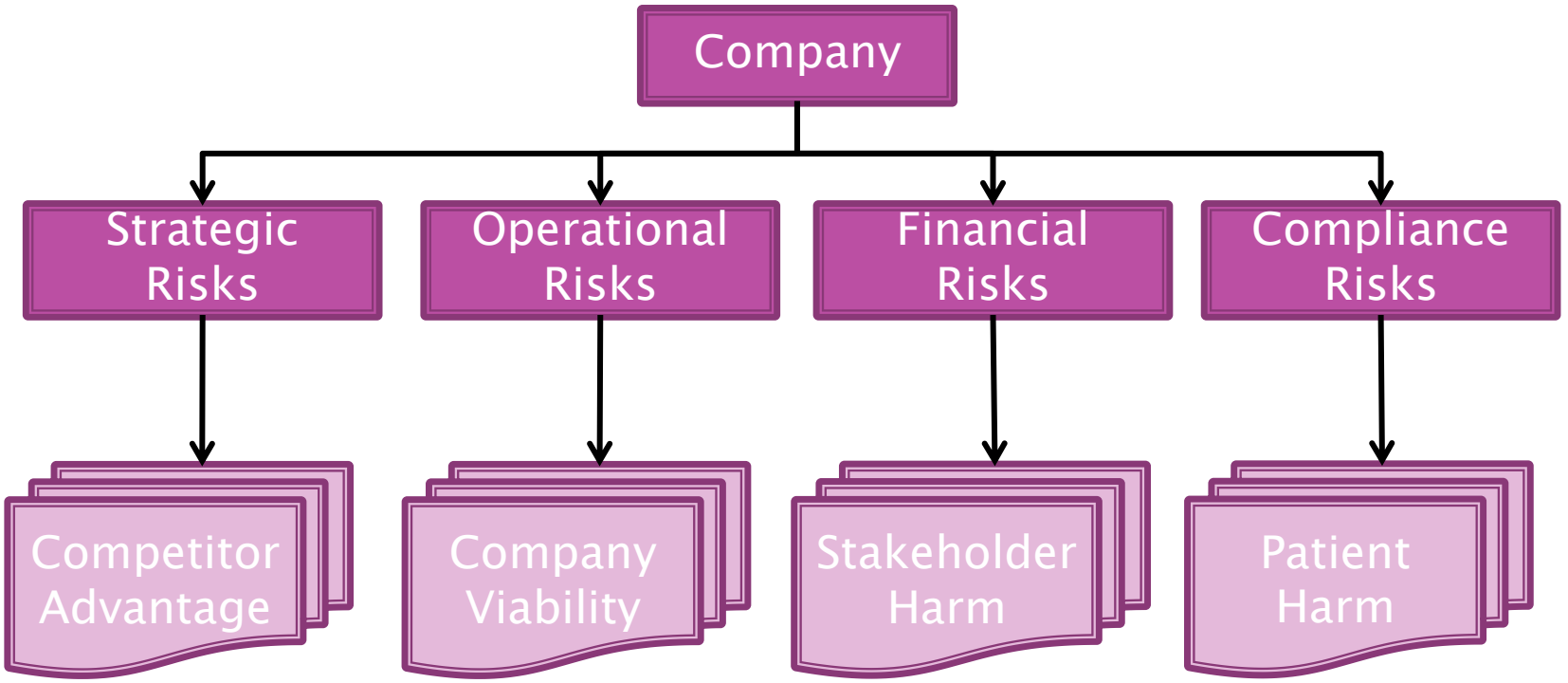


Managing Risk in our Business

Project Planning



Risk Management is universal



Tool Considerations

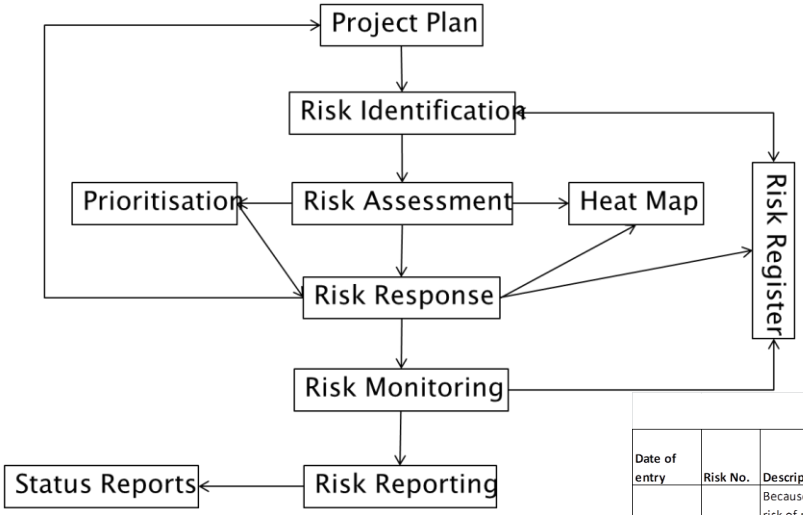
- A formal risk management tool is not essential. However they can be very valuable in the right circumstances
- No single tool or method can be applied to all situations
- All tools require a good understanding of the process under review
- The team provides a range of expertise and various perspectives to enhance the tool

More important than any tool:

The right people having the right conversation at the right time!

Plan Delivery Risk Management

PMI/APM



RISK REGISTER

Date of entry	Risk No.	Description	Probability	Impact	Severity	Key Risk?	Expected Date of occurrence	Strategy	Actions	Action Cost	Severity post action	Action Owner
21/01/2013	1	Because of low solubility at low pH there is a risk of reduced absorption after oral dosing in the oral ADME studies resulting in inadequate exposure in humans at viable doses	VH	H	VH/H	Y	15/04/2013	Mitigate	Further development of chemical series find compounds with increased solubility	£10k	L/L	J Smith
21/01/2013	2	Because of	VL	L	VL/L	N	03/04/2013	Accept	None	£0		F Bloggs

OPPORTUNITY						RISK				
VH/VH	VH/H	VH/M	VH/L	VH/VL	VH	VH/VL	VH/L	VH/M	VH/H	VH/VH
H/VH	H/H/	H/M	H/L	H/VL	H	H/VL	H/L	H/M	H/H/	H/VH
M/VH	M/H	M/M	M/L	M/VL	M	M/VL	M/L	M/M/	M/H	M/VH
L/VH	L/H	L/M	L/L	L/VL	L	L/VL	L/L	L/M	L/H	L/VH
VL/VH	VL/H	VL/M	VL/L	VL/VL	VL	VL/VL	VL/L	VL/M	VL/H	VL/VH
VH	H	M	L	VL		VL	L	M	H	VH

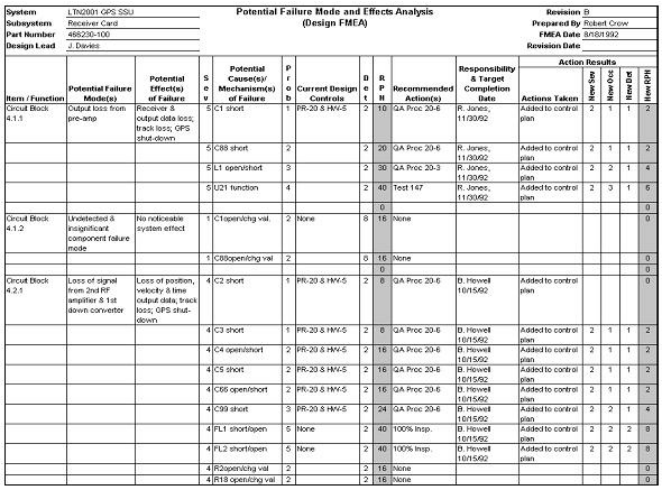
Tool Comparison

Not all tools assess all risks / not all risks are failures

Tool	Acronym	Common Uses	
Failure Modes & Effects Analysis	FMEA	Evaluate equipment & facilities	Quantitative Uses data based on scientific understanding to determine probability & impact
Fault Tree Analysis	FTA	Investigate product complaints	Quantitative/Qualitative Evaluates system failures one at a time
Hazard Analysis & Critical Control Points	HACCP	Preventive applications	Qualitative Bottom up approach to prevent hazards occurring
Hazard Operability Analysis	HAZOP	Evaluate process safety hazards	Qualitative Identifies potential deviations from norm

FMEA – Failure Modes & Effects Analysis

- Prospective tool to quantify risks involved in different stages of a process
- Scoring method to identify points of greatest risk
- Prioritises areas for attention/resources
- Developed in aerospace industry – 1940-60s
- Increasingly used in healthcare
  - Clinical trials
  - Drug prescribing



Potential Failure Mode and Effects Analysis (Design FMEA)

System	LTN2001 GPS SSU										**Revision**	B			
Subsystem	Receiver Card										**Prepared By**	Robert Crow			
Part Number	468230-100										**FMEA Date**	8/18/1992			
Design Lead	J. Davies										**Revision Date**				
												Action Results			
Item / Function	**Potential Failure Mode(s)**	**Potential Effect(s) of Failure**	**Sev**	**Potential Cause(s)/ Mechanism(s) of Failure**	**Prob**	**Current Design Controls**	**Det**	**RPN**	**Recommended Action(s)**	**Responsibility & Target Completion Date**	**Actions Taken**	**New Sev**	**New Occ**	**New Det**	**New RPN**
Circuit Block 4.1.1	Output loss from pre-amp	Receiver & output data loss; track loss; GPS shut-down	5	C1 short	1	PR-20 & HW-5	2	10	QA Proc 20-6	R. Jones, 11/30/92	Added to control plan	2	1	1	2
			5	C88 short	2		2	20	QA Proc 20-6	R. Jones, 11/30/92	Added to control plan	2	1	1	2
			5	L1 open/short	3		2	30	QA Proc 20-3	R. Jones, 11/30/92	Added to control plan	2	2	1	4
			5	U21 function	4		2	40	Test 147	R. Jones, 11/30/92	Added to control plan	2	3	1	6
								0							0
Circuit Block 4.1.2	Undetected & insignificant component failure mode	No noticeable system effect	1	C1open/chg val	2	None	8	16	None						0
			1	C88open/chg val	2		8	16	None						0
								0							0
Circuit Block 4.2.1	Loss of signal from 2nd RF amplifier & 1st down converter	Loss of position, velocity & time output data, track loss; GPS shut-down	4	C2 short	1	PR-20 & HW-5	2	8	QA Proc 20-6	D. Hewell 10/15/92	Added to control plan				0
			4	C3 short	1	PR-20 & HW-5	2	8	QA Proc 20-6	D. Hewell 10/15/92	Added to control plan	2	1	1	2
			4	C4 open/short	2	PR-20 & HW-5	2	16	QA Proc 20-6	B. Hewell 10/15/92	Added to control plan	2	1	1	2
			4	C5 short	2	PR-20 & HW-5	2	16	QA Proc 20-6	B. Hewell 10/15/92	Added to control plan	2	1	1	2
			4	C66 open/short	2	PR-20 & HW-5	2	16	QA Proc 20-6	D. Hewell 10/15/92	Added to control plan	2	1	1	2
			4	C99 short	3	PR-20 & HW-5	2	24	QA Proc 20-6	B. Hewell 10/15/92	Added to control plan	2	2	1	4
			4	FL1 short/open	5	None	2	40	100% Insp.	D. Hewell 10/15/92	Added to control plan	2	2	2	8
			4	FL2 short/open	5	None	2	40	100% Insp.	D. Hewell 10/15/92	Added to control plan	2	2	2	8
			4	R2open/chg val	2		2	16	None						0
			4	R18 open/chg val	2		2	16	None						0

Will good risk management prevent issues occurring?

NO!

- Not all risks can be completely mitigated or avoided
- Not all risks can be identified – stuff happens!
- The issue list is transient as they are identified and resolved but they may lead to changes for the project

Case Study 1 – Preclinical Data

Risk Management can save money

- Project team brainstormed potential risks for completing a phase 2 clinical programme as scheduled.
- Multi disciplinary team contribution with 'invited' facilitator.
- Clinical study potentially impacted by outcome of a high risk toxicology study.
- Review of the critical path by the PM identified float so study could be delayed until after the tox results were available without impacting the regulatory submission date.

- Outcome: negative tox study results and project terminated. Saving to company of not starting the clinical study ~£1 million pounds

Case Study 2 – Audits

FDA Warning Letter / French Authority observation

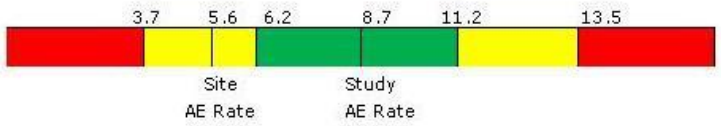
- ‘Your firm failed to review all aspects of the risk assessment process to determine if other components were lacking, review other risk assessments for similar short comings and evaluate related procedures and subsystems to determine if they also needed to be addressed in a similar ,manner. In addition, your firm did not provide evidence of implementation of all the planned actions.’

- ‘There is no risk assessment procedure to evaluate risks related to the products manufactured in the plant (e.g. toxicity, design of facilities…) the equipment used, the qualification/validation needs or related to judgement when initiating new projects’

Case Study 3 – Clinical Studies

Site Quality Risk assessments direct monitoring focus

- Measures can be captured for each participating site and for the study overall.
- Unusually high deviations from an observed study benchmark can be flagged and a "site quality risk level" assigned for each site for the given measure.
  - In this example, the overall Adverse Event rate for the study is 8.7 AEs per subject-year. The given site in the study currently has an AE rate of 5.6 AEs per subject-year, which places it in the "yellow" or elevated quality risk level for this measure.



- Depending on the nature of the identified issue, potential follow-up actions may include the following:
  - • Increasing the percentage of Source Document Verification required at the site;
  - • Delivering additional guidance and training on specific aspects of the protocol;
  - • Planning additional on-site visits to more closely monitor certain aspects of the site's study conduct.

Case Study 4 – High risk prescribing

Ensuring a process is robust

- Rituximab – biological, systemic therapy licensed for non-Hodgkins Lymphoma & rheumatoid arthritis.

- Four risk factors
  - Therapeutic risk
  - Complex dose calculation
  - Part or multiple vials to be added to infusion bags
  - Pump requires frequent setting adjustments

- FMEA used as a proactive approach to managing the risks
  - Focus groups identified failure modes in each stage of the process
  - For each mode the cause & effects were identified and scored to produce the RPN.
  - Highest RPN modes affecting patients were investigated for modifications that could lower the risk e.g.
    - Failure mode – wrong body surface area calculated – RPN – 600
    - Cause – incorrect data for height & weight on prescription

- Risk reduction strategies are being put in place including:
  - Routine weighing of patients before prescriptions are written

FMEA: a new approach to manage high risk medicines
S Williamson, N Wake, G Donovan (Northumbria Healthcare Trust)
British Journal of Clinical Pharmacology, Vol 1.December 2009

Case Study 5 – Team resistance
Its not what you call it it's what you do that matters

- Project team didn't have time to 'naval gaze' they were 'too busy' dealing with the issues to assess risks.
- PM introduced an assessment of the future issues
- Team adopted a Future Issues Log
- Outcome: 18th months later recognised as the team with the best risk management practice!

Poor reporting of risk

- Impatience or Over confidence
  - We'll cross that bridge when we come to it
  - We'll fix that later
- Vested interest
  - I'm determined to see my project through regardless
  - Once it's an issue I can get rewarded for solving the problem
- Secrecy or 'your problem'
  - It'll be seen as excuses for failure
  - I don't have a solution
  - We don't want their interference
- Messenger Syndrome
  - Blame culture
  - Bearers of bad news get punished

Communicating risks

- In failed projects the PM is often unaware the ‘big hammer’ that was about to hit them. Frequently someone on the team actually did see that hammer, but didn't inform the PM.
  - If you don't want this to happen in your project, you better pay attention to risk communication.
- Consistently include risk communication in what you do. If you have a team meeting, make project risks part of the default agenda (and not the final item on the list!).
  - This shows risks are important and gives team members a "natural moment" to discuss them and report new ones.
- Communication is key between the PM and project sponsor or principal. Focus your communication on the big risks here.
  - Make sure you don't surprise the boss or the customer!

Summary

Risk Management

- Effective risk management is consistently shown to be positively correlated with on time delivery
- Failure to manage project risk leads to project issues
- If you don't manage risk you had better be exceptional at issue management!

Thank You

Questions?

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