



A Brief History of Project Risk



Problems

Successful Projects

High levels of collaboration

- Clearness of project objectives
- Flexibility (willingness to make changes if required)
- Solidarity (avoidance of behaviour detrimental to the relationship)
- Information exchange (proactive sharing of relevant information)

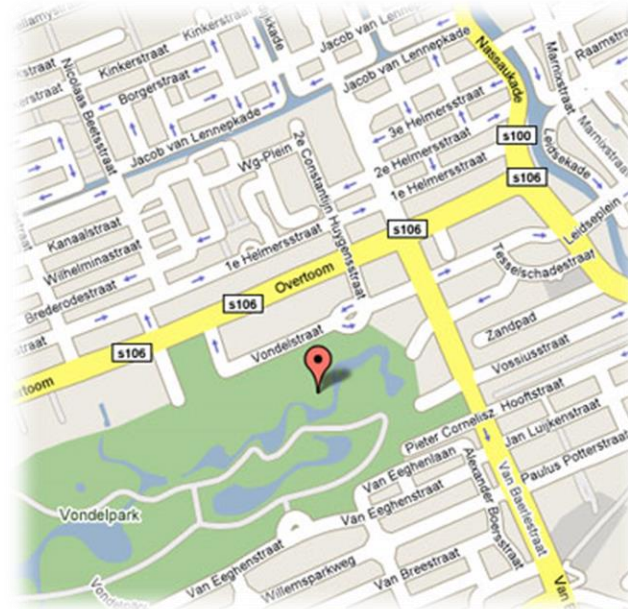
J. R. Turner, R Muller (2004) "Communication and Co-operation on Projects between the Project Owner as Principal and the Project Manager as Agent", European Management Journal Vol. 22, No 3 pp 327-336.



Successful Projects

Medium Levels of Structure (1)

- Clearness of methodology



Successful Projects

Medium Levels of Structure (2)

- Level of Control



What causes Project to fail

- Unclear objectives
- Scope Creep
- Unrealistic Timelines
- Inadequate Resources
- Lack of Planning
- Poor Communication
- Confused roles and Responsibilities
- Focus on cost instead of benefits
- Lack of control



Project Uncertainty

1 KNOWLEDGE

(known knowns)

- Predicable future states
- Project Data
- Independently verifiable evidence

2 RISK

(known unknowns)

- Possible states identified
- Ambiguous outcomes
- Quantifiable variables
- Known contingency actions

3 UNTAPPED KNOWLEDGE

(unknown knowns)

- Researchable facts
- Unshared skills and information
- Untapped resources

4 UNCERTAINTY

(unknown unknowns)

- Hidden knowledge
- Unknown relationships between key variables
- Unpredictable events
- Bolts from the blue

**Sometime written in blood –
not always accurate**



Projects sourced from an external organisation

- Create temporary multi-organisation structures (TMOs)
- Involve Principal-Agent Relationships
- Susceptible to the “agency problem”



Temporary Multi Organisations (TMOs)

- Members differ not only in their roles and responsibilities but also in their affiliation to different firms
- Can be:
 - a short-term focus
 - adversarial relationships
 - emphasis on low price rather than added value
 - little interest in sharing risks



Principal-Agent relationships

- Where there is a contract by which a person(s) [the Principal] engages another person [the Agent] to perform a service on their behalf
- Involves the delegating of decision-making authority by the Principal to the Agent

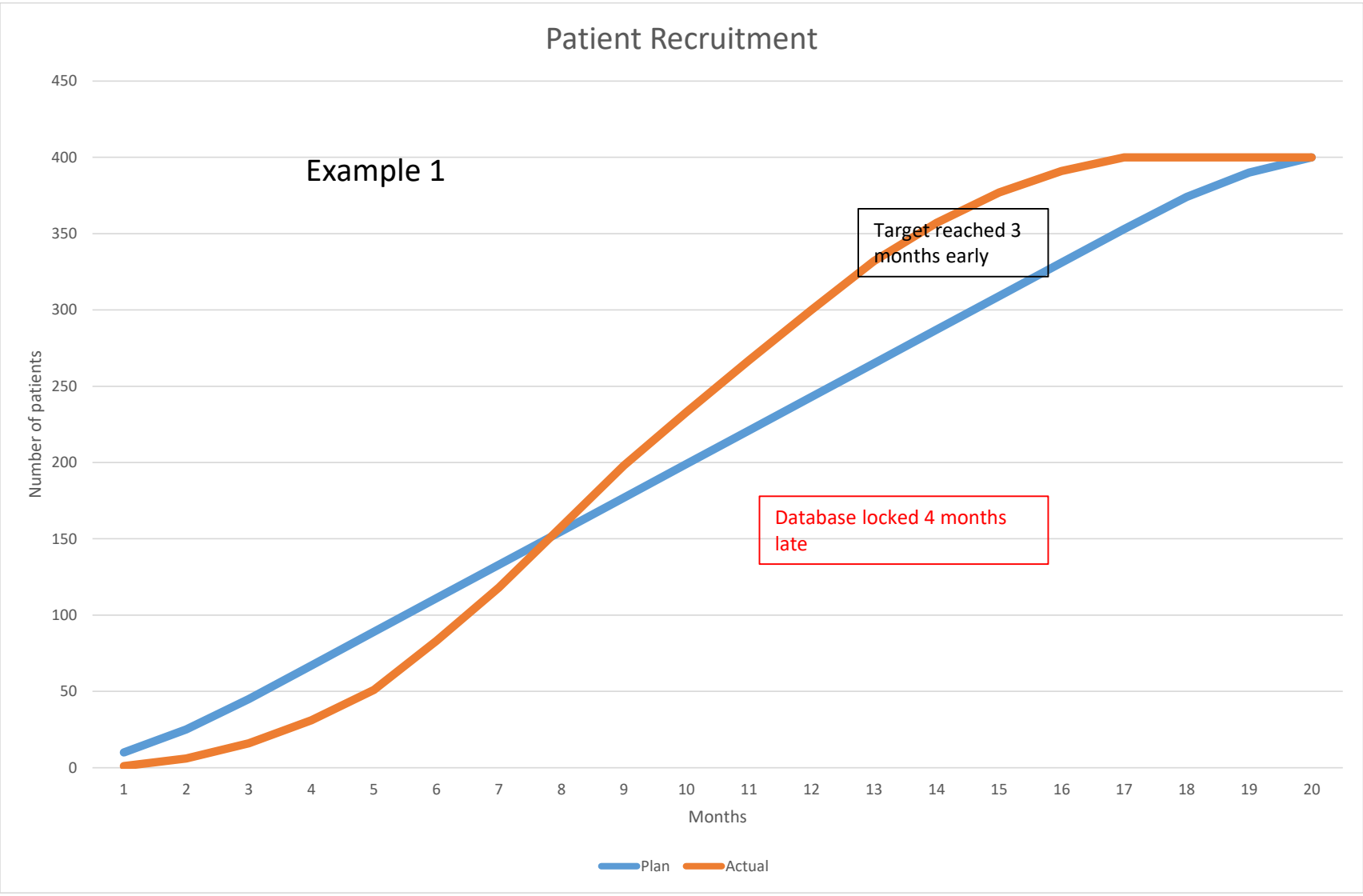


The “Agency” Problem

- High degree of conflict over goals
- High degree of opportunistic behaviour
- High degree of asymmetry of information



We also looked at agency costs, trust, uncertainty, information and level of concealment.





Solutions



Performance Risk

Project Risk Analysis and Management PRAM

Risk

‘Combination of the probability or frequency of occurrence of a defined threat or opportunity and the magnitude of the consequences of the occurrence.

(APM 2000)



The Risk Management Process



Risk Planning Control Techniques

- **Avoidance** - to totally eliminate uncertainty
- **Transfer** - move ownership to 3rd party
- **Reduction/
Mitigation** - actions down grade risk level
- **Contingency** - actions occur if the risk arises
- **Absorption** - assumes the risk is unlikely or
that countermeasures are too expensive



Define and Focus

- What is really important in the context of both the Project and the Programme.





RISK IDENTIFICATION







- Brain storming
- Lists
- SWOT Analysis
- Root Cause Analysis
- Feasibility

RISK IDENTIFICATION

SWOT ANALYSIS

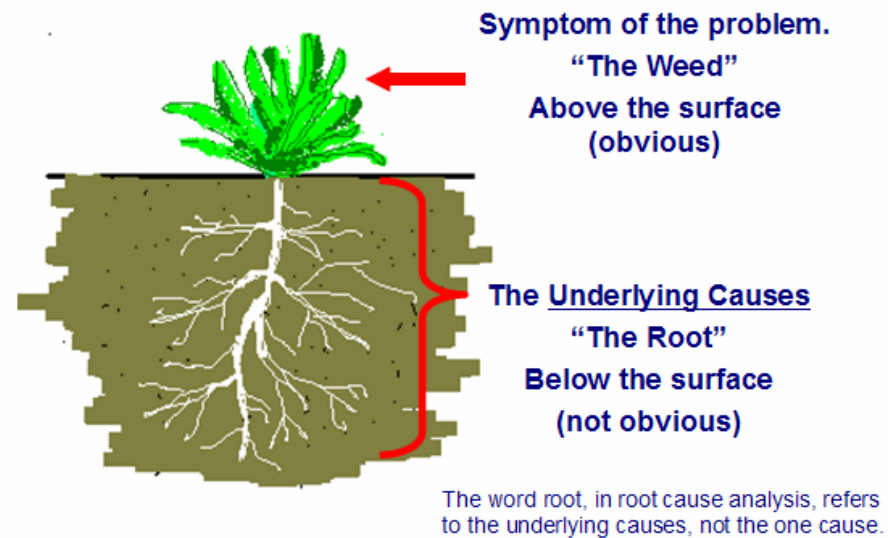


RISK IDENTIFICATION – Six Hats

	<u>The White Hat</u> Information available and needed.		<u>The Red Hat</u> Intuition, feelings & hunches.
	<u>The Black Hat</u> Cautions & Difficulties. Where things might go wrong.		<u>The Yellow Hat</u> Values & Benefits Why something might work.
	<u>The Green Hat</u> Alternatives & Creative Ideas		<u>The Blue Hat</u> Managing the thinking process.

RISK IDENTIFICATION

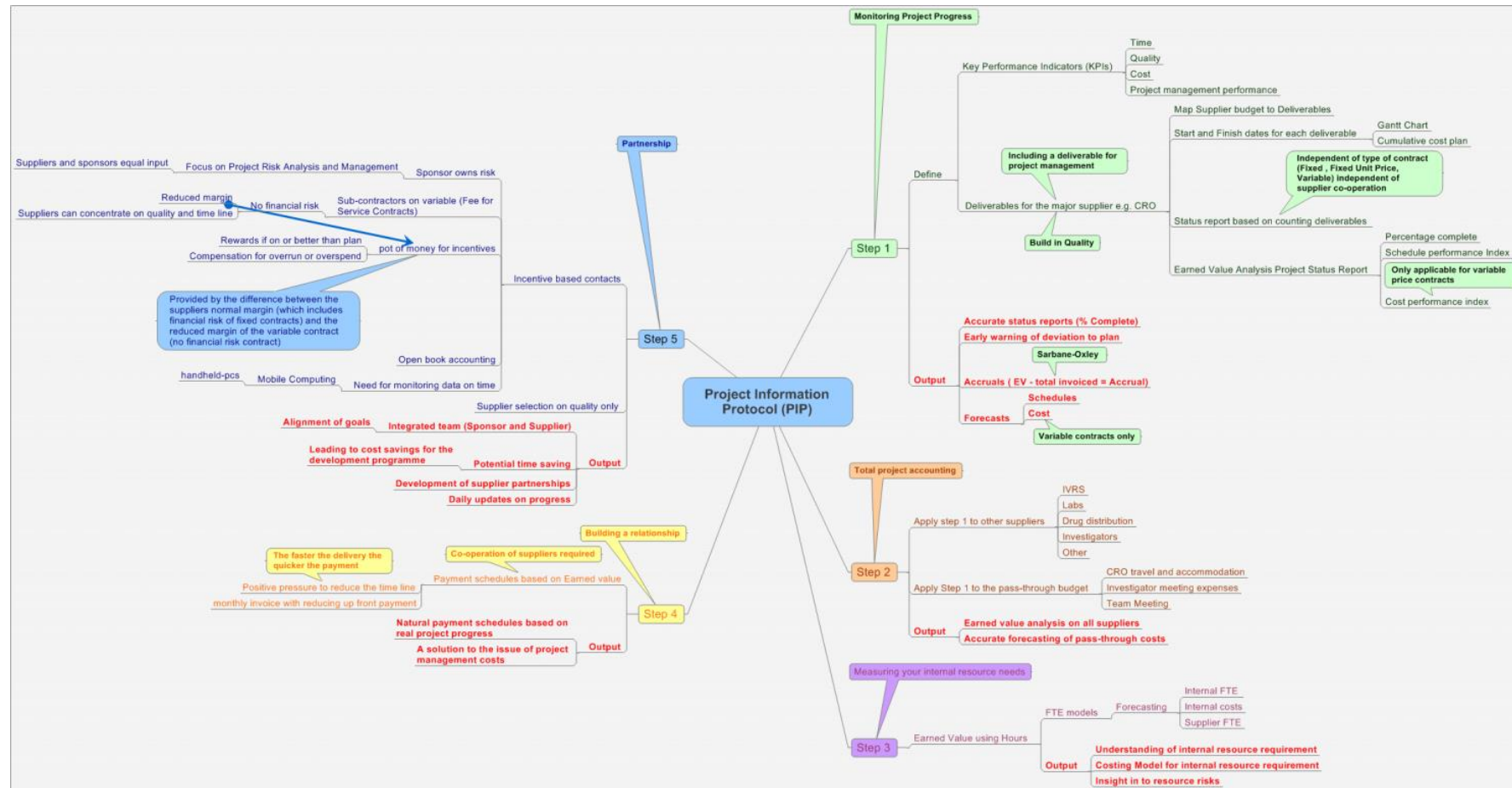
Root Cause Analysis Basics



RISK IDENTIFICATION – 5 Whys

Defect	Reasons
Why-1: Why did THE DEFECT occur?	
Why-2: Why did THAT occur?	
Why-3: Why did THAT occur?	
Why-4: Why did THAT occur?	
Why-5: Why did THAT occur?	
Why-6: Why did THAT occur?	

Mind Maps



Feasibility



Patient Enrolment

- High Quality Protocol
- Accurate enrolment forecast
- Selection of only high enrolling sites
- Fast site initiation
- Site specific plans
- CRA support



Identifying High Quality Sites

1. Past performance in general
2. Past performance in similar indication
3. Ability to conform to GCP
4. Experienced and stable staff
5. Good facilities
6. Competitive trials
7. History of fast contracting
8. Access to electronic Patient records
9. Understands protocol
- 10.PI interested
- 11.Site standards in line with protocol
- 12.Disease prevalence
- 13.Patient demographics



Lasagna's Law

Principle Investigators perception:

Before Trial 5

During Trial 2

After Trial 5



Range Forecasting

- Best case and worst case
- Protocol optimisation
- Risks and opportunities



Risk Assessment

		Impact		
		Low	Medium	High
P r o b a b i l i t y	High			
	Medium			
	Low			?

Risk Planning

- Specific
- Measurable
- Achievable
- Realistic
- Time-bound



Risk	Probability (0.1-1)	Impact (1-10)*	Score	Solution	Management plan	Trigger	Responsible person	Opportunity	Cost implication of plan	Comments
Slow patient recruitment USA	0.9	8	7.2	Reduction	Further feasibility including follow-up with Dr. M and Dr A report by 01may09	N/A	Roger Joby	Find potential sites for Project 02 and Project 03		
Slow overall patient recruitment	0.6	8	4.8	Contingency	If less than 10 but greater than 6 patient have been enrolled by trigger date then open 2 sites in UK	01-Jan-11	Roger Joby	Lock database early		Extra £60,000 for two extra site check cost 60,000with CRO
Failure of any site to recruit a patient	0.6	6	3.6	Contingency	Close the site	If a site has not recruited a single patient 3 calendar months after site initiation the it will be closed	Roger Joby to inform the Responsible CRA	Save money on monitoring.		Investigators and CRO must be made aware of this policy
Study start-up delayed in Turkey due to third party CRO negotiations	0.4	8	3.2	Reduction	Review CRO plans identify potential issues	N/A	Roger Joby	Similar issues may apply to other countries		
Rejection of Protocol by FDA	0.3	9	2.7	Reduction	Hold a review meeting with FDA before Application is required	N/A	Roger Joby to arrange teleconference with FDA			
Poor patient retention	0.3	8	2.4	Reduction	Patient motivation plan.	N/A	CRO Project manager			
Interruption to Drug supplies	0.2	9	1.8	Reduction	Ensure Supplier has an up to date requirement schedule	N/A	Roger Joby to review stock requirements with Supplier each calendar month			



Thing to consider

- Risk Registers
- Root cause analysis
- Focus
- Risk efficiency

Risk efficiency - Example

- **Phase IV** Time and Quality maybe less important , so it is not very efficient to spent a lot of money on covering these risks
- **Pivotal Phase III.** Spend the money



Critical Chain and the Theory of Constraints



Critical Chain and the Theory of Constraints

- Critical Chain is a method for planning and managing projects
- Developed by Eliyahu M Goldratt (1997)
- Critical Chain Methodology is based on Goldratt's Theory of constraints
- Critical Chain is currently being used on the £653M upgrade of Bank Tube Station



Theory of Constraints

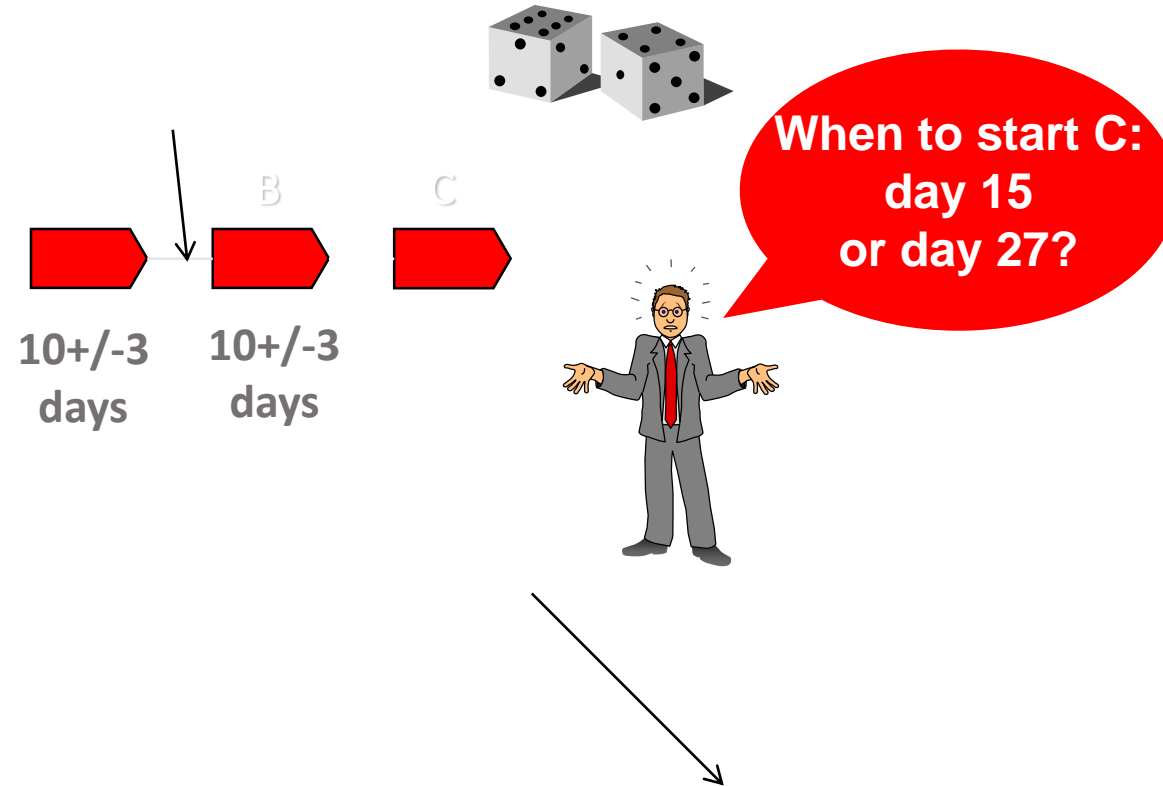
- ▶ The theory of constraint requires you to define the goals for the organisation / project.
- ▶ To identify the constraints (the elements that prevent you from achieving your goal also known as the Weakest Links)
- ▶ Take action to breakdown the constraints
- ▶ Clean data on 400 patients by 1st February 2020
- ▶ Constraints are typically:
 - ▶ Equipment
 - ▶ People (suitably skilled)
 - ▶ Policies

Critical Chain

The Bank Station Project

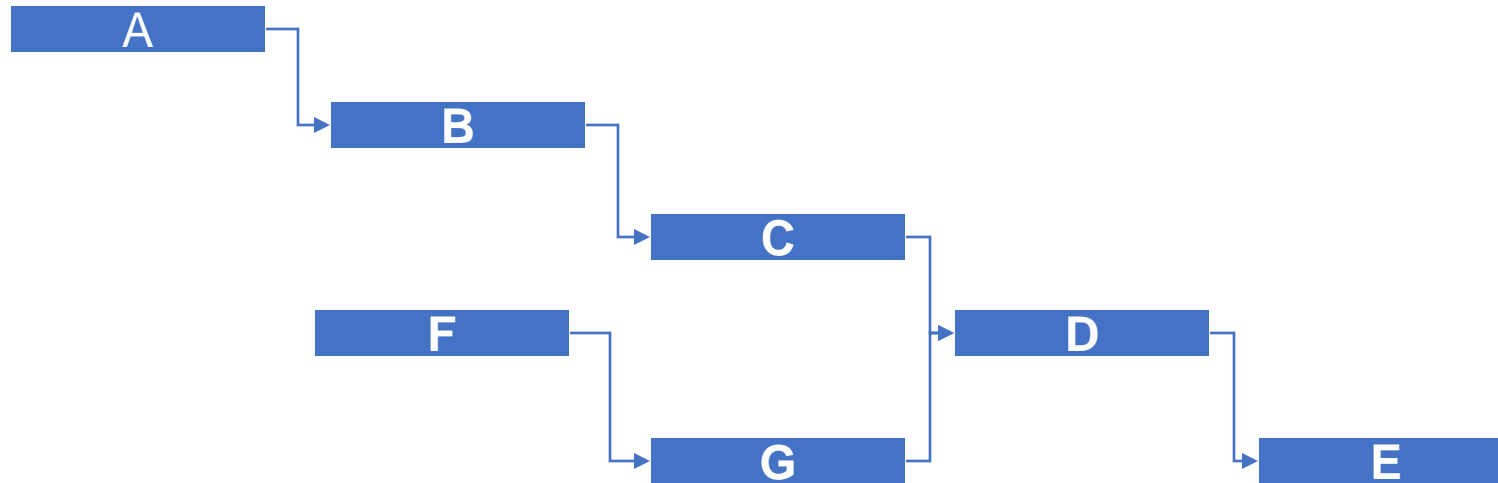


Uncertainty is intrinsic to project work



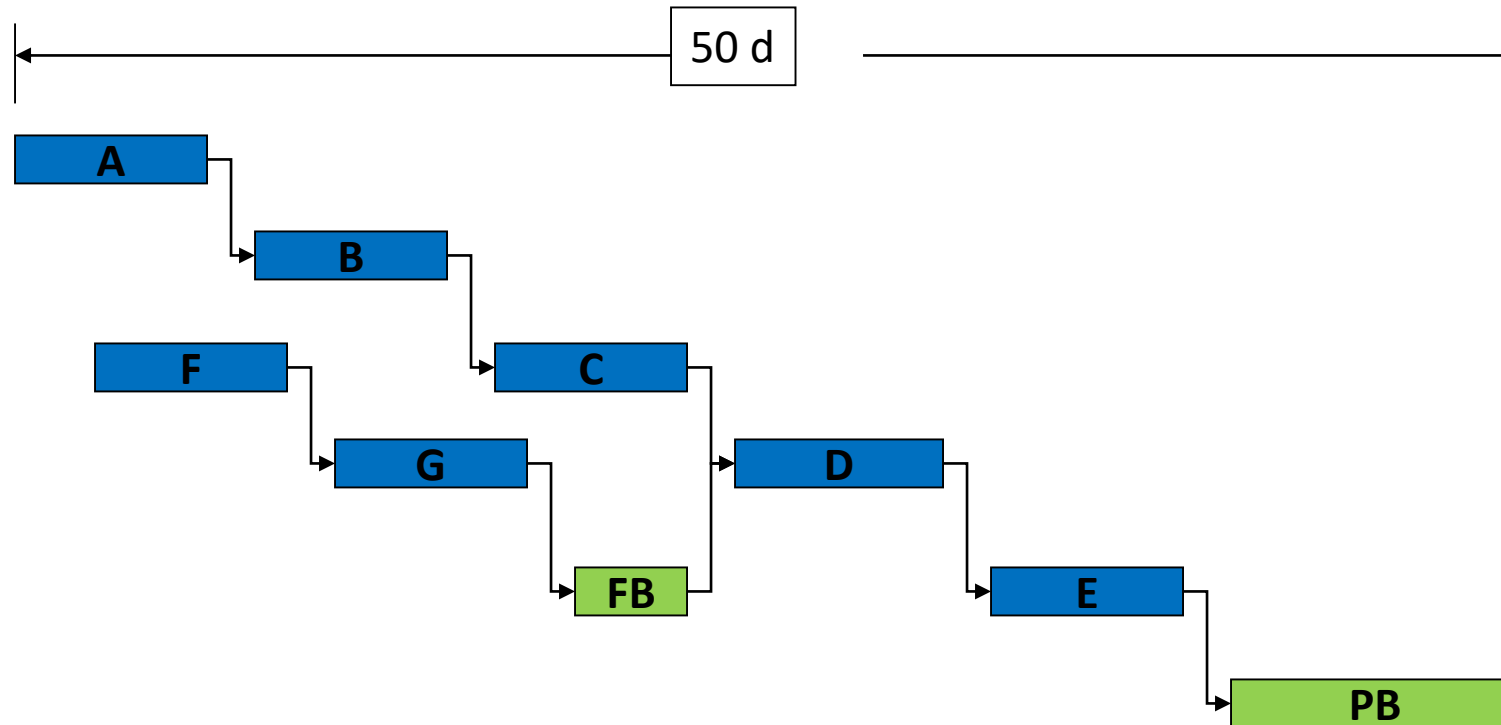
Conventional Projects

50 Days



All tasks 10 days long

B4B PM applies an Aggregated Tolerance to the Task Flow called a 'Buffer' to manage the uncertainties





Relational Risk



Relational risk

- Adverse Selection and Moral Hazard
- Uncertainty
- Value sharing and risk sharing perspectives
- Formal v informal approaches

The Projects

<p>CASE D Clinical Trial project 2 – Investigational product for the treatment of haemophilia</p>	<p>CASE A Construction project 1 – Airport terminal</p>
<p>CASE B Construction project 2 – New water reservoir</p>	<p>CASE C Clinical Trial project 1 – Investigational product for the treatment of lung cancer</p>

LOW

HIGH

Level of success

Causes of failure – lens of agency theory

Project	Level of Success	Contract Suitability	Degree of Goal Conflict	Degree of Opportunistic Behaviour	Degree of Information Asymmetry	Level of Trust	Level of information to verify Contractor performance	Level of concealment of negative outcomes
Airport terminal refurb.	High	High	Low	Neutral	Low	Neutral	High	Neutral
New water reservoir	Low	Low	Low	High	Neutral	Low	Low	High
Treatment of lung cancer	High	High	Low	Low	Low	High	Neutral	Low
Treatment of haemophilia	Low	Low	High	High	High	Low	High	High

The CURED framework

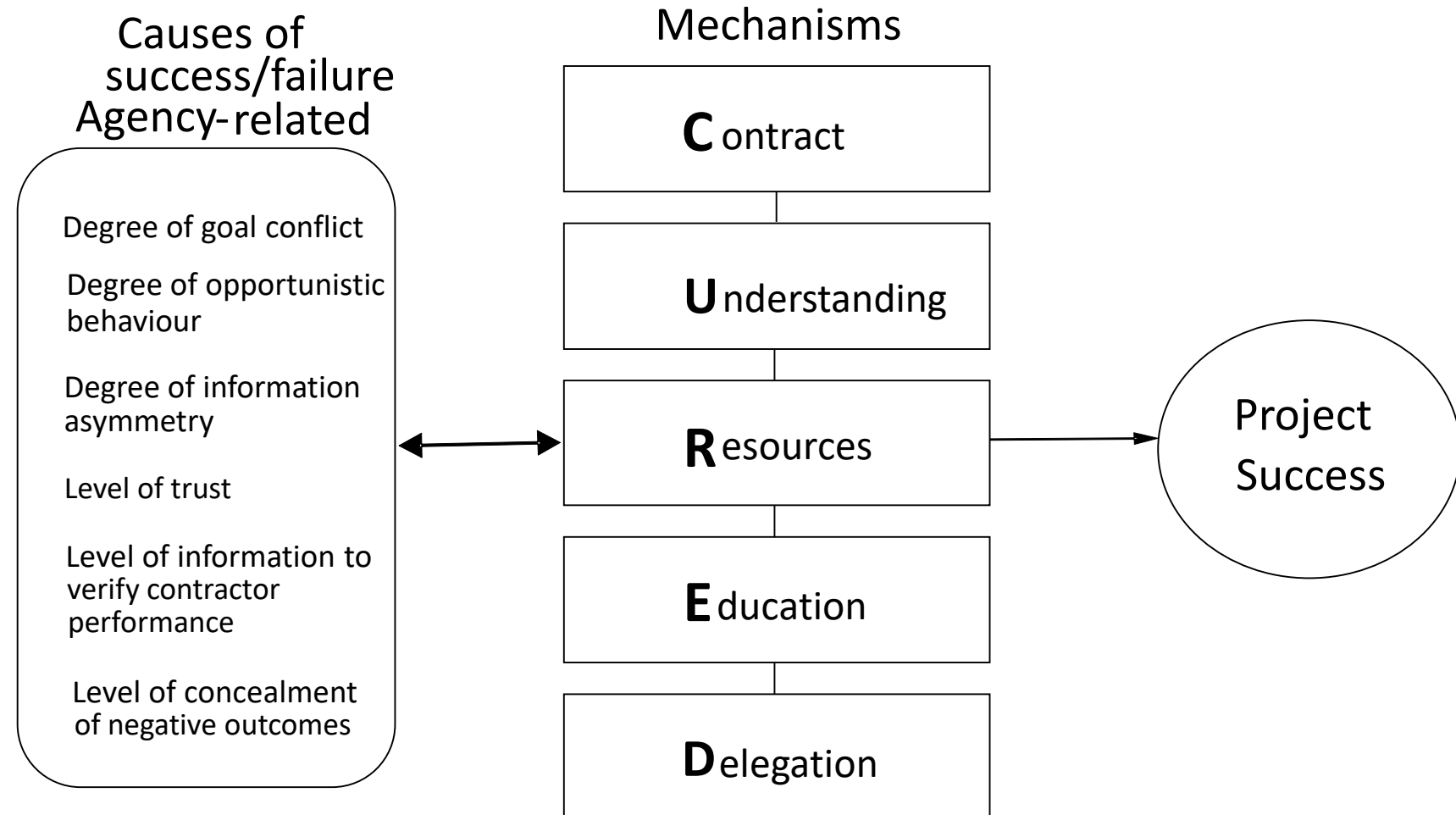


Figure 1 – The CURED framework for resolving agency-related issues to deliver project

NEC Contracts

Risk management is Better than Crisis Management

Early warning provisions

There is a duty on both sides to notify each other if they become aware of a matter that:

1. Increase the total price
2. Delay completion
3. Delay meeting a key date
4. Impair performance



NEC Risk Register

The contacts specifies:

- Once early warning has been given the matter is entered onto a risk register.
- There is an instruction to attend risk reduction meeting where attendees consider proposals to avoid or reduce risk and agree appropriate action



The NEC Objective

- Flexibility
- Clarity
- Stimulus to good management



NEC on Relationships

Clause 10.1

- Parties act in spirit of mutual trust and cooperation



Conclusion

