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)

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

David Cleden 2009 Managing Uncertainty Published by Gower
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"
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

Temporary Multi Organisations (TMOs)
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.
Example 1

Patient Recruitment

Target reached 3 months early

Database locked 4 months late
Performance Risk
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

1. Define & focus
   - Reasons?

2. Risk Identification
   - What are they?

3. Risk Assessment
   - How important are they?

4. Risk Planning
   - What can and will we do?

5. Risk Management
   - How’s progress?
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

- Strengths
- Weaknesses
- Opportunities
- Threats
RISK IDENTIFICATION – Six Hats

- **The White Hat**: Information available and needed.
- **The Red Hat**: Intuition, feelings & hunches.
- **The Black Hat**: Cautions & Difficulties. Where things might go wrong.
- **The Yellow Hat**: Values & Benefits. Why something might work.
- **The Green Hat**: Alternatives & Creative Ideas.
- **The Blue Hat**: Managing the thinking process.
Root Cause Analysis Basics

Symptom of the problem.
“The Weed”
Above the surface
(obvious)

The Underlying Causes
“The Root”
Below the surface
(not obvious)

The word root, in root cause analysis, refers
to the underlying causes, not the one cause.
RISK IDENTIFICATION – 5 Whys

<table>
<thead>
<tr>
<th>Defect</th>
<th>Reasons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why-1: Why did THE DEFECT occur?</td>
<td></td>
</tr>
<tr>
<td>Why-2: Why did THAT occur?</td>
<td></td>
</tr>
<tr>
<td>Why-3: Why did THAT occur?</td>
<td></td>
</tr>
<tr>
<td>Why-4: Why did THAT occur?</td>
<td></td>
</tr>
<tr>
<td>Why-5: Why did THAT occur?</td>
<td></td>
</tr>
<tr>
<td>Why-6: Why did THAT occur?</td>
<td></td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Probability</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- High Impact and High Probability: Red
- High Impact and Medium Probability: Yellow
- High Impact and Low Probability: Green
- Medium Impact: Yellow
- Low Impact: Green
- Low Impact and Low Probability: Green
- Low Impact and Medium Probability: Yellow
- Low Impact and High Probability: Green

The cell with a question mark represents the unknown risk area where both impact and probability are high, but the specific impact level is not specified.
Risk Planning

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

Our Disaster Recovery Plan Goes Something Like This...
<table>
<thead>
<tr>
<th>Risk</th>
<th>Probability</th>
<th>Impact (0-10)</th>
<th>Score</th>
<th>Solution</th>
<th>Measurement plan</th>
<th>Trigger</th>
<th>Responsible person</th>
<th>Opportunity</th>
<th>Cost implication of site</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slow patient recruitment USA</td>
<td>0.9</td>
<td>8</td>
<td>7.2</td>
<td>Reduction</td>
<td>Further feasibility including follow-up with Dr. M and Dr. A report by 01-May-09</td>
<td>N/A</td>
<td>Roger Joby</td>
<td>Find potential sites for Project 02 and Project 03</td>
<td></td>
<td>Extra £60,000 for two extra site check costs</td>
</tr>
<tr>
<td>Slow overall patient recruitment</td>
<td>0.6</td>
<td>8</td>
<td>4.8</td>
<td>Contingency</td>
<td>If less than 10 but greater than 6 patient have been enrolled by trigger date then open 2 sites in UK</td>
<td>01-Jan-11</td>
<td>Roger Joby</td>
<td>Lock database early</td>
<td></td>
<td>£60,000 with CRO</td>
</tr>
<tr>
<td>Failure of any site to recruit a patient</td>
<td>0.6</td>
<td>6</td>
<td>3.6</td>
<td>Contingency</td>
<td>Close the site</td>
<td>If a site has not recruited a single patient 3 calendar months after site initiation then it will be closed</td>
<td>Roger Joby to inform the Responsible CRA</td>
<td>Save money on monitoring</td>
<td></td>
<td>Investigators and CRO must be made aware of this policy</td>
</tr>
<tr>
<td>Study start-up delayed in Turkey due to third party CRO negotiations</td>
<td>0.4</td>
<td>8</td>
<td>3.2</td>
<td>Reduction</td>
<td>Review CRO plans identify potential issues</td>
<td>N/A</td>
<td>Roger Joby</td>
<td>Similar issues may apply to other countries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rejection of Protocol by FDA</td>
<td>0.3</td>
<td>9</td>
<td>2.7</td>
<td>Reduction</td>
<td>Hold a review meeting with FDA before Application is required</td>
<td>N/A</td>
<td>Roger Joby</td>
<td>Roger Joby to arrange teleconference with FDA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor patient retention</td>
<td>0.3</td>
<td>8</td>
<td>2.4</td>
<td>Reduction</td>
<td>Patient motivation plan.</td>
<td>N/A</td>
<td>CRO Project manager</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interruption to Drug supplies</td>
<td>0.2</td>
<td>9</td>
<td>1.8</td>
<td>Reduction</td>
<td>Ensure Supplier has an up-to-date requirement schedule</td>
<td>N/A</td>
<td>Roger Joby</td>
<td>Roger Joby to review stock requirements with Supplier each calendar month</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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
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

When to start C: day 15 or day 27?
Conventional Projects

50 Days

A → B → C → F → G → D → E

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

<table>
<thead>
<tr>
<th>CASE D</th>
<th>CASE A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial project 2 – Investigational product for the treatment of haemophilia</td>
<td>Construction project 1 – Airport terminal</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CASE B</th>
<th>CASE C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Construction project 2 – New water reservoir</td>
<td>Clinical Trial project 1 – Investigational product for the treatment of lung cancer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LOW</th>
<th>HIGH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of success</td>
<td></td>
</tr>
<tr>
<td>Project</td>
<td>Level of Success</td>
</tr>
<tr>
<td>-----------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Airport terminal refurb.</td>
<td>High</td>
</tr>
<tr>
<td>New water reservoir</td>
<td>Low</td>
</tr>
<tr>
<td>Treatment of lung cancer</td>
<td>High</td>
</tr>
<tr>
<td>Treatment of haemophilia</td>
<td>Low</td>
</tr>
</tbody>
</table>
Figure 1 – The CURED framework for resolving agency-related issues to deliver project success
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

Performance Risk (PRAM)

Theory of Constraints

Relational Risk