Three Pronged Attack on Project Risk
The three prongs

Performance Risk (PRAM)

Theory of Constraints

Relational Risk
Performance Risk

The conventional approach

Project Risk Analysis and Management (PRAM)

- Threats and Opportunities associated with Time lines, Budgets and Quality

- Process:
  - Define and Focus
  - Risk Identification
  - Risk Assessment
  - Risk Planning
  - Management of plan
Performance - Risk Assessment

Impact

Low  Medium  High

High  [Yellow]  [Red]
Medium [Green]  [Yellow]  [Red]
Low   [Green]  [Yellow]  [Red]

[?]
Performance Risk Plans

• Avoidance

• Reduction (mitigation)

• Contingency

• Acceptance
<table>
<thead>
<tr>
<th>Risk Description</th>
<th>Probability (0-1)</th>
<th>Impact (1-10)</th>
<th>Score</th>
<th>Solution</th>
<th>Trigger</th>
<th>Responsible person</th>
<th>Opportunity</th>
<th>Cost implication of plan</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>N/A</td>
<td>Roger Joby</td>
<td>Find potential sites for Project 02 and Project 03</td>
<td>Extra £10,000 for two extra sites</td>
<td></td>
</tr>
<tr>
<td>Slow overall patient recruitment</td>
<td>0.6</td>
<td>8</td>
<td>4.8</td>
<td>Contingency</td>
<td>01-Jan-11</td>
<td>Roger Joby</td>
<td>Lock database early</td>
<td>£0,200 check cost with CRO</td>
<td></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 the it will be closed</td>
<td>Roger Joby to inform the Responsible CRA</td>
<td>Save money on monitoring</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>
</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>
</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>
</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>
</tr>
</tbody>
</table>
Performance risk examples

Number of patients lost to follow up

• How important is it
• How will you detect it
• What action are you going to take - reduction, contingency, acceptance?
Theory of Constraints (TOC)

- Constraints are typically about:
  - Equipment
  - People
  - Policies

Diagram:
1. Define Goals for the Project
2. Identify Constraints
3. Instigate action to breakdown the constraint
Theory of Constraints Example

Introduction of eTMF
Relational Risk

• Dealing with the people
## Causes of Failure

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

• TOC and Relational risks are less likely to be identified by the traditional performance risk methodology.

• Can be too sensitive to put down on a risk register, but research shows that they are probably more important.