

Comprehensive Program on Effective Project Management

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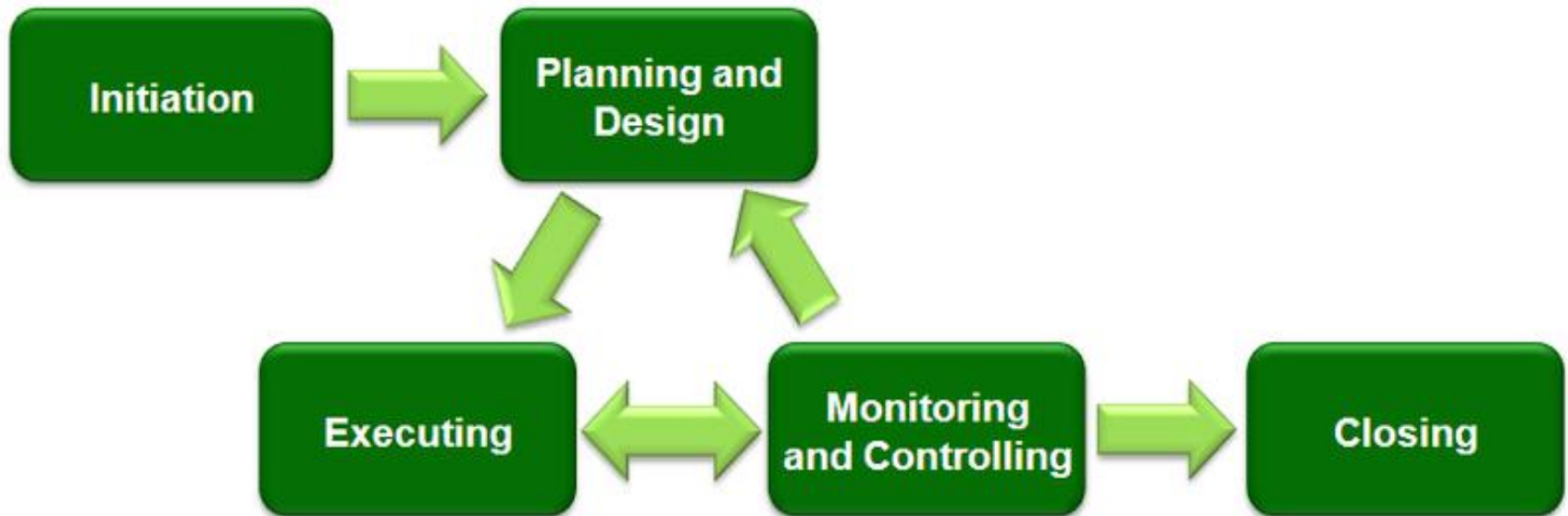
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Definitions



- **Project Management:** The body of knowledge concerned with principles, techniques and tools used in planning, control, monitoring, and review of projects (<http://www.investopedia.com>)



Creativity

Elizabeth Gilbert



- Ability to produce something new through imaginative skill, whether a new solution to a problem, a new method or device, or a new artistic object or form (Britannica Concise Encyclopaedia)

Creativity Quotes

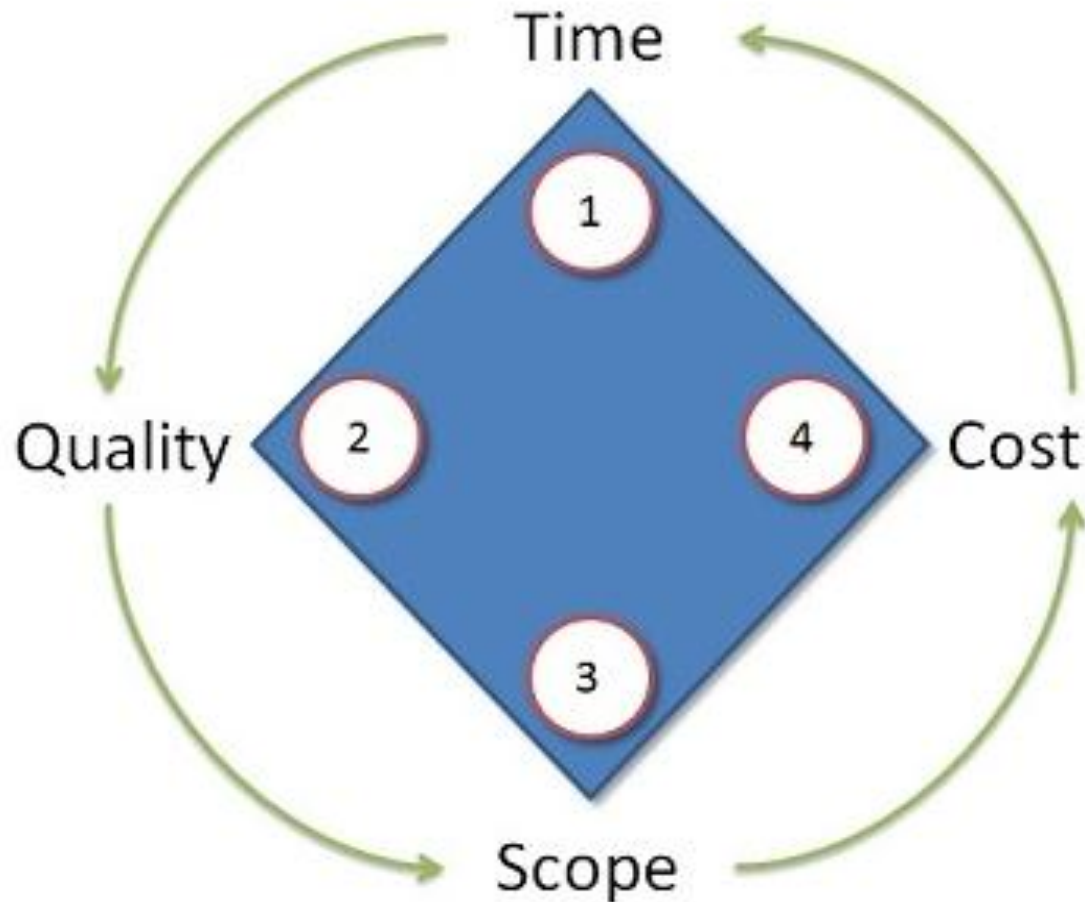
- *“Creativity is not the finding of a thing, but the making something out of it after it is found.”*

- James Russell Lowell

- *“The things we fear most in organizations- fluctuations, disturbances, imbalances, are the primary sources of creativity.”*

- Margaret J. Wheatley

The Project Diamond



Example 1: Patient Recruitment

Scenario

- Study in Obese subjects with Dyslipidemia
- Our competitive quote was aggressive on project timelines

Challenge

- Patient recruitment compressed timelines
- Patient compliance to be ascertained (CRC motivation)

Conventional Approach

- Recruit as they come (= Passivity; No control on footfalls)
- Recruit more (= lose more) ; More sites

Karmic Solution

- Single centre
- Free Check-up camps;
- Captive populations; Registry

Impact

- Reduced cost; High quality; Lesser data cleaning = lesser time for CDM/Statistics/MW Team

Example 2: Ethics Committee

Scenario

- Multi-Centric study in Oncology
- Recruitment – 6 mths; FV to LV – 6 months.

Challenge

- ? Footfalls; ? Exclusions;
- ? Dropouts; ? Deaths

Conventional Approach

- Increase number of centers = High Costs
- Lesser recruitment = violate timelines

Karmic Solution

- 6 sites aggressive; 4 sites stand-by; Site-Inspections complete/EC approvals – sounded
- Recruitment tracker – daily follow up till 3 mths.

Impact

- Only 1 extra site activated
- Costs contained; timelines followed.

Example 3: Screening Failures

Scenario

- Antibiotic Efficacy in Resp. Tract Infection
- 11 Exclusion Criteria - ∴ Costs of selection

Challenge

1. Post randomization screening failures
2. Subject exclusion threatening “Blinding”

Conventional Approach

- High financial quote (= less competitive bid)
- Prayers ...

Karmic Solution

- Sputum examination as a pre-screening test
- Single consultant with access to lab report deciding on patient exclusion and informing so to the sites

Impact

- Reduced screen failures; cost cutting
- No threat to blinding

Example 4: Scope of Work

Scenario

- Open label Study in Oncology
- Adjuvant efficacy

Challenge

- Low budget
- Narrow timelines

Conventional Approach

- Hidden costs; disclaimers
- Desperate measures = High Costs

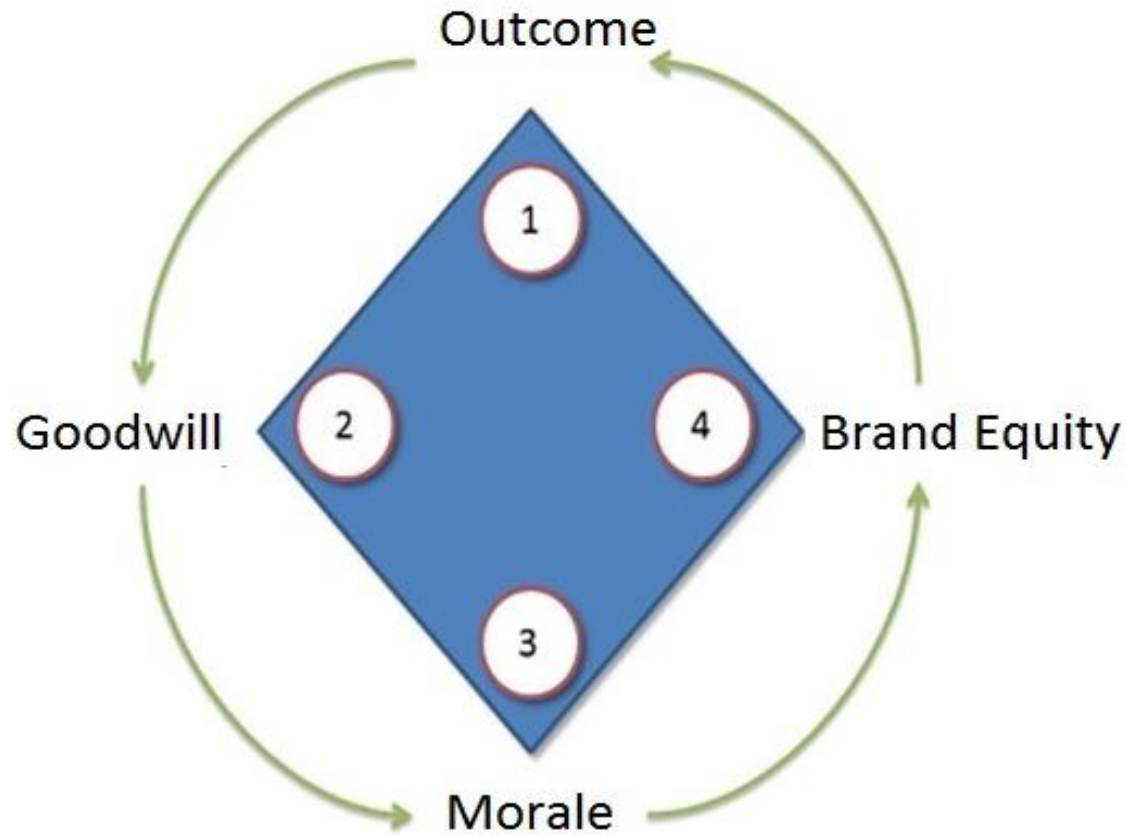
Karmic Solution

- Interim analysis of data when patient flow was poor. Favorable results. Study concluded.

Impact

- Lesser payment (\because Less no. of complete CRF)
- Timeline honored = goodwill generated.

The Impact Diamond



Introspective Check List

Investigator

- Can I recruit faster / more?
- Do the subjects & CRCs confide in me?

CRC

- How can the subjects co-operate more?
- Do I need reminders from PI / CRA?

CRA

- Am I ready for an Audit?
- Can I better communications?

CRO

- What can be alternative strategies?
- Is my back up Plan I, II, III Ready?

Sponsor

- Do the CROs have a say? Are we supportive of CRO? Can we detect early signals?

Lessons Learnt



- The creative solutions were driven by necessity
- In most cases the solutions were proposed by “Juniors”
- Metrics and e-databases flagged the problems at an earlier date – enabling corrective action
- Senior Management shared the problems with the team; encouraged dialogue and gave due credit – individually and collectively.



Thank You



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