

# Medical Devices: SEM Essentials

Where Financial Performance Meets Quality

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# Defining Performance

- “The way someone or something functions”
  - “The pilot thought that the plane performed well”
    - *The American Heritage Dictionary of the English Language, 4<sup>th</sup> Edition, 2009, Houghton, Mifflin, Harcourt.*
  
- Performance must be measured.

# Defining Performance (2)

- Performance is a quantitative attribute, associated with a metric or set of metrics taken in their appropriate context, which determine the relative level of success of a process, system, individual or organization.
  - *Yves Theriault, 2014*

# Defining Performance (3)

- A word On Overall Organizational Performance
  - The is more than Financial Metrics
  - Social Responsibility; Sustainability...

# Performance Metrics for R&D

- Cost of Development per commercial Medical Devices.
  - Is not a great metric.
  - Some devices may cost more to develop but bring higher revenues.
- The Ratio of Total Revenues over a defined period of time to the R&D cost of the commercial devices developed during same period.
  - Is a better metric.

# Performance Metrics for R&D

- Number of proprietary products versus competitors.
- Time to develop new products.
- Affordability on the Marketplace.

# About Performance

- Performance must be planned for.
- Performance must be monitored and measured.
- Performance enhancement is realized via lessons learned and the consequent taking of appropriate actions.
- Strategic implementation constitutes the cornerstone of any R&D-based organization.
- To ensure performance in strategic implementation, a SYSTEM must be put in place
- The Integration of PMI and SEM Global Standards Constitute a Framework for that System.

# Multidirectional Alignment

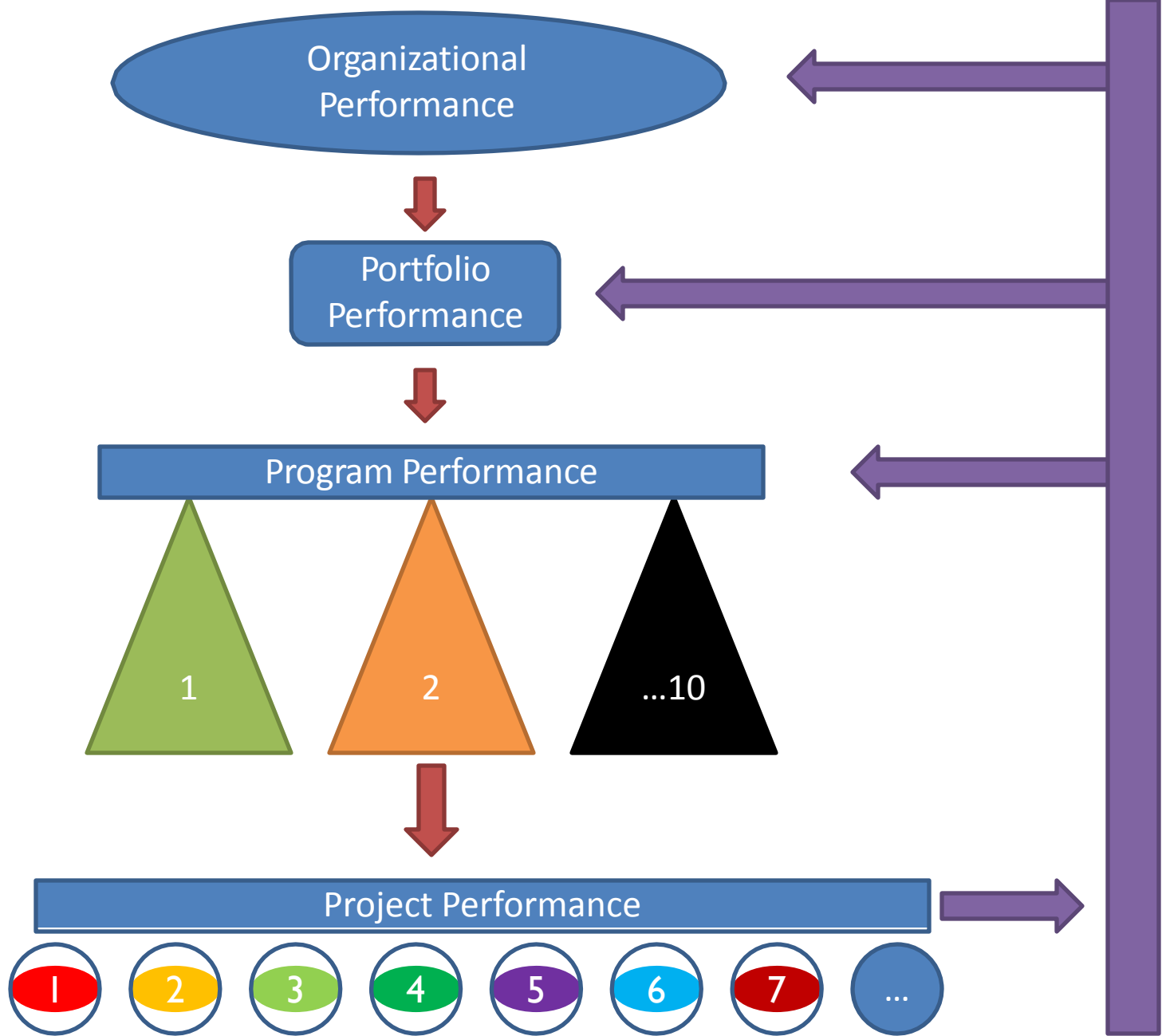
- Multidirectional Alignment is the ensemble of processes enabling real-time triggering of responses from strategically deployed core competencies at all levels of an organization's multi-functional infrastructure in order to ensure the deployment, execution, focused compliance, re-assessment, modification, improvement and re-deployment of its strategic programs on an ongoing basis.

- *Yves Theriault, 2008*

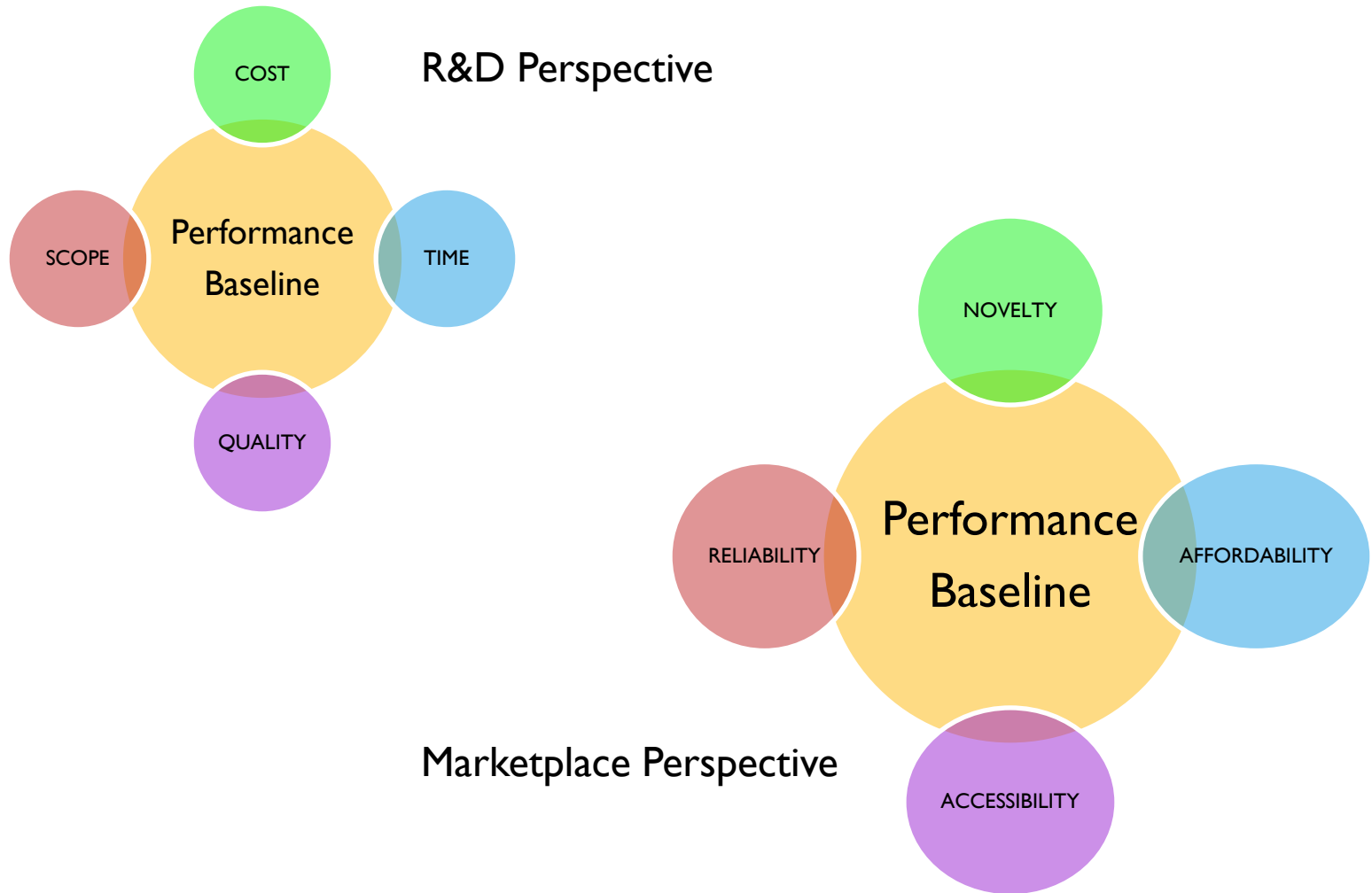


# SEM and MDA

- SEM is MDA applied in the context of integrated system engineering team and total quality management.
- Optimization of Total Life Cycle Value Management



# A Project Management Perspective

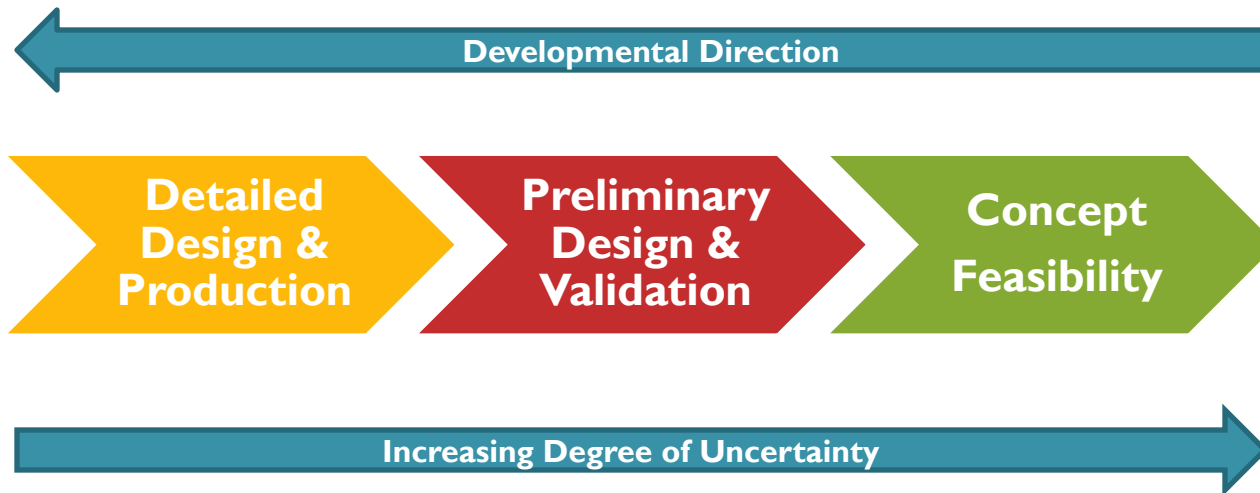


# Performance Baseline Uncertainty

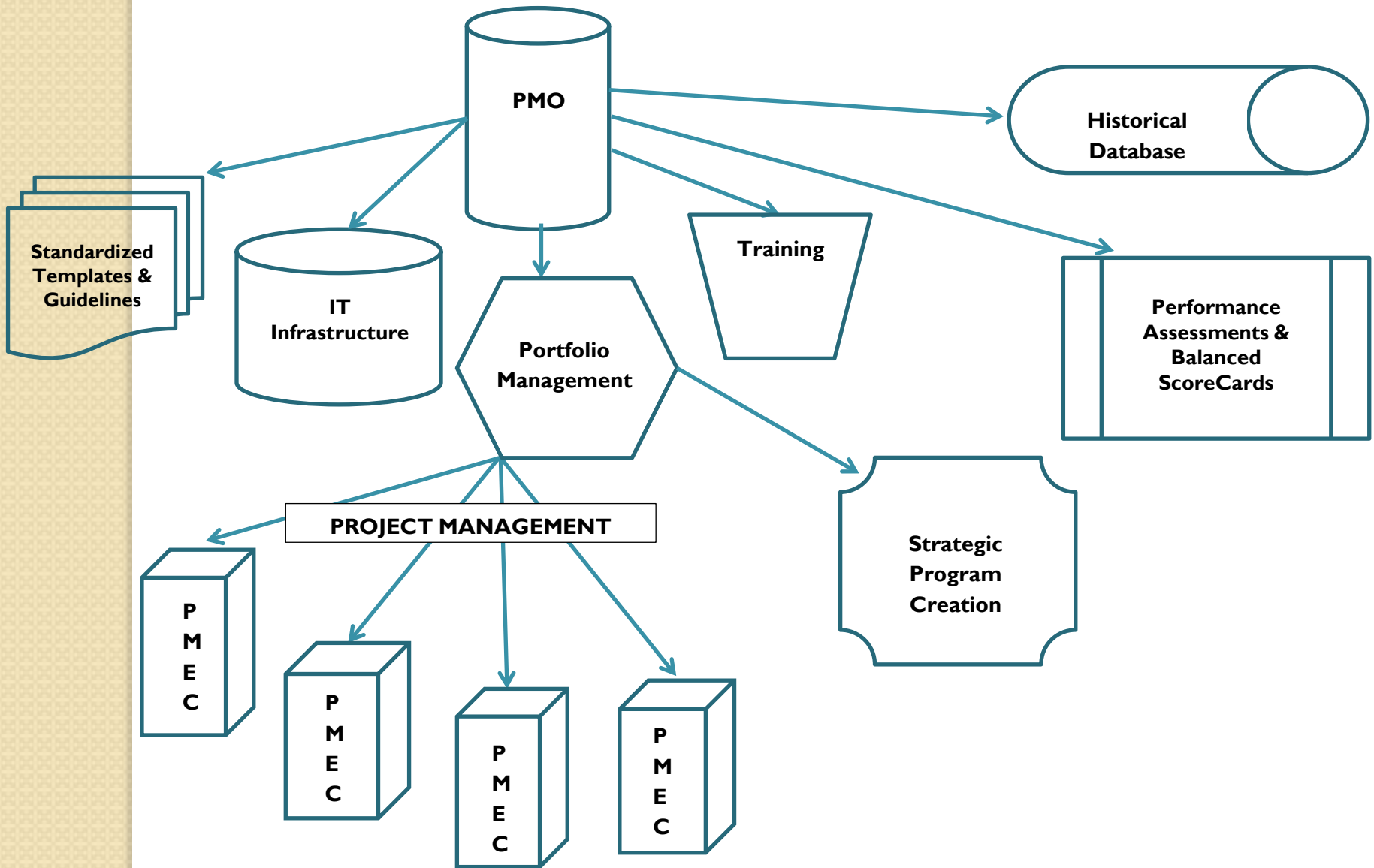
- The ability to establish a reliable performance baseline and conform to it is directly proportional to the degree of control that the performing organization has on the project development.

# Performance Baseline Uncertainty

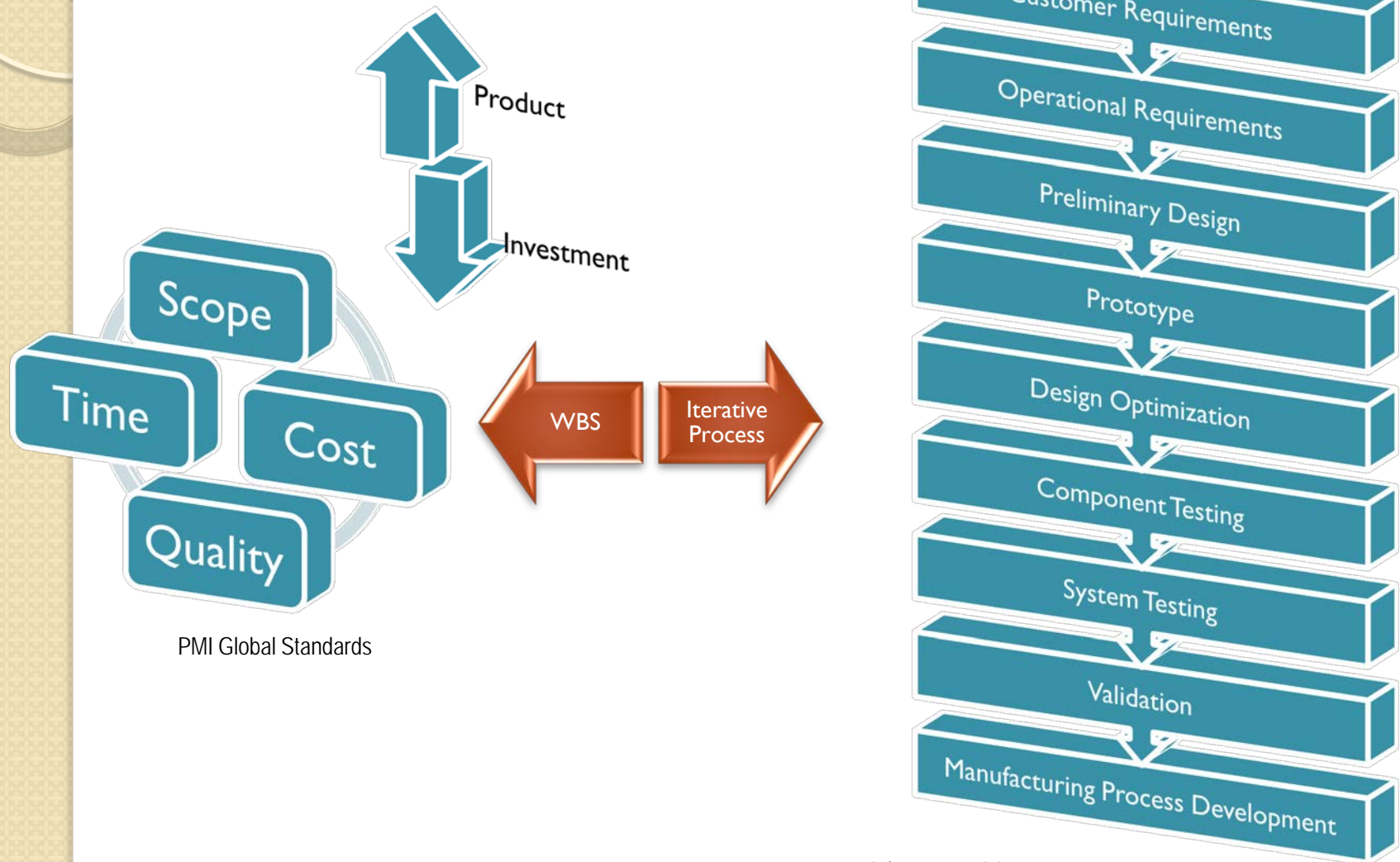
- By Phase



# PERFORMANCE MANAGEMENT SYSTEM = PMO

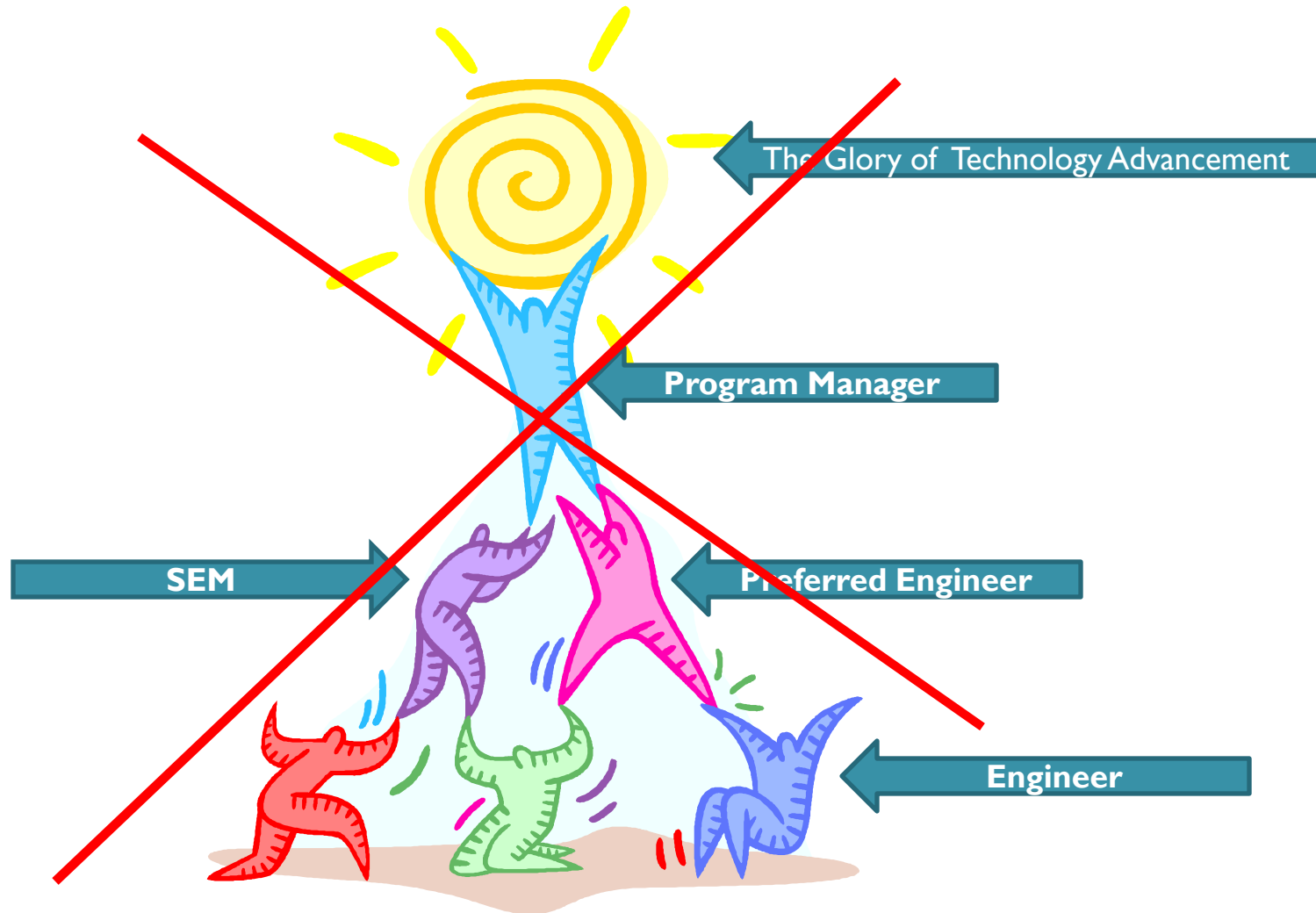


# PM - SEM



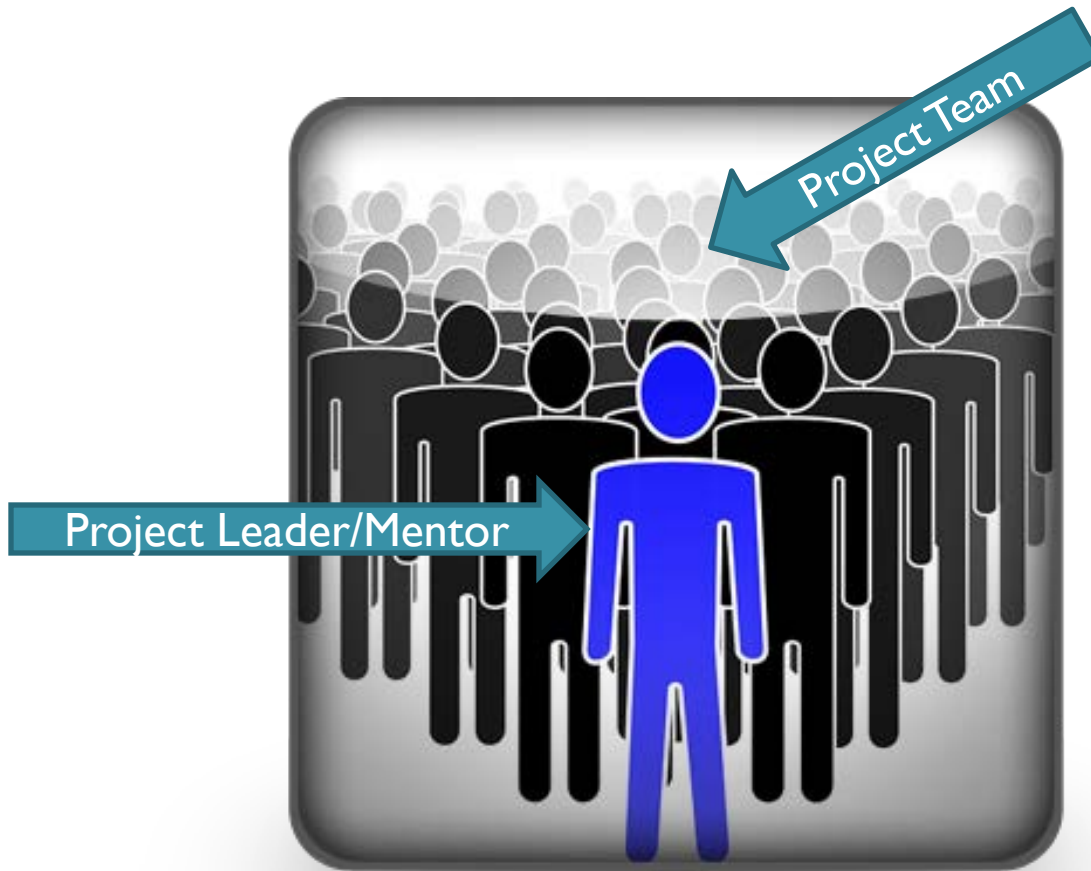
ANSI/EIA-632; ISO-15288; IEEE-1220  
ISO 13485 Standards

# Political Pyramid $\neq$ Leadership





# The Face of Leadership



# Conclusion

- SEM is essential in achieving developmental and quality performance.
- The Integration of PM and SEM Global Standards is essential to optimize overall organizational performance.
- Program Manager and System Engineering Manager must work in harmony.
- Leadership is a must, not an option.
- All of the above are essential to affordable healthcare.