



44TH
Annual Meeting



Boston 2008

Six Sigma and Clinical Research Operations: Square Peg in Round Hole?

Eric Lake
Partner

Pharmica Consulting



Agenda

- A Brief Origin of Six Sigma
- What is Six Sigma?
- Why use Six Sigma?
- Six Sigma and Lean Sigma
- Characteristics of “good” Six Sigma projects
- Areas Appropriate for Six Sigma
- Conclusion



Origin of Six Sigma

- Sigma is a statistical term
 - Application of sigma inappropriate for non-normal systems
- Originated from production processes
- Six Sigma focuses on developing and delivering near-perfect products and services consistently
 - End Objective: **Delight Customers**

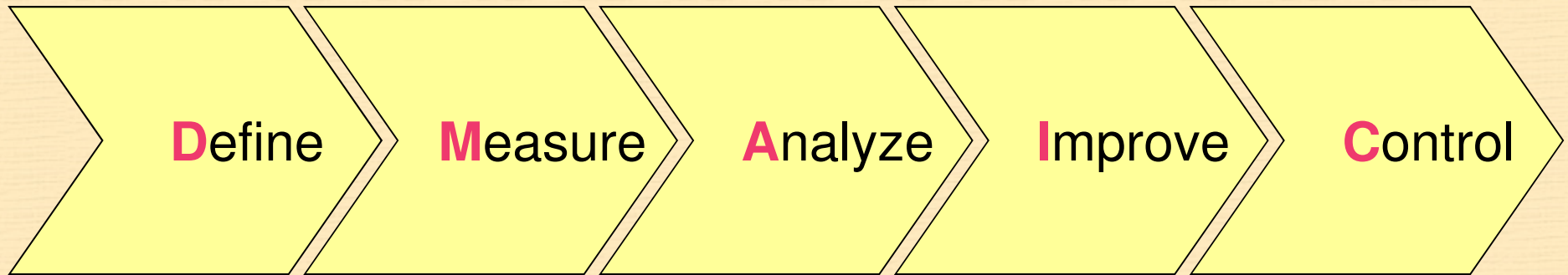


What is Six Sigma?

- Business philosophy focusing on continuous improvement
 - Understand customer needs
 - Analyze business processes
 - Utilize proper measurement methods
- Focus on key business processes
 - Improve ones that would reap most benefits
 - Reduce variation (defects)

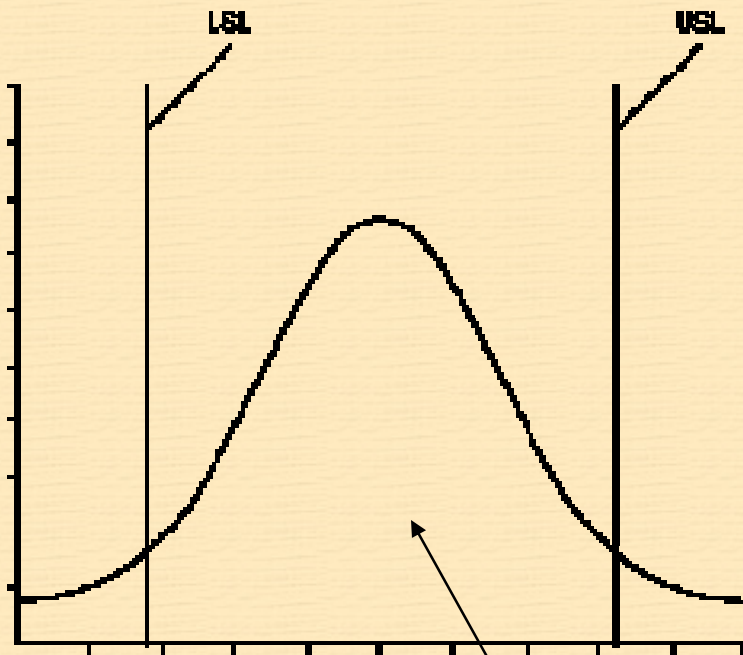


DMAIC

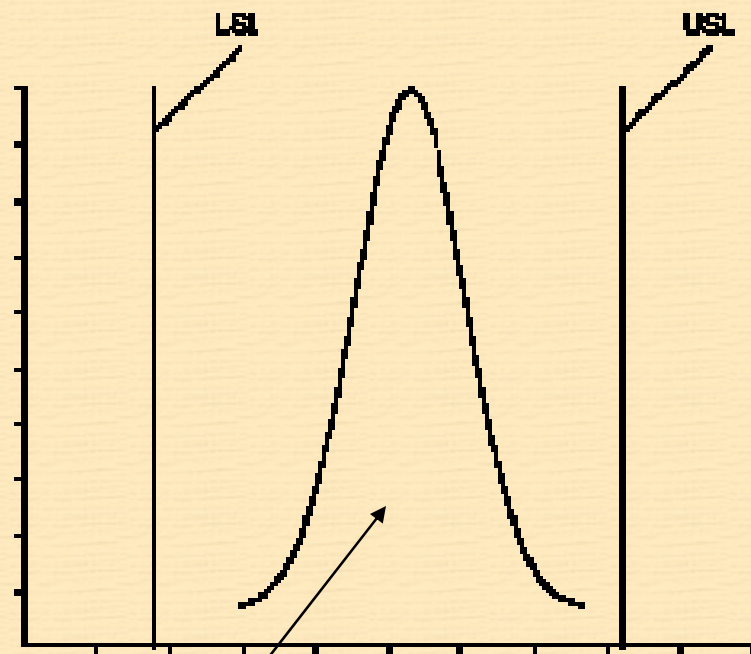


Process Capability

Low Capability Process



High Capability Process

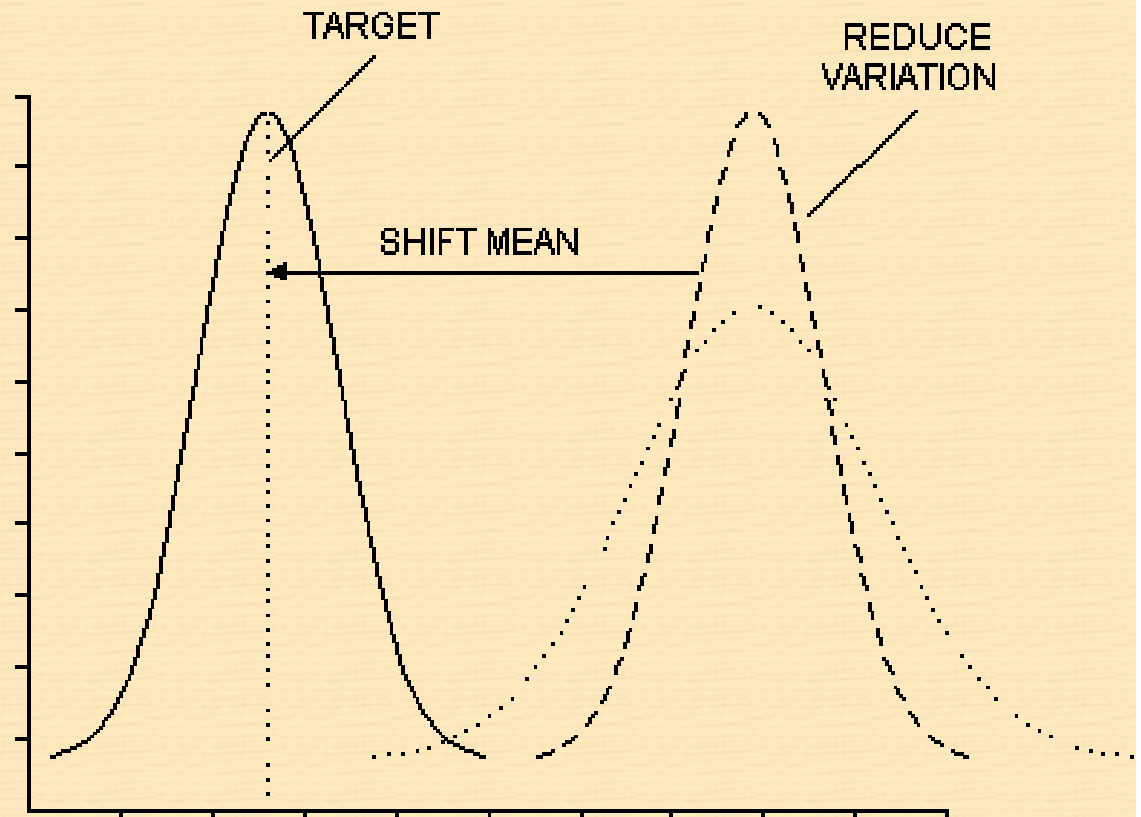


Process Spread



Corrective Actions

- For a process with low capability:
 - Reduce variation in the process
 - Shift mean of the process towards the target



Why Use Six Sigma?

- To focus attention on process management
- To have a standardized method for tracking process improvement
- To systematically align your processes with your customers' needs
- To please your customers!



Six Sigma and Lean Six Sigma

- Lean: Eliminating non-value waste in a process
 - Reduce cycle times
 - Improve on-time delivery
 - Reduce cost
- Six Sigma: Using statistical techniques to reduce process variation
- Lean + Six Sigma = Lean Six Sigma
 - Speed and consistency



Six Sigma Results

- Average Black Belt project will save \$175,000

*Harry (1998) "Six Sigma: A Breakthrough Strategy for Profitability"

- Having 1% of employees as Black Belts can provide 6% cost reduction per year
- Why Six Sigma works
 - Bottom line results
 - Senior management is involved
 - Disciplined approach using sound statistics
 - Short, focused projects
 - Customers and processes are the focus

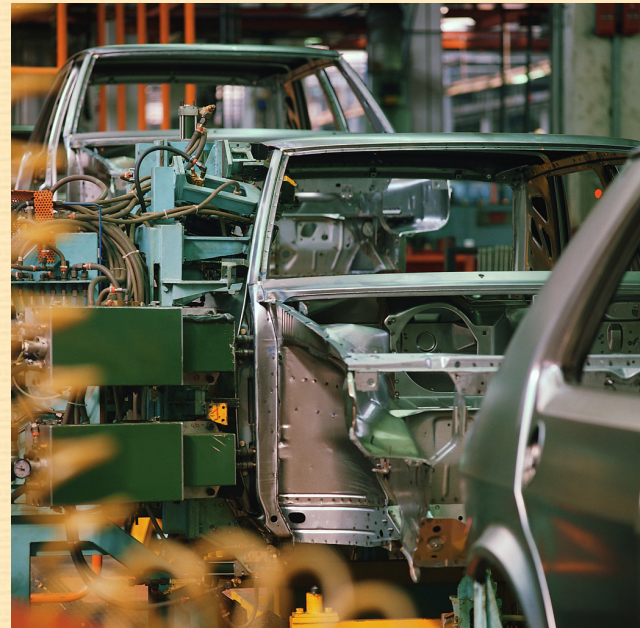


Applying Six Sigma

Sounds great! So what's the issue?



Vs.



Six Sigma and Clinical Operations

- Is Six Sigma really applicable?
 - Lean concepts can generally be applied to any system
 - Six Sigma's statistical methods tend to focus on repeatable processes
 - Manufacturing origins
- Clinical operations is “people oriented” with a service slant
 - Patients, doctors, CRAs, regulatory authorities, etc



Who is the Customer?

- The ultimate customers (end users) are patients
- Doctors (intermediates) usually are the decision makers*
- For clinical operations, who is the customer?
 - Biostatistics (internal customer)?
 - The FDA (customer by proxy)?
 - Doctors and patients?

*Don't forget the insurance companies!



Who is a good Six Sigma Candidate?

- Low performing companies

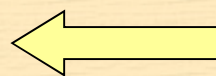
- Concentrate on basics
- Problem solving teams
- Cost management



Low Hanging Fruit

- Medium performing companies

- Set & monitor goals
- Simplify processes
- Department improvement teams/middle management



Ramp Up

- High performing companies

- Benchmark others
- Empower employees
- Continuously improve



6 Sigma Candidate



Characteristics of “Good” Projects

- Basic, repeatable processes (“machine like”)
- Processes that remain virtually the same from study to study, country to country
- Processes that are easily measurable, with larger sample sizes
- Processes that are within your control
- Processes that have a large effect on the bottom line



Potential Areas for Six Sigma

- Data management (paper based)
- Study monitoring activities
- Supply chain management
- Financial processes



Areas to Avoid Using Six Sigma

- Regulatory approval processes
- Data management (EDC)
- Recruitment efforts
- Site start up efforts



Potential Pitfalls

- Poor understanding of Six Sigma
- Improper application of statistics/methodology
- “Going through the motions”
- Forcing Black Belts on everyone
- Negative perceptions of methodology



Conclusion

- Lean principles are typically universally applicable
- Being “people driven” makes clinical development a challenging area to apply Six Sigma
- However, given the variation inherent in such a system, there is a greater need for such a methodology

