

Ice-Breaker Catch Phrase

rlalaldlilnlg

1

The Left Dark

Uckly

Lkylu

Lucky

No No
No Punch No
No No No

ECNALG

STAND

I

Lean Six Sigma – the 5 Why's

PhUSE 09

Accelerating
Clinical
Development

Welcome



Agenda

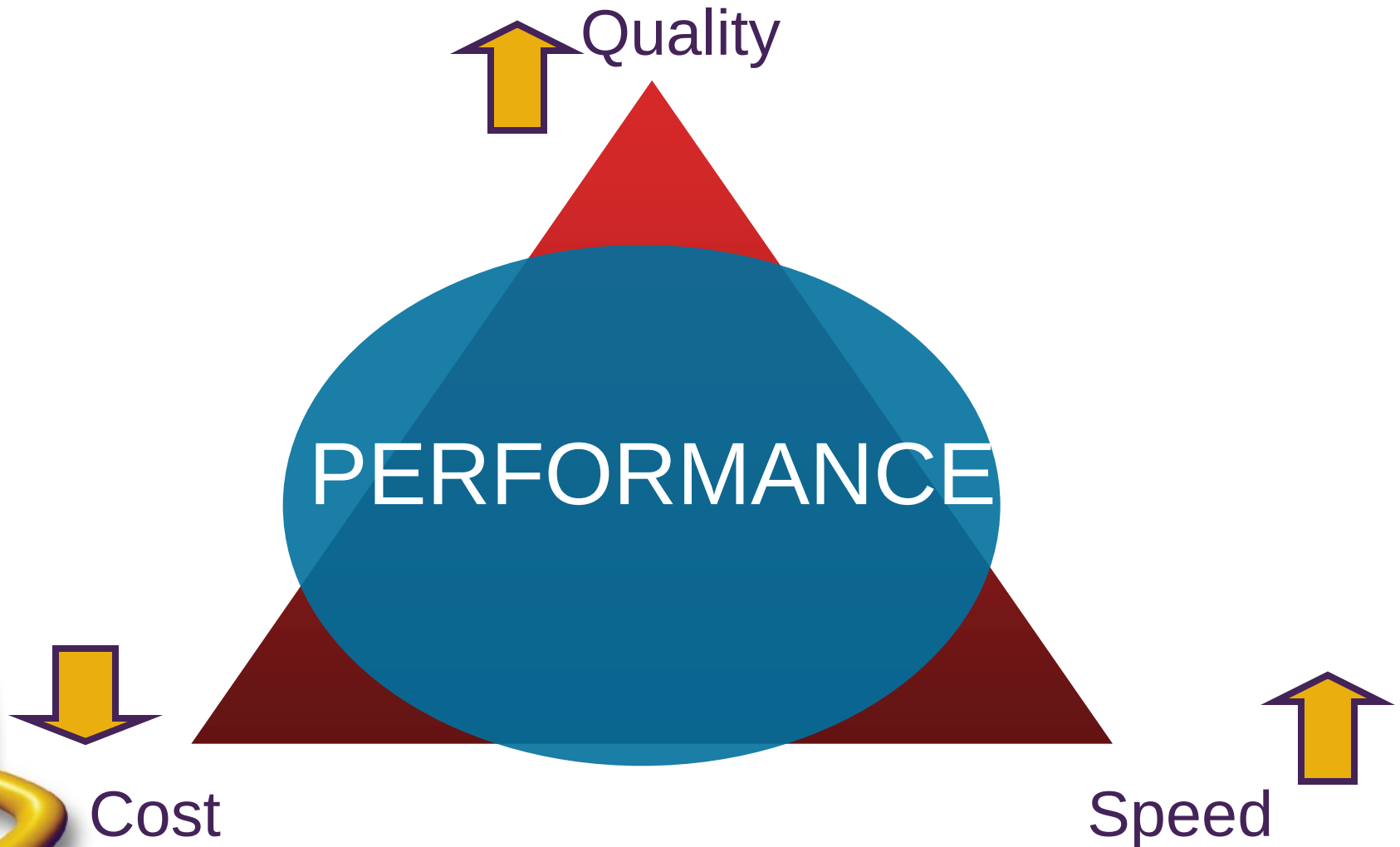
- **What is Lean Six Sigma?**
- **DMAIC : Process Improvement**
- **The 5 Why's**

-Panel Discussion

Accelerating Clinical Development

8.30-9.15 (1-17)

Objectives



What is Lean Six Sigma?

- Lean Six Sigma is a methodology which combines two improvement trends
- **Lean** is about making **work faster** using Lean principles
- **Six Sigma** is about making **work better** by improving quality



General Comment

- “Lean Six Sigma is all common sense”
- Lean Six Sigma is a structured way of improving ways of working which strives for business perfection



Toyota Reports:

- “We get brilliant results from average people operating and improving brilliant processes”
- “Our competitors get mediocre results from brilliant people working around broken processes”
- “When they get in trouble, they try to hire even more brilliant people”
- “We are going to win!”

95% of problems result from how the work is done



Lean Six Sigma

- DMAIC (Improving on a Process)
 - Define-Measure-Analyze-Improve-Control
 - Is an analytical, data-driven approach to eliminating weakness in active processes, products, and services.



DMAIC - Process Improvement Approach

DEFINE

Establish the project & provide direction on what is to be achieved

Key Output:

- Project Charter
- Voice of the Customer & CTQ
- SIPOC

What do we want to achieve and why?

MEASURE

Gather Data to understand current performance and problems in the process

Key Output:

- Process 'current state' maps (SIPOC & VSM)
- List of issues/ problem areas
- Data/KPIs to verify problem

How are we doing?

ANALYZE

Identify the Root Causes of waste & develop potential solutions

Key Output:

- Understanding of Root Causes
- List of prioritized improvement opportunities; 'future state'

What is wrong?

IMPROVE

Identify & Implement key changes that will improve the process

Key Output:

- Key process improvements implemented
- Documentation and Training for new process

What needs to be done?

CONTROL

Maintain & Control the Improvement

Key Output:

- Processes, Procedures, Tools
- Improvements, monitoring process
- Project Comm. Benefits Verified

How do we sustain improvements?

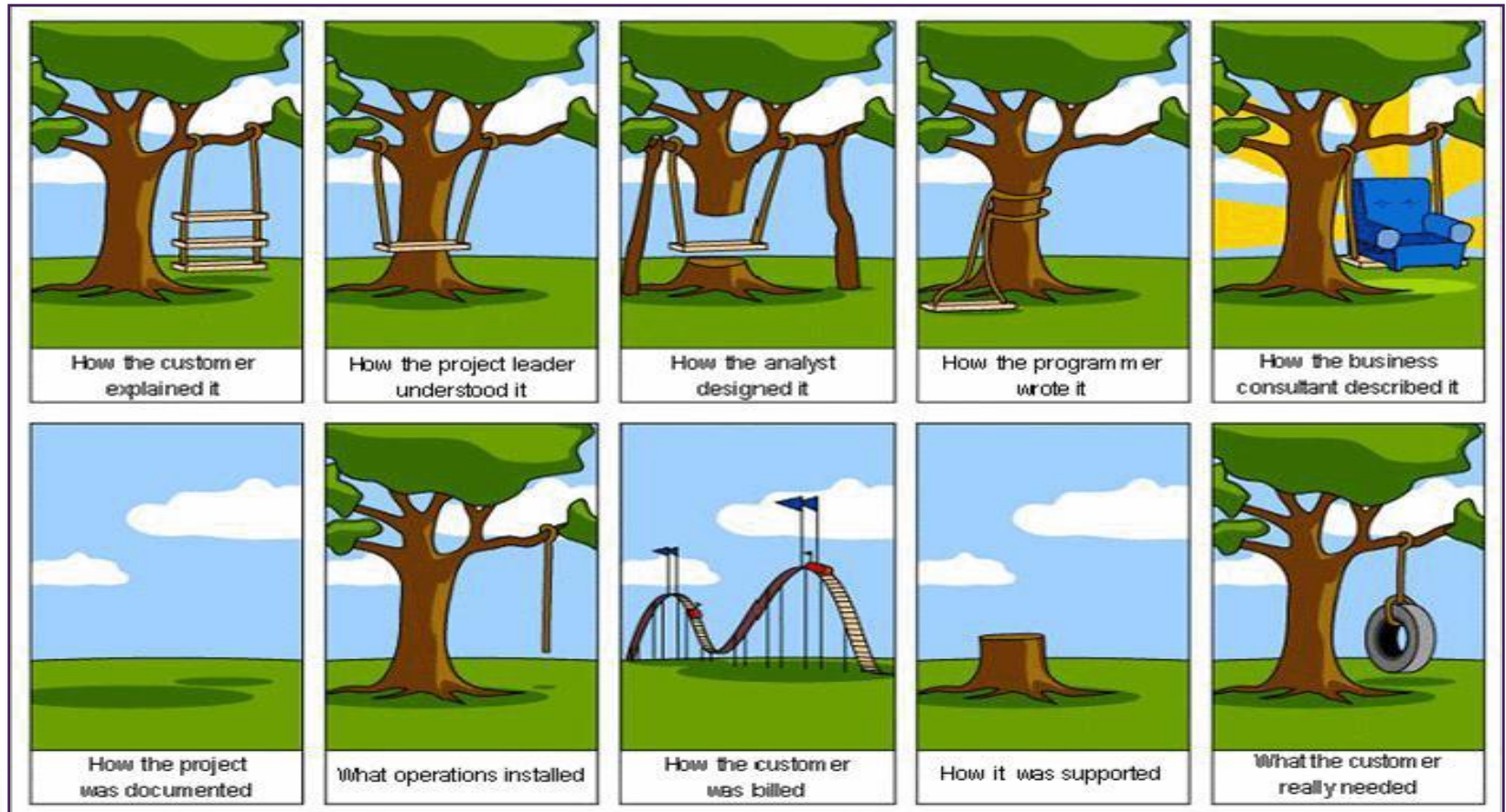
Define

- Definition: **Establish the project & provide direction on what is to be achieved**
- Topics
 - Project Charter
 - Stakeholder Analysis
 - Voice of the Customer
 - SIPOC

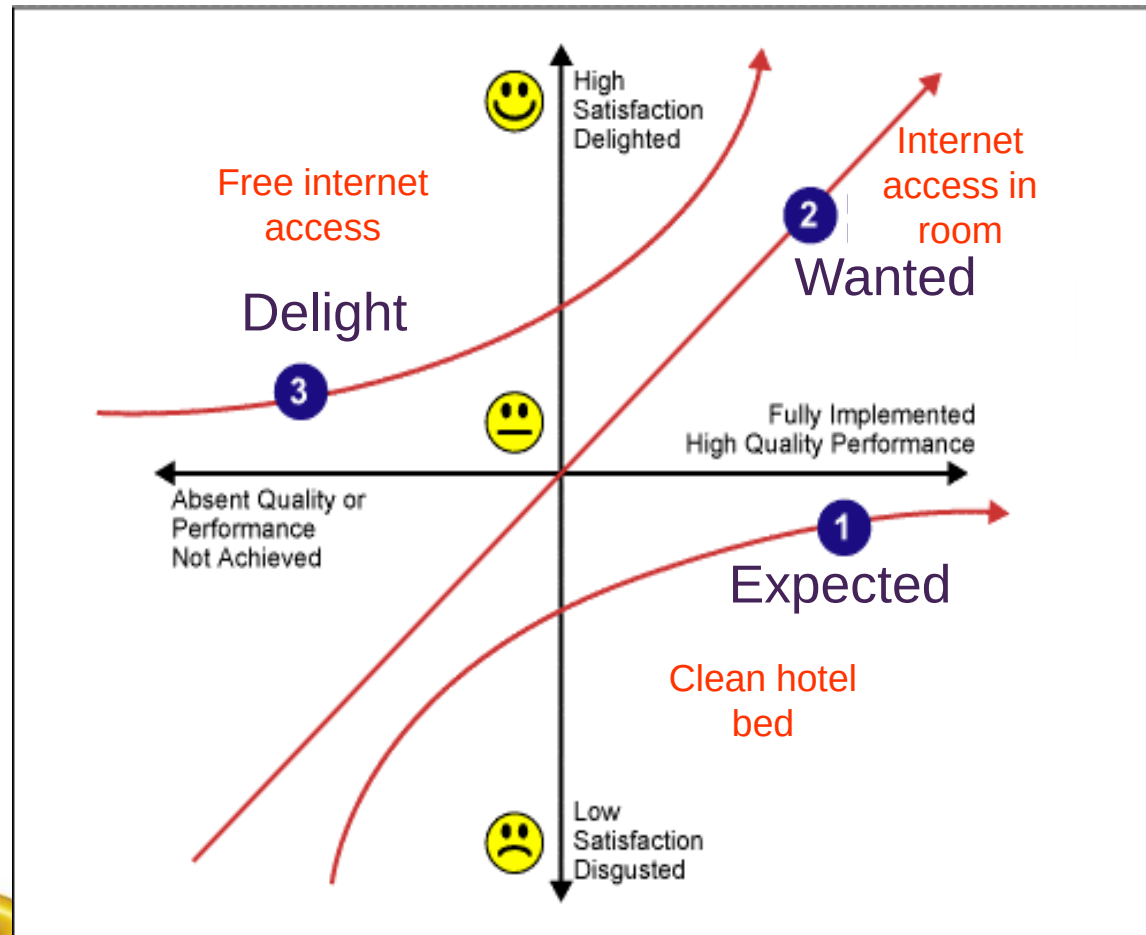


Voice of the Customer

- Listen to the Customer - understand the requirements



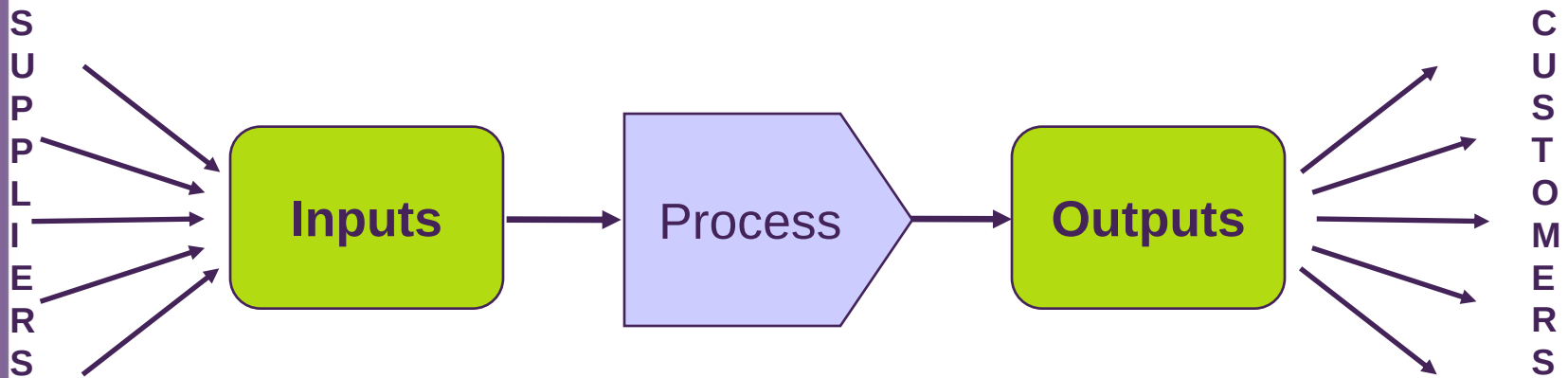
KANO Model for types of customer requirements



The Kano model identifies characteristics of the products or service which drive customer satisfaction from a customer's perspective

- Customers are most likely to describe Wanted
- Delights and Expected often unstated
- Delights become Expected over time

SIPOC – High Level Process Description



- Supplier:** Whoever provides the inputs to your process
- Input:** Materials, resources, data, etc. required to execute the process
- Process:** A process is a collection of activities that takes one or more kinds of input and creates output(s)
- Output:** The tangible products or services that result from the process. Equivalent to a customer need.
- Customer:** Whoever receives the outputs of your process – internal or external

Measure – How are we doing?

- Definition: **Gather Data to understand current performance and problems in the process**
- Topics
 - Process Map
 - Value Stream Mapping
 - Data Collection
 - Failure Modes and Effects Analysis (FMEA)



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The diagram shows a Petri net with 6 places (green circles) and 4 transitions (orange diamonds). The places are arranged in a sequence: a place at the top left, followed by a place at the top right, then a place at the bottom left, then a place at the bottom right, then a place at the bottom center, and finally a place at the bottom right. The transitions are arranged in a sequence: a transition at the top left, followed by a transition at the top right, then a transition at the bottom left, then a transition at the bottom right, and finally a transition at the bottom center. The places and transitions are connected by directed edges (arrows).

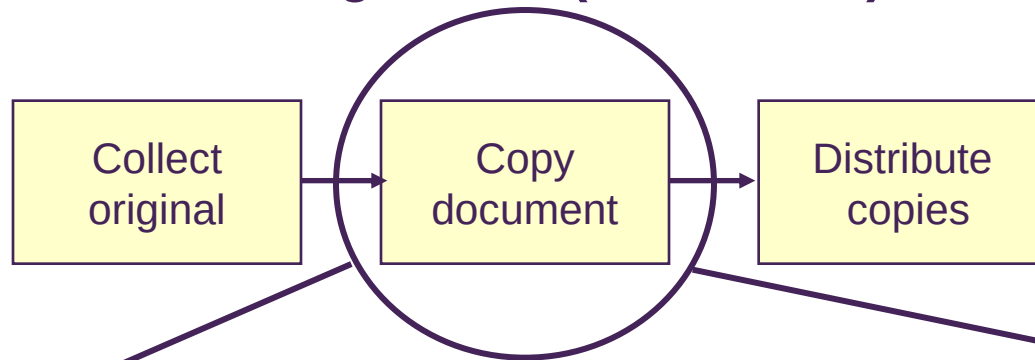
The graph consists of 15 nodes and 20 directed edges. The nodes are colored green, yellow, or orange. The flow starts from a yellow node at the top left, goes through a green node, a purple node, a yellow node, and an orange node, then to a green node. From there, it goes to a yellow node, then a green node, and finally exits to the right. There are several loops and cross-connections between the different paths.

How you would like it to be...

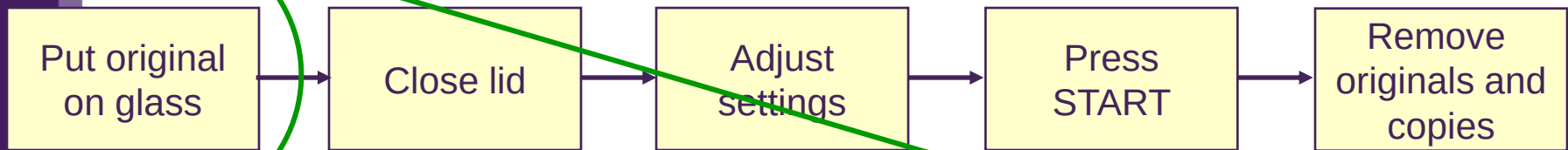


Levels of process mapping

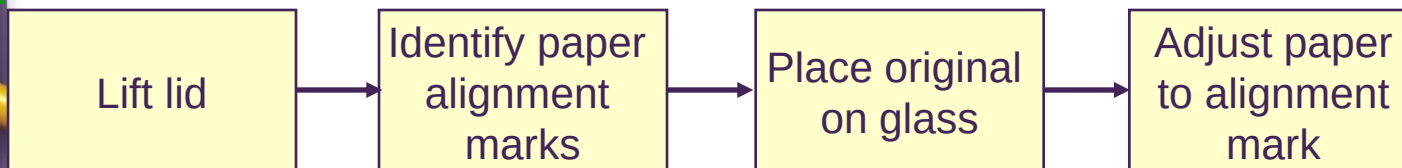
High Level (Moon View) Process Map



Steeple View Process Map



Micro View Process Map



Examples of data that can be collected

Collect data relevant to what you are trying to achieve in your project.

- Demand
- Staffing levels
- Capacity
- Equipment availability
- Failure rates at each process step
- Type of defect
- Lead time
- Cycle time
- Set-up time
- Defect rates
- Work in progress
- Output



Analyse – what is wrong?

- Definition: **Identify the Root Causes of waste & develop potential solutions**
- Topics
 - Root Cause Analysis
 - Waste
 - Process Map & VSM (To Be)



What is Root Cause Analysis?

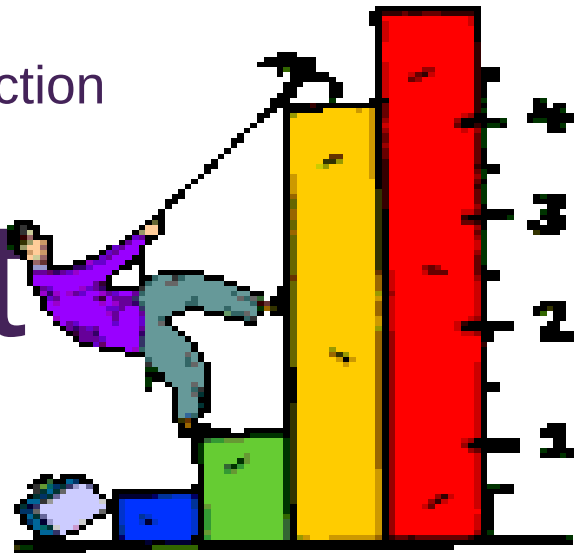
- RCA is fundamental to process improvement
- RCA is based on the belief that problems are best solved by attempting to correct or eliminate root causes
 - not just addressing the symptoms



Variation

- Controlling variation leads to
 - increased process efficiency
 - shorter lead times
 - higher quality
 - lower costs
 - greater customer satisfaction

And trust



WASTE - TIMWOOD

- Transportation
- Inventory
- Motion
- Waiting
- Overproduction
- Over-Processing
- Defects



RCA Tools

- Which tools?
 - Interrelationship diagram
 - 5 Whys*
 - Cause and Effect diagrams
 - Reality Trees
 - Matrix Diagram



The 5 Why's

- Example of handover from Programming to Medical Communications
- Takes 12 weeks to publish
 - Why? Because the database gets relocked ??? times.
- So if the database was completely locked how long would it take? 8 weeks. Why?
- SAS programming don't always get the margins correct. Why ?
- If the margins were correct first time how long would it take? 4 weeks. Why?



The 5 Why's

- Because the publishing tool doesn't always complete all the tables and listings so we have to send some through again.
- So if the tool worked first time how long would it take?
- 2 weeks. Why?
- Because we need to check all the output is correct.
- But let's assume everyone has done their job right and the tool works how long would it take? 1 week
- But don't be restricted to weeks how long?
- Well a day....



The 5 Why's

- If I was to allow you to use a smaller unit how long would you say...?
- Probably about 4 hours....



IMPROVE – what needs to be done?

- Definition: **Identify & Implement key changes that will improve the process**
- Topics
 - Generate a future state map
 - Pilot & verify solution
 - Key process improvements Implemented
 - Documentation and Training



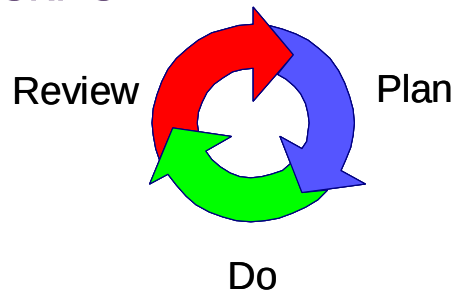
Control – How do we sustain?

- Definition: **Maintain & Control the Improvement**
- Topics
 - Sustainability
 - Control Plan



Ingredients for Sustainability

- People engaged and involved
- Developing new skills
- KPIs



- 'Discipline'
- Time set aside for improvement
- Sponsorship
- Ongoing interactions with customers

Relentless pursuit of perfection

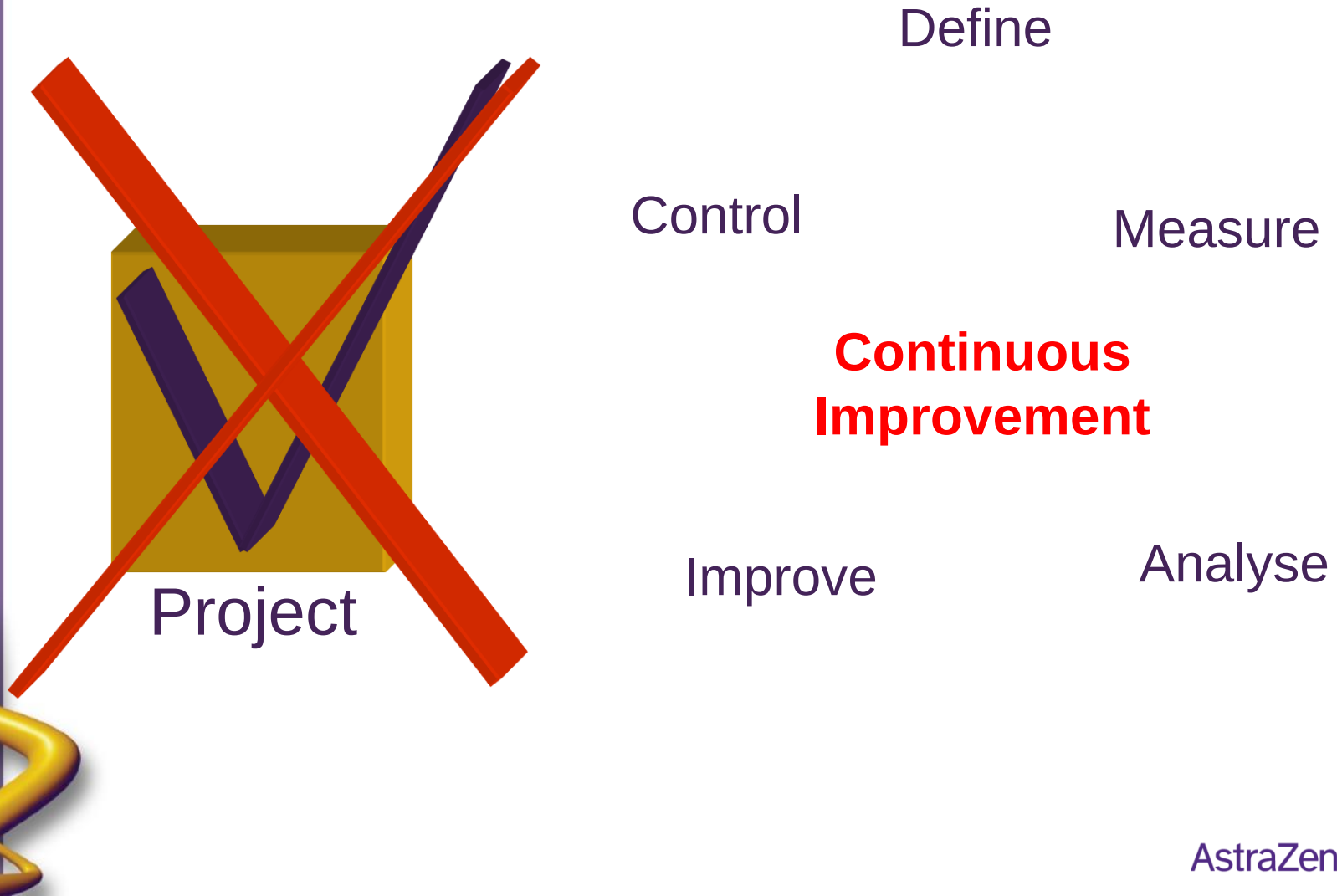
Key Steps - Considerations

- How will we control the process to ensure sustainability?
- What is the plan for full scale implementation?
- Opportunities to apply learning's elsewhere
- Moving from Detection (good) to Prevention (best)
- Transfer of ownership



Control Plan

Lean Sigma is a long term journey – not just a quick project



Something to take away

- Specify what you need as a customer
- Ask YOUR customers what they want and work out what they actually need
- Use common sense
- Put in controls to sustain and continuously improve the process improvements



Left & Right Brain Thinking

Read out the color not the word

Yellow

Blue

Orange

Black

Red

Green

Purple

Yellow

Red

Orange

Green

Black

Blue

Red

Purple

