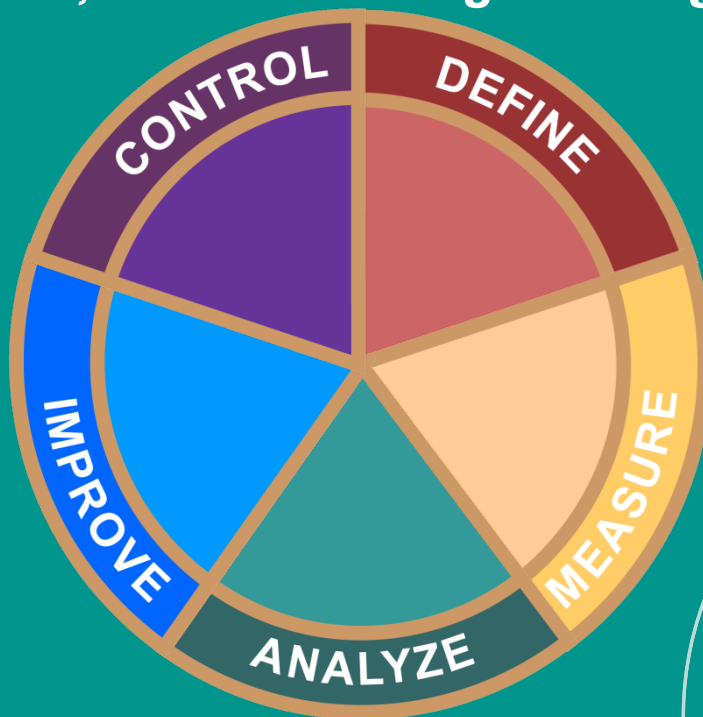


Is the Statistical Programming process LEAN enough?

*Simon Jennings,
Sr Director, Statistical Programming*

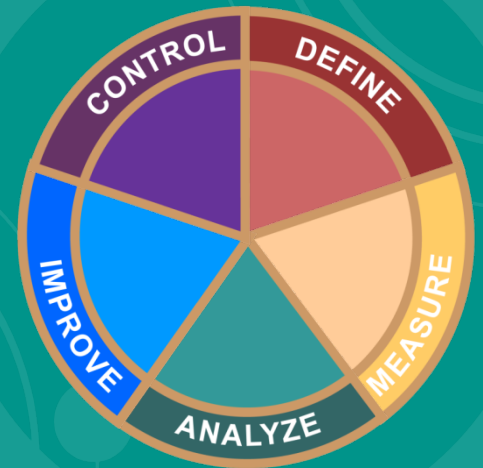
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What can we learn from the
Lean Six Sigma process?
Have we used this methodology
to improve the programming
process?



Core objectives of Lean Six Sigma

Customer satisfaction

Delight them. Don't just hit targets, exceed them.

Adding value

Everything you do adds value in the eyes of the customer.

Eliminating waste and improving flow

If an activity doesn't add value or satisfy customers – remove it.

Capitalising on opportunities

Profit from overlooked value-add activities.



Complementary goals of “Lean” and “Six Sigma”

LEAN

A set of principles and tools that help us to eliminate process activities that don't add value (waste) and to improve “flow”

Efficiency

SIX SIGMA

A collection of methods and tools aimed at the significant reduction of unwanted variation in products and processes to improve yield

Effectiveness

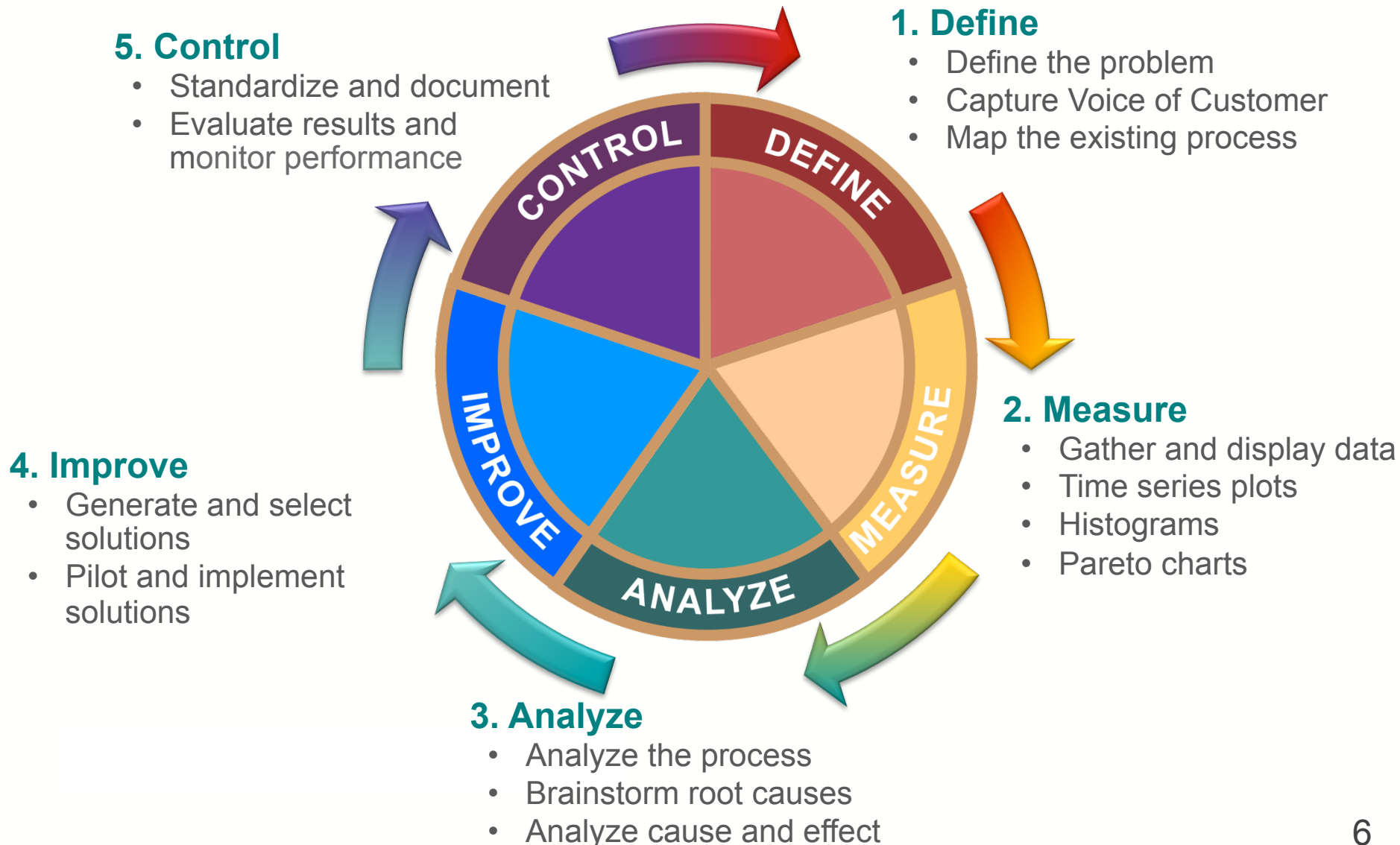
COST

**Improved
Process
Performance**

TIME

QUALITY

DMAIC – Continuous improvement's foundational problem-solving discipline



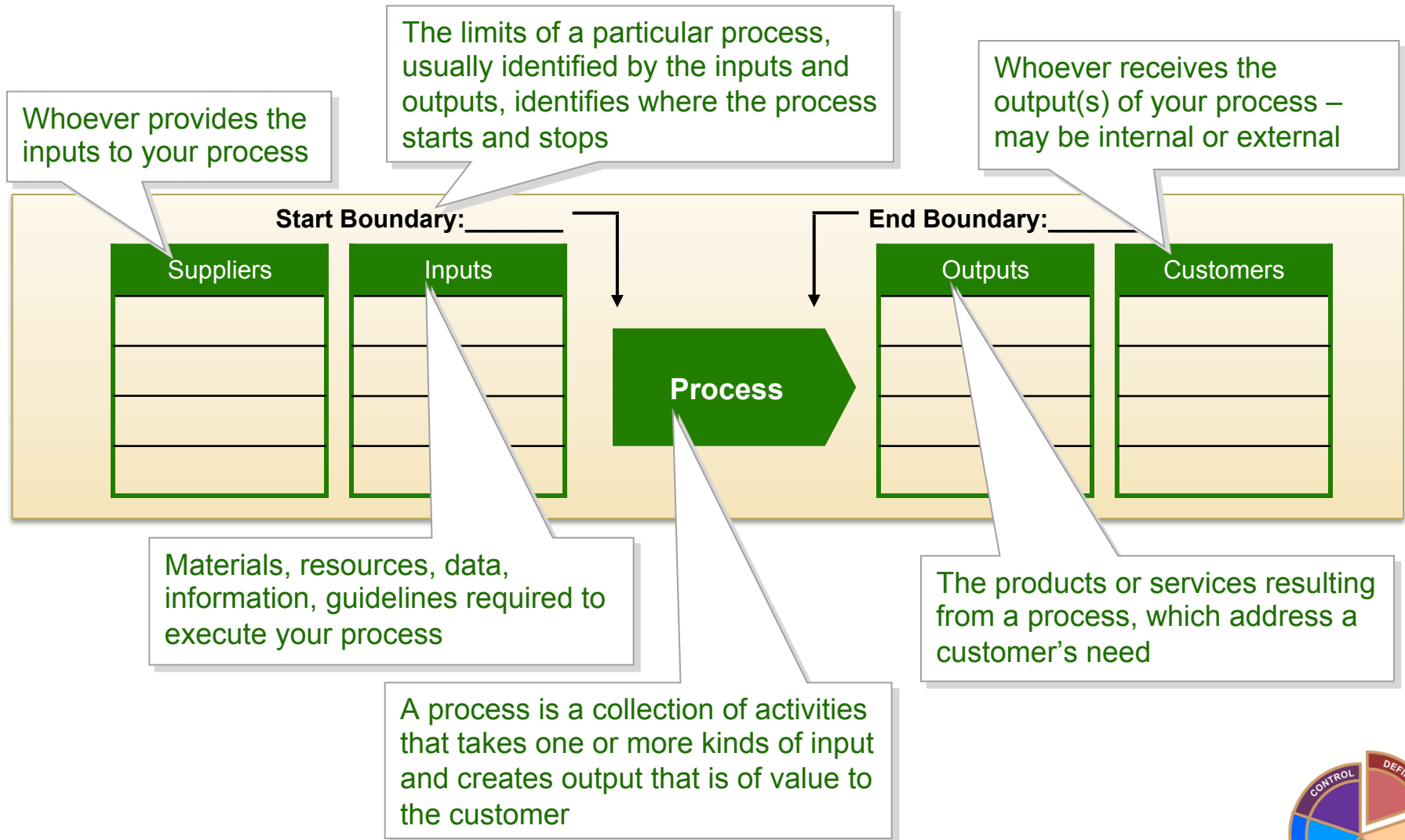
'Define' stage of process improvement

SIPOC is a process mapping tool used to help visualize the full scope of a process and what influences it, in terms of:

Suppliers
Inputs
Process
Outputs
Customers



SIPOC



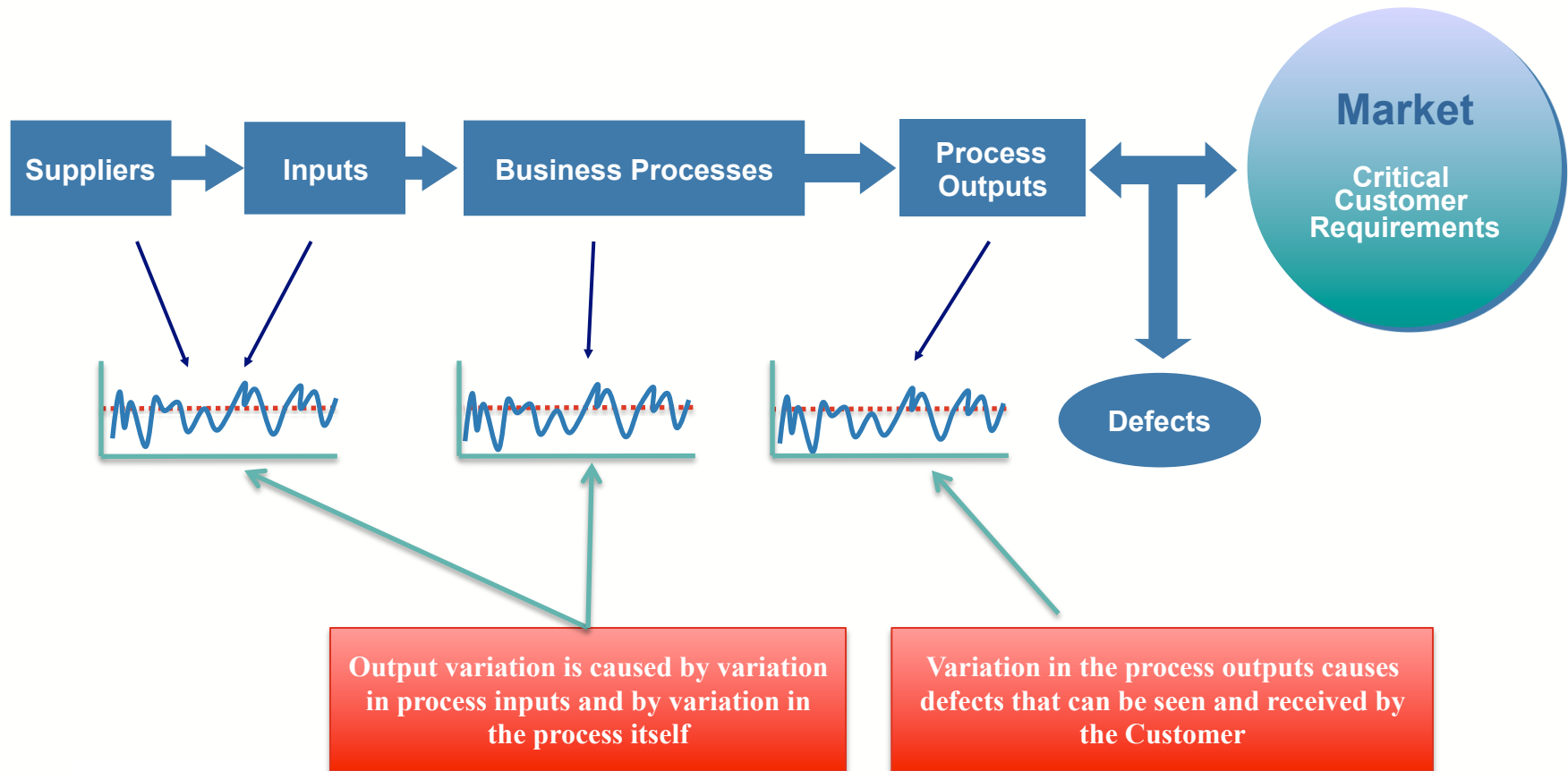
Defining the high level programming process

SIPOC – Supplier, Input, Process, Output and Customer

Suppliers	Inputs	Process	Outputs	Customers
• DM • Clients/ sponsor • Biostatistics • Clinical • Patients	• Protocol • Data • DM Plan • SAP • TLF Mocks • Programming conventions	• Training • People • Program development & testing • Program validation • Code review • Lead Programmer review • Statistical review	• TFLs • Datasets • Programs • Logs • Documentation	• Biostatistics • Medical Writing • Clients • Regulatory authorities • Patients

Focus on variation

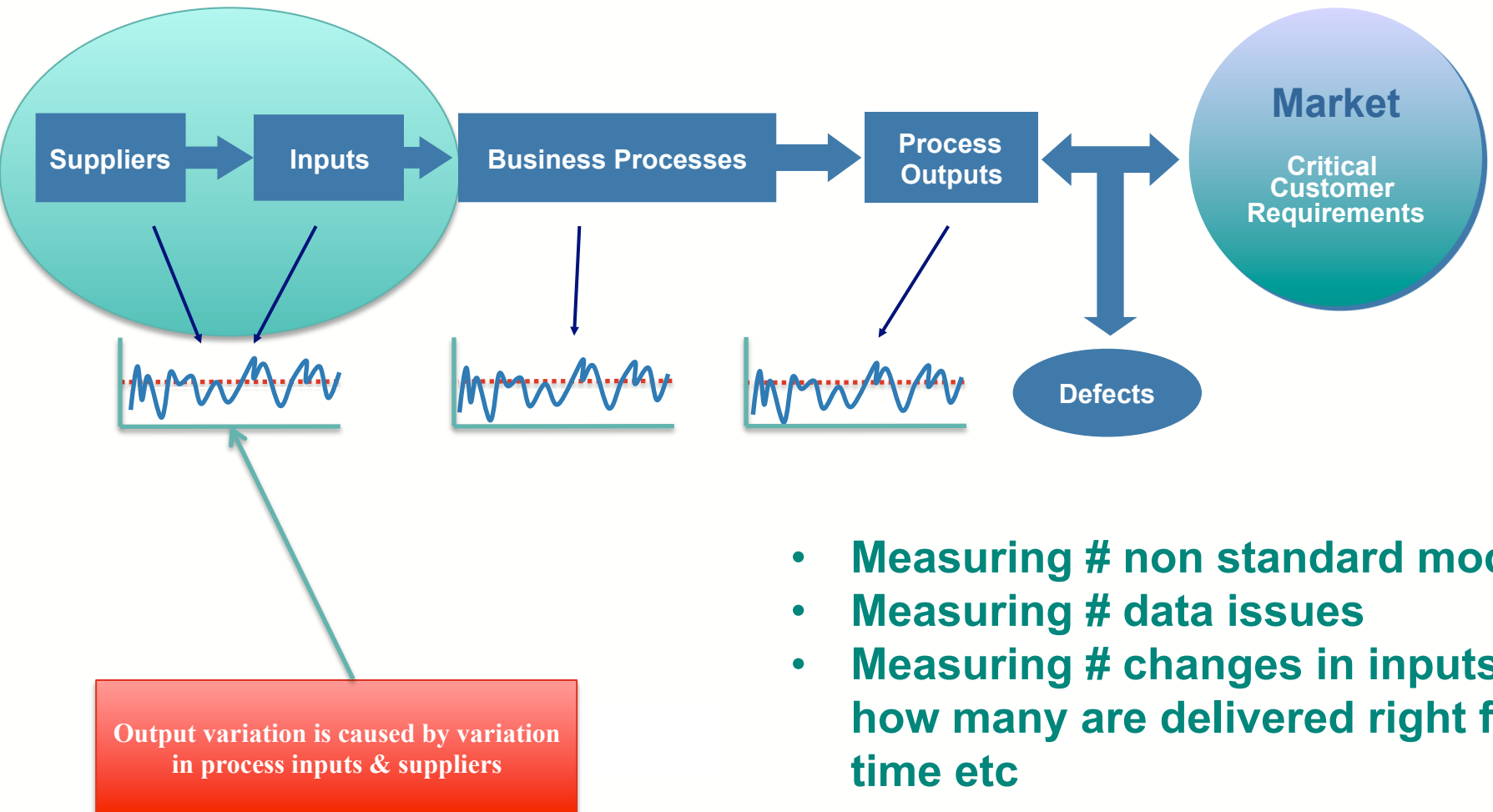
SIPOC – Supplier, Input, Process, Output and Customer



Within Biostats and Programming what do we do to control variability in inputs & suppliers?

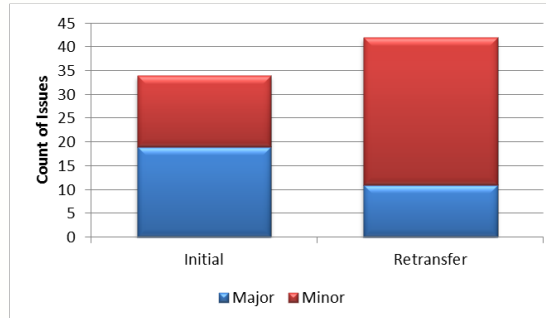
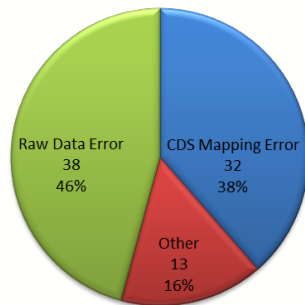
	Methods to control variation
Data (quality)	• Standard CRFs e.g. CDASH • Standard edit/consistency checks • Data standards e.g. SDTM • Data transfer quality checks e.g. SDTM datasets • Handover acceptance criteria/clean data requirements
TLF mocks/shells	• Standard TLF mock templates • Standard formatting conventions e.g. significant digits, precision, display rules, treatment ordering, etc.

Measurement in variability of suppliers/inputs

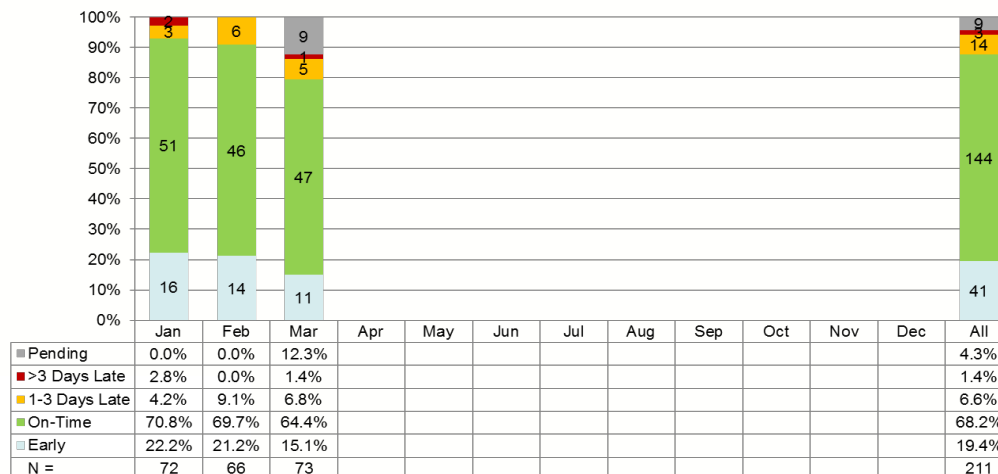


Example: Data quality and timeliness

Issue Classification & Severity



Timeliness of CDS Deliveries



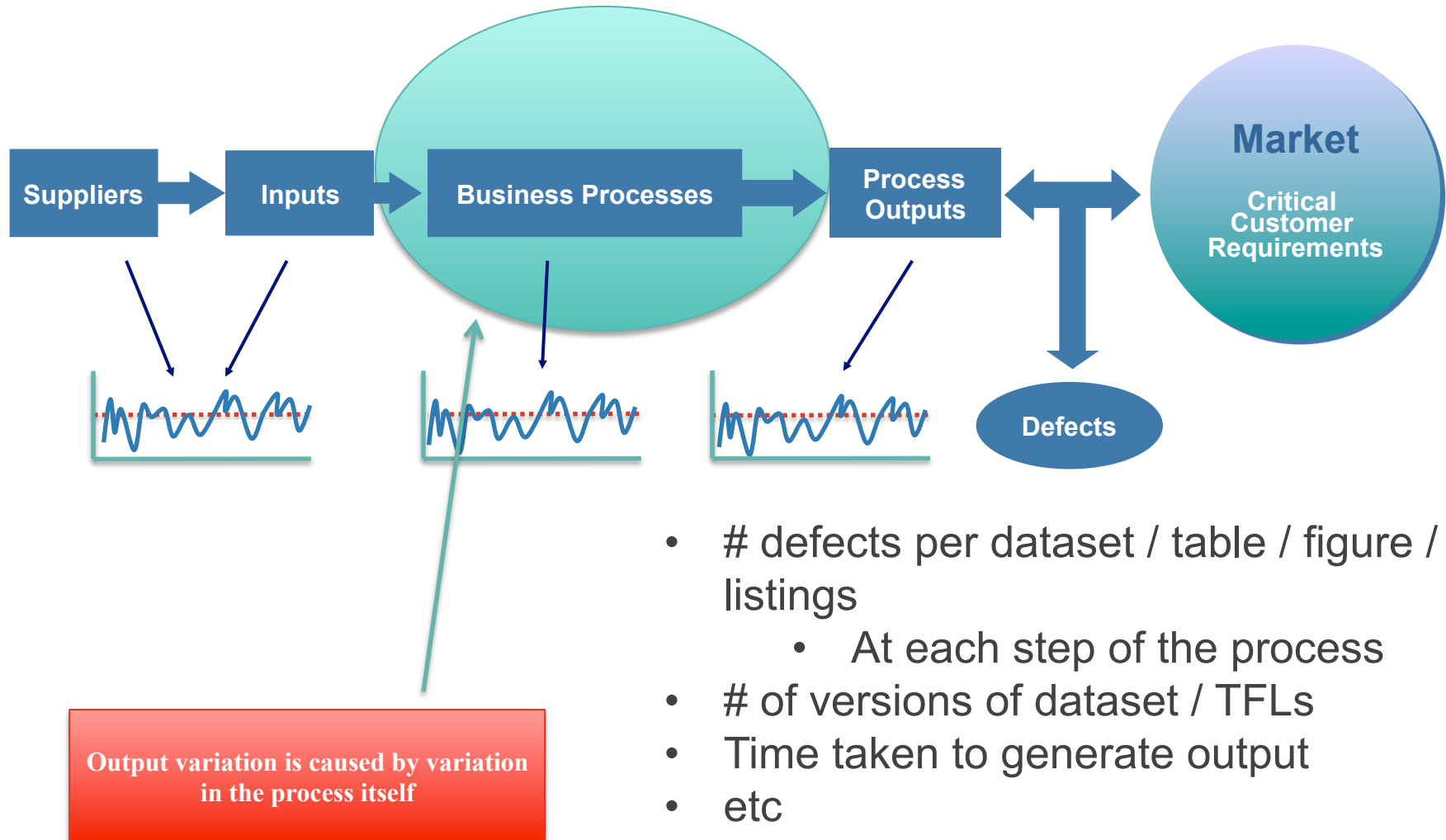
Sources of variation in programming

Output variation is caused by variation in process

Within Biostats and Programming what activities control the variability in process?

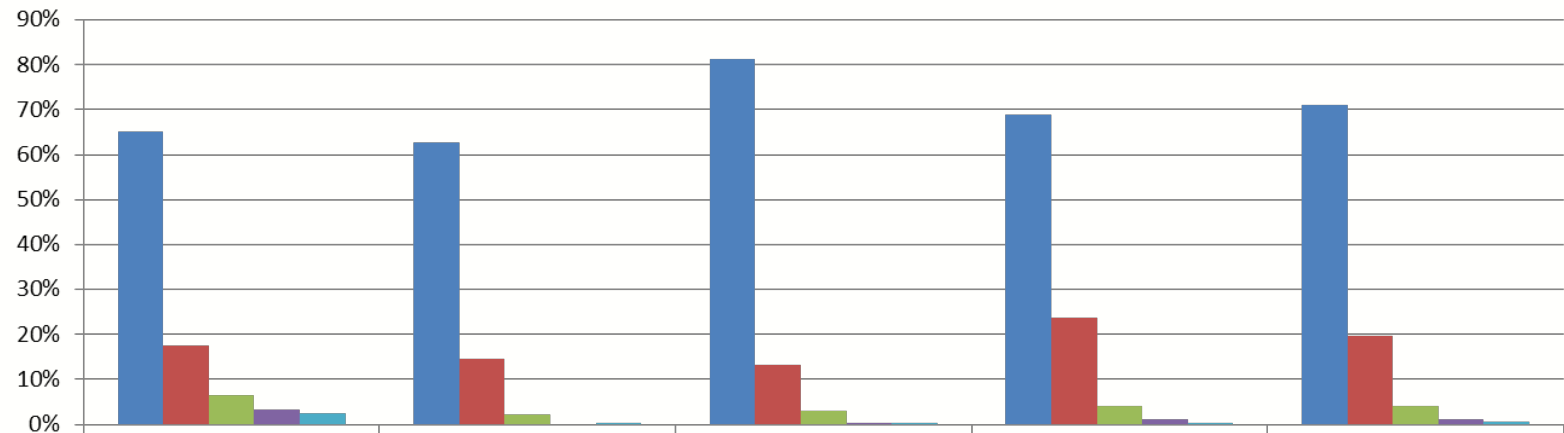
Methods to control variation
• Team consistency • SOPs • Training (process, technical, therapeutic, study-specific) • Defined roles and responsibilities; RACI • Standard macros/tools, standard directory structures • Global, harmonized programming environment • Template code; code libraries • Metadata-driven reporting systems; dependency-management systems • Programming guidelines/conventions • Best practices/guidelines • Subject matter experts

Measurement of variability in process



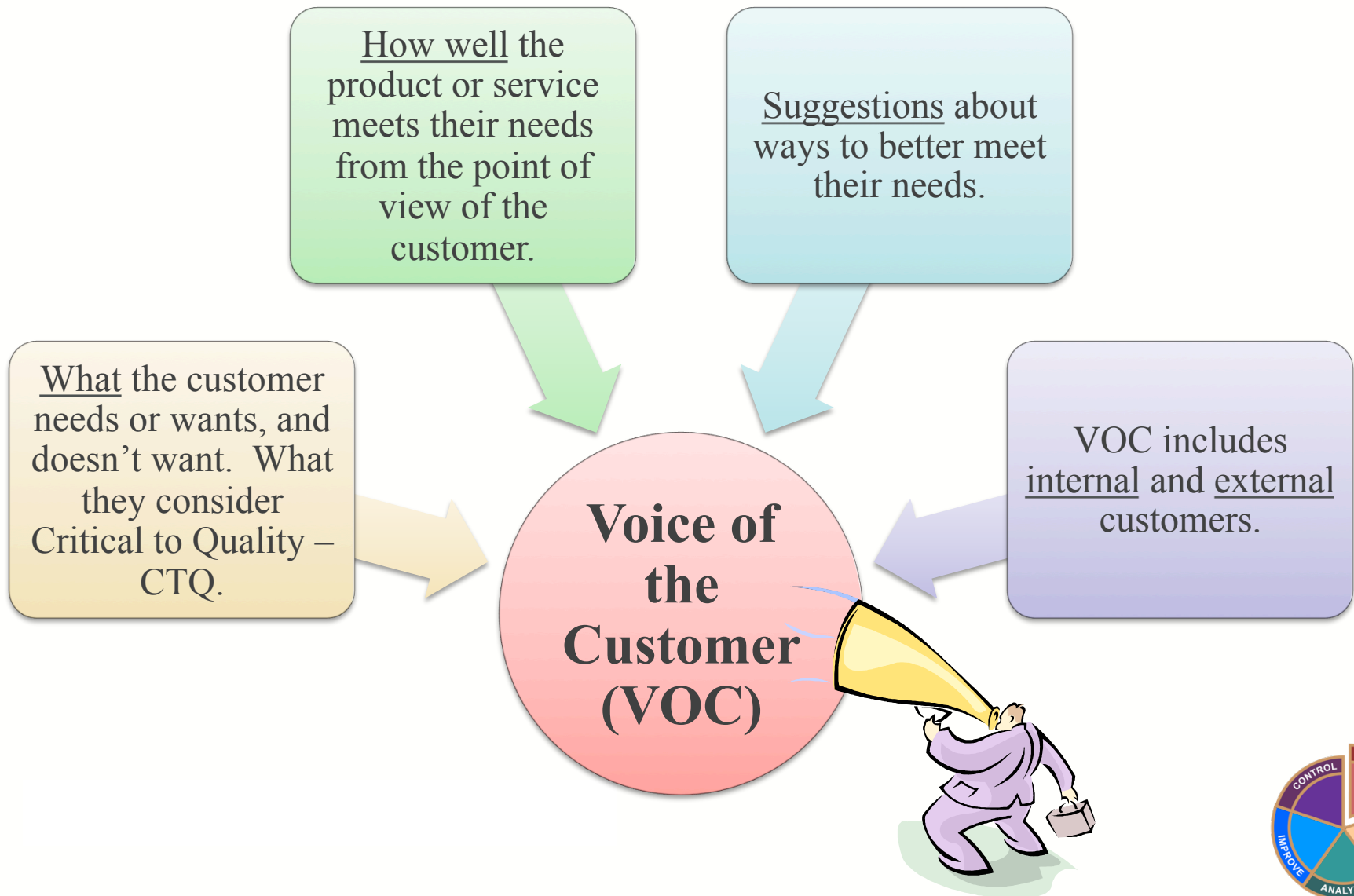
Measurement of variability in process

What % Of Deliverables Pass Validation At Each Cycle



■ Cycle 1	65%	63%	81%	69%	71%
■ Cycle 2	18%	15%	13%	24%	20%
■ Cycle 3	7%	2%	3%	4%	4%
■ Cycle 4	3%	0%	0%	1%	1%
■ Cycle 5	2%	0%	0%	0%	1%

Another concept from the 'Define' stage of DMAIC is the Voice of the Customer



Two ways to obtain customer data

Passive Systems

Information comes to you whether you take action or not:

- Customer complaints
- Sales data
- Existing reports
- System alerts



Proactive Systems

You put effort into gathering the information:

- Ask the customer
- Brainstorm
- Focus groups
- Surveys



Common VOC mistakes

- Failing to probe for precise customer needs.
- Failing to probe for additional information: Why? How often? When?

Three features of *effective* customer questions:

1. Specific

- You said our outputs are poor quality. How do you define quality? What specific features do you look for?

2. Measurable

- You said that we are often late. What is late for you?
- You said we produce too many tables. What number do you want?

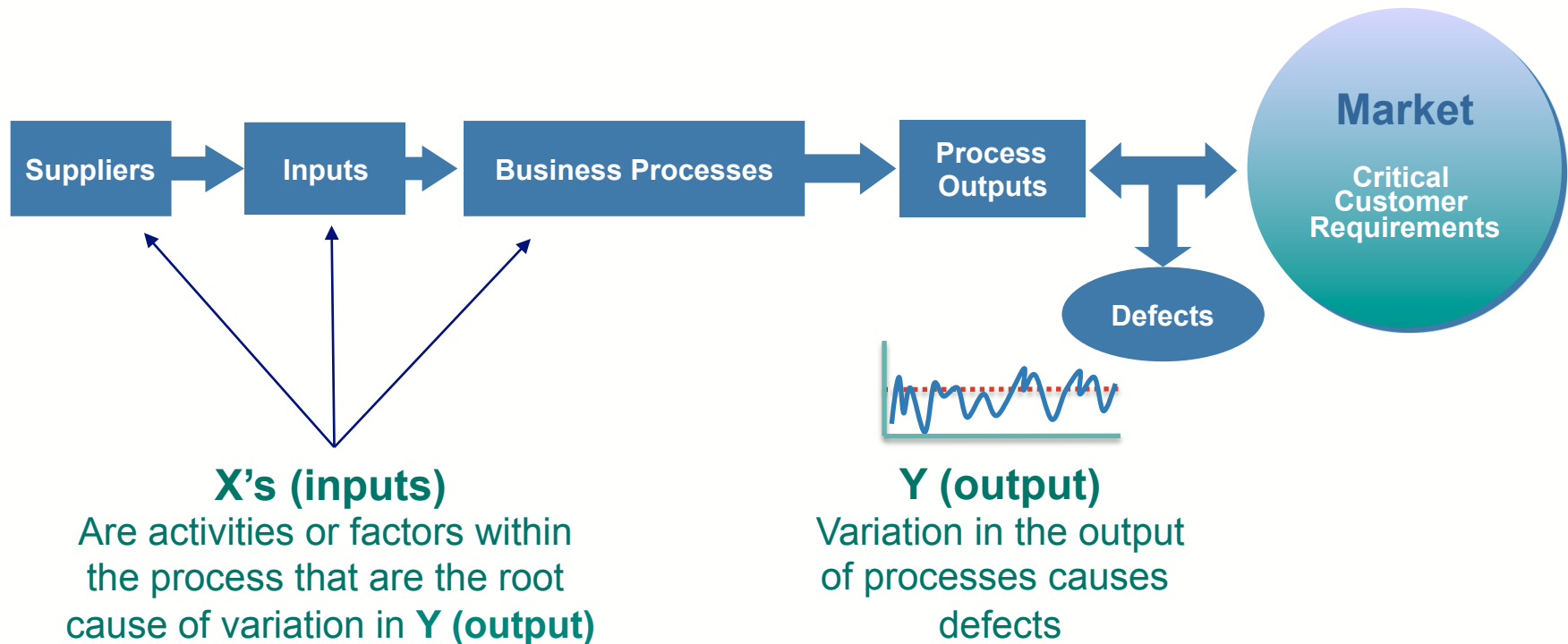
3. Prioritised

- You listed five features. Could you rank them?
- What are your non-negotiable requirements? . . . What else is important? . . . What would surprise and delight you?
- What do you like most? Least?



Locate root causes

- Defects are the source of customer dissatisfaction and poor business performance.

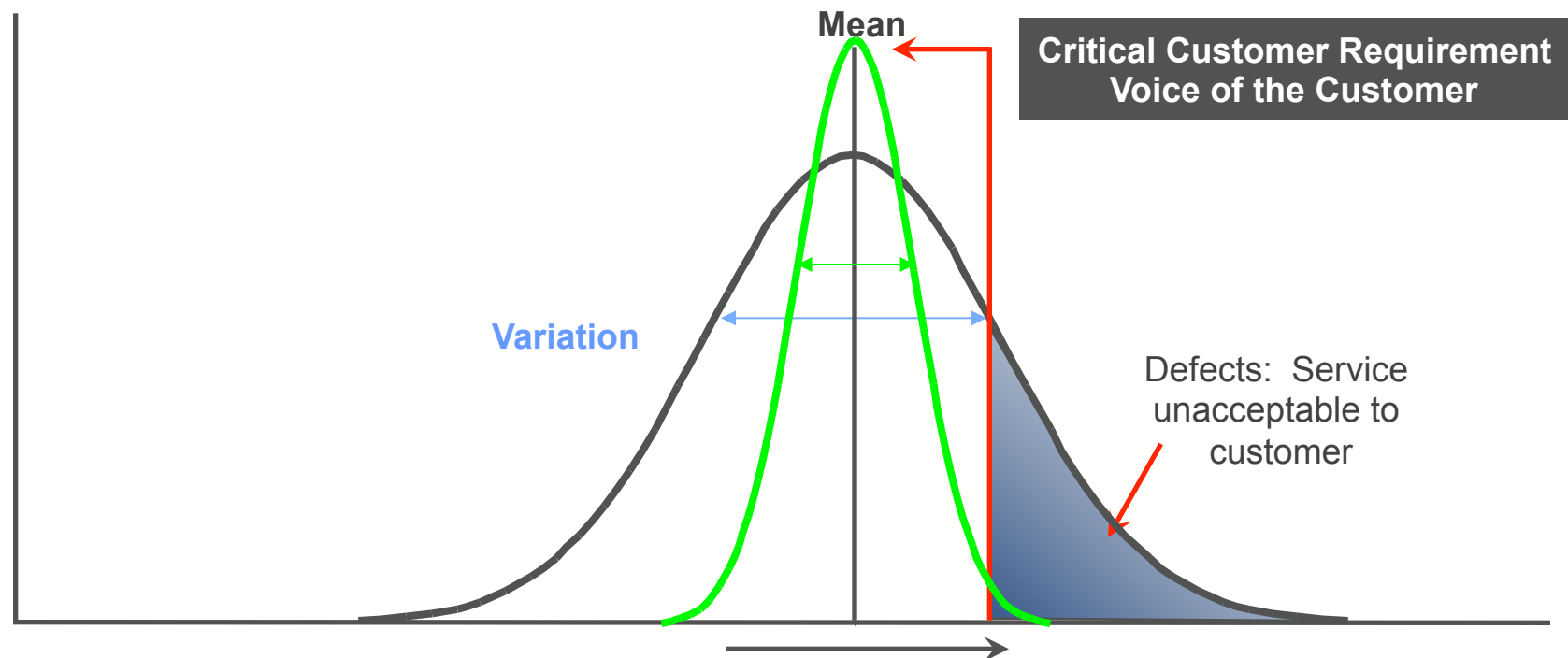


$$Y = f(X_1, X_2 \dots, X_k)$$

The fundamental equation of Six Sigma

Reduce process output variation

– Voice of the Customer (VOC)



***Pointing to what we are all trying to achieve
A consistent, right first time output....***

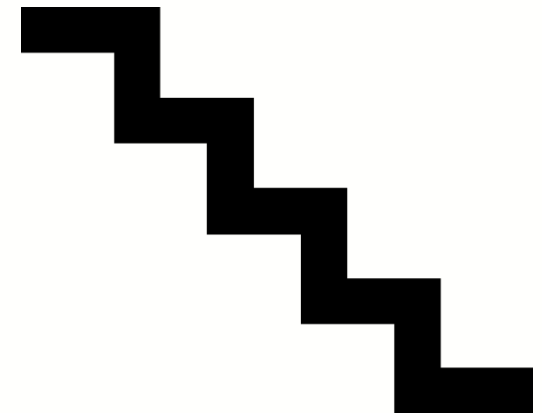
Measuring output variation

Process Output	Measure	Defect (examples)
Datasets & TLFs	# of major/minor programming errors (per deliverable)	1+ major programming errors and/or 10+ minor programming errors (major/minor as per agreed definition)
	% of deliverables not fit for purpose (i.e. with at least one defect)	>5%
Documentation	# of critical/major audit findings	>0 critical and/or >1 major finding
Cost	Average cost/TFL	
Time	# days deviation from agreed delivery plan (per deliverable)	>1 day late
	% of deliverables on (or before) time	≤90%
Customer satisfaction	Meets/exceeds expectations (e.g. rated on 5 point scale)	<85% of studies rated as meets/exceeds expectations

Balancing expectations of the customer vs need to eliminate waste in the process



Additional



To manage performance/process step you have to measure it

Ideally would like to measure in automated fashion or easy to measure

Measure should be objective & specific

Each step of the process should have a performance measure associated with it

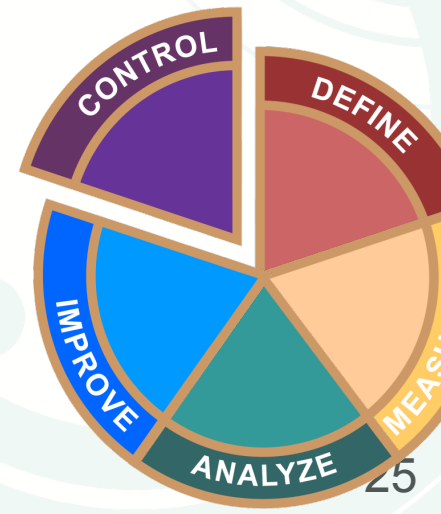
“Without data, you are just someone else with an opinion”

Some concluding thoughts

Tools from Lean Six Sigma can be used for programming process improvement

Lean six sigma reminds us of

- Importance of metrics
- Importance of voice of the customer
- Importance of trying to standardise and eliminate waste
- Planning vs fixing



Thank you for your attention

