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Use of KPIs in measuring performance

General Introduction / Focus on Clinical Development

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Introductions

Who are we

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Dr Stephen Gunnigle

- Steve is a Senior Manager in Deloitte's Life Sciences R&D advisory practice. He has 12 years of business and consulting experience working extensively within the global pharmaceutical industry.
- Steve brings experience of organisational design, process improvement and performance management across Development and has functional experience within clinical development, clinical operations, medical affairs, regulatory affairs, quality assurance and pharmacovigilance.
- Prior to his consulting career Steve worked for Johnson & Johnson in the US and UK. He has a Ph.D. and MBA from Leeds University, UK.

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Johnathan Lowery

- Johnathan is a manager in Deloitte's Life Sciences R&D practice. He has over 12 years experience in pharmaceutical product development gained at multinational pharmaceutical companies, biotech companies and CROs.
- He has broad experience of clinical development, lifecycle project management and CRO management encompassing clinical development phases I-IV in a range of therapeutic areas. He has recently completed a project for a major pharmaceutical company to develop outsourcing options.
- Within the biopharmaceutical industry Johnathan has worked at ICON, Chiron Vaccines, Novartis, Élan, and Roche. Prior to joining Deloitte Johnathan pursued an MBA from Cass Business School in London. He also has an MSc in Molecular Medicine from Trinity College, Dublin.

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Contents

What we will talk about today

- Introduction to Deloitte Life Sciences & Healthcare
- Metrics and Key Performance Indicators (KPIs): What's the difference
- Characteristics of KPIs
- How context impacts KPIs
- Metrics in the management of clinical trials

- Organising on outputs and performance management
- Choosing the right metrics
- Measuring process performance
- The "Voice of the Business"
- Metrics in the management of clinical sourcing groups

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Deloitte Ranked #1 Life Sciences Consulting Provider*

Deloitte Consulting ranked #1 Life Sciences provider, based on revenue, in Kennedy Information's report *Consulting to the Life Sciences Sector*.

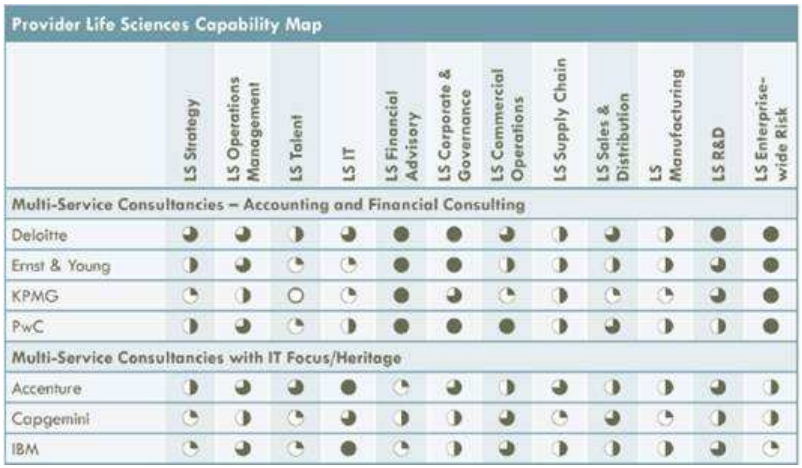
Key Findings:

- Deloitte continues to be the world's largest life sciences consultancy by a comfortable margin
- Deloitte ranked 'strong' or 'very strong' in 75% of the capabilities areas, far exceeding the nearest competitor (58%) which clearly speaks to the strength of our practice
- Kennedy calls out our post-transaction services, regulatory and risk expertise, and commercial operating models as key strengths

Life sciences consulting providers by client spend ($M), 2011

Rank	Firm	CY2011	2011 Growth	Market Share
1	Deloitte	$1,207	10%	22%
2	Accenture	$678	17%	13%
3	PwC	$587	13%	11%
4	Covance	$523	10%	10%
5	McKinsey	$458	7%	9%
6	ZS Associates	$329	9%	6%
7	The Boston Consulting Group	$236	15%	4%
8	Quintiles	$217	18%	4%
9	IMS Health	$214	14%	4%
10	IBM	$184	5%	4%

Life sciences consulting provider capabilities



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Deloitte Life Sciences & Healthcare

HCLS is one of the fastest growing industries within Deloitte

Client challenges

- Improve ROI in drug development
- Reduce the cost of success
- Develop more compelling payer propositions
- Maintain licence to operate
- Access and commercialise the best science

Go to market Offerings

- R&D Strategy & Value Measurement
- Portfolio & Product Differentiation
- R&D Sourcing & Collaboration
- Drug Safety & PV
- R&D Operational Excellence
- R&D Quality & Compliance

Leveraging Deloitte

- Regulations and Compliance
- Technology Analytics, Delivery & Dev
- Target Operating Model Design
- Lean Six Sigma
- Continuous Improvement
- Programme Leadership
- Organisation Design
- Strategy
- Deloitte Analytics
- Outsourcing Advisory Services

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Metrics and KPIs: What's the Difference?

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Metrics and KPIs: What's the Difference?

Potential definitions

KPI

A KPI is a type of performance measurement.

An organisation may use KPIs to evaluate its success, or to evaluate the success of a particular activity in which it is engaged. Sometimes success is defined in terms of making progress toward strategic goals, but often success is simply the repeated, periodic achievement of some level of operational goal

Metric

Parameters or measures of quantitative assessment used for measurement, comparison or to track performance

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Metrics and KPIs: What's the Difference?

Sample characteristics

Metric

- A metric may or may not be a KPI
- Any sort of measurement used to assess a business process or activity
- Cost, time, productivity and quality
- Often large numbers of metrics accompanied by significant quantities of data
- "Difficult to see the wood for the trees"
- Should/Can be used for operational improvement
- But not metrics for metrics sake

Key Performance Indicator

- A KPI is a metric
- Aligned to corporate or functional goals/strategy
- Set by leadership
- Translated to functional levels
- Understood by everyone in the organisation
- Need to be taken in context
- Data-derived
- Easy to understand
- Prompts action
- KPIs drive an organisation towards strategic objectives
- Under the control of the organisation
- Limited in number i.e. "key"

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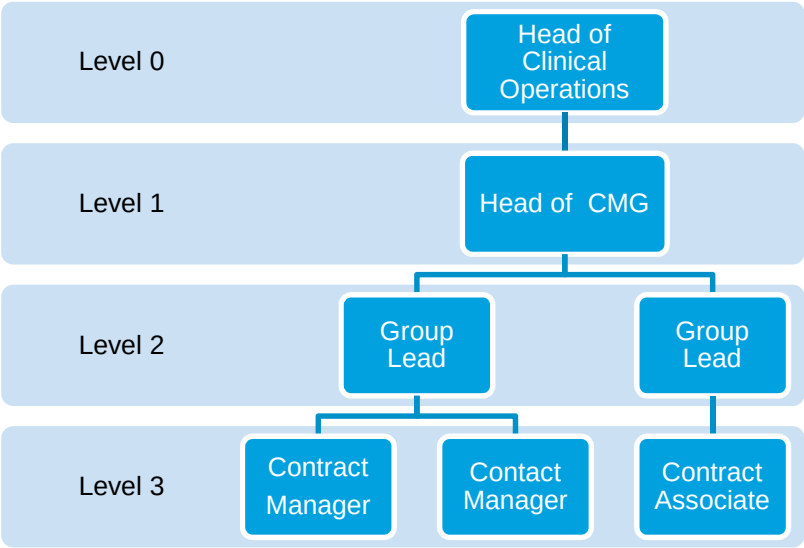
“One person’s metric is another person’s KPI”

Key

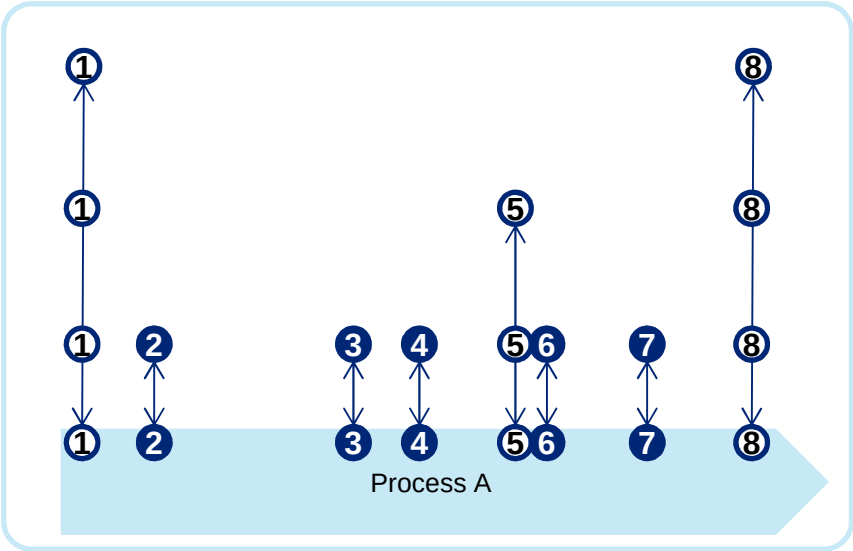
1 KPI

2 Metric

Organisational Structure



KPI and Metrics



- Leadership should define KPIs
- Additional metrics may be useful in support of KPIs
- Different levels of the organisation will be interested in different levels of performance information
- Individual and team performance should be tied to achievement of KPIs
- KPIs and metrics should be used to incentivise the right behaviours

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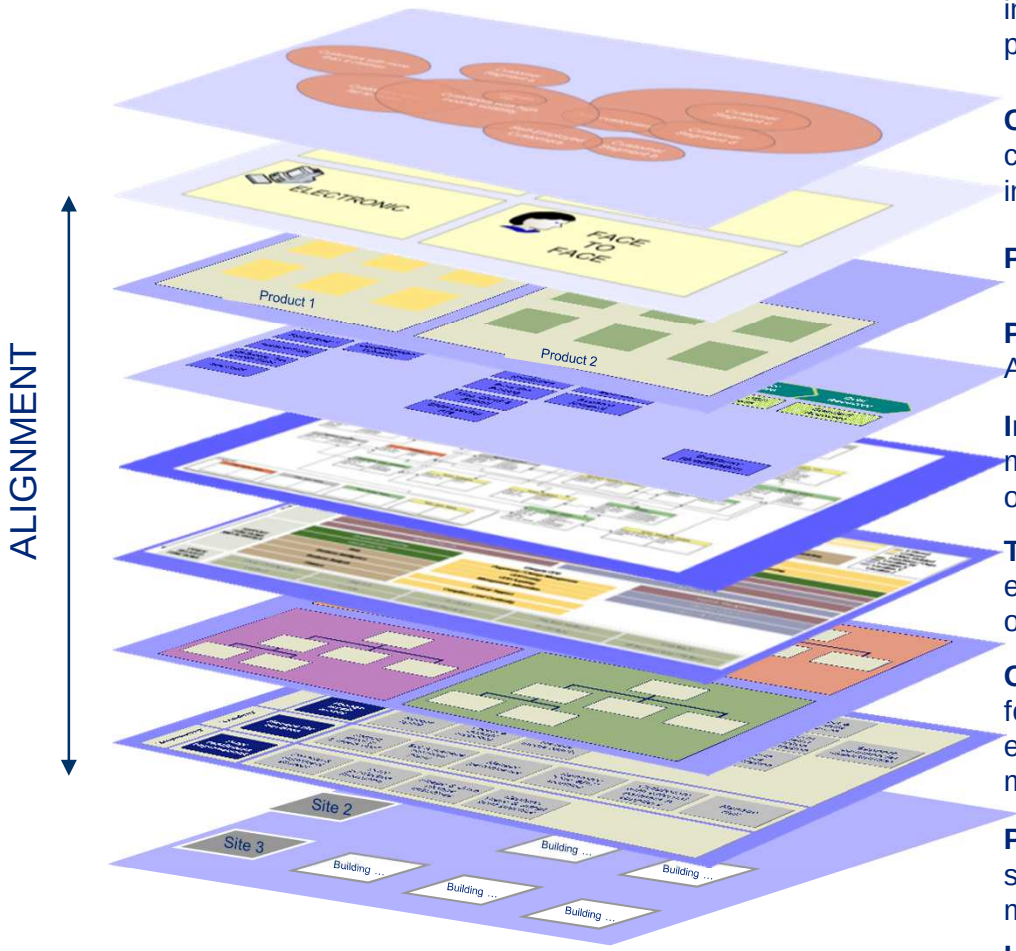
How the Operating Model Impacts KPIs

Factors influencing KPIs and Metrics in managing clinical trial performance



Customer segments Focus on new therapeutics areas, niche indications and patient stratification is likely to impact performance

Channels Remote and risk-based monitoring, investigator and clinical site relationships with 3rd parties, need to identify new investigators for new indications will have an impact on metrics

Products Delivery of clinical trials to time, cost and quality

Processes Do our processes support our new ways of working? Are these aligned to delivery to internal customers?

Information It is critical to understand what needs to be measured and how this aligns with the overall business objectives

Technology Should enable processes and delivery of products efficiently. Impacts ability to achieve metrics and business objectives

Organisation Traditional pharmaceutical organisational design follows functional logic, creating silos. A failure to leverage expertise and can have conflicting performance goals and metrics

People Competency requirements continuously evolve. The skills required to manage a clinical trial in-house is different to managing a 3rd party vendor relationship

Location Capabilities that support an end-to-end process are increasing being located in different geographical and 3rd party locations

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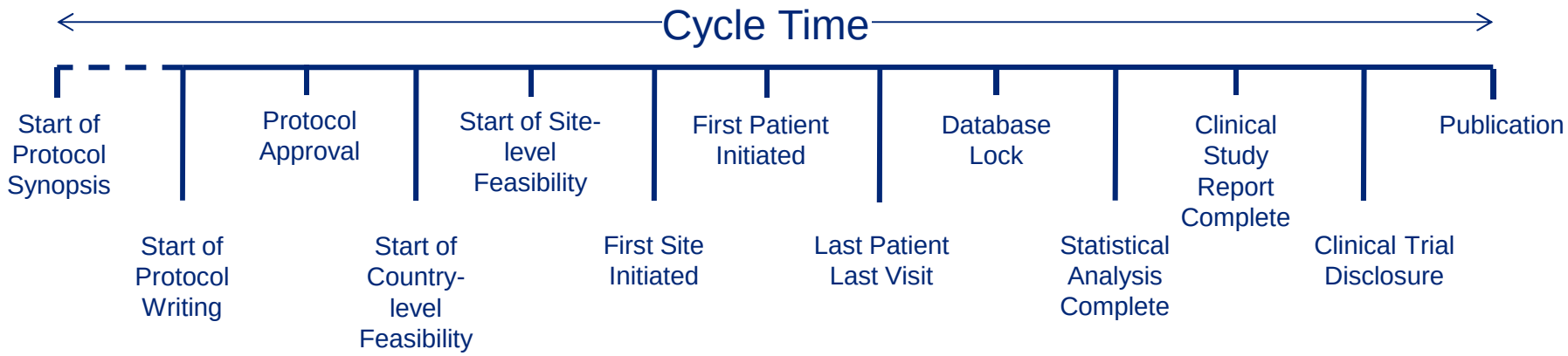
Metrics

Time, cost, resource and quality metrics in managing clinical trial performance



Selected Examples:

Cost

- Cost per patient completed
- Cost per clinical site initiated
- Cost per clinical FTE
- Cost per milestone achieved
- Cost as compared to budgeted costs
- Total cost of clinical study

Quality

- Conformance to plan
- Protocol amendments
- % of sites which fail to recruit
- Number of protocol non-compliance
- Number of serious breaches
- GxP audit/inspection findings
- Adherence to Monitoring Visit Report timelines
- % Data Clarification Forms

Resource Management

- Sites per monitor
- Patients per monitor
- Patients-delivered against country commitment
- Monitor attrition
- Study management attrition

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Summary

Quick recap

- A metric is not necessarily a KPI
- KPIs need to be aligned to business objectives
- KPIs and metrics are impacted by changes to the operating model
- Poor performance downstream maybe as a consequence of poor performance upstream
- Pharmaceutical companies and CROs would benefit from analysis and evaluation of performance against agreed metrics and/or KPIs.
- Once root causes have been identified, these lessons should be applied across the relationship

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Can metrics strengthen relationships with vendors?

Lessons from Around the Industry

Some typical pain points experienced in clinical outsourcing

- Anticipated savings are not always realised
- Clinical development is becoming more complex and more costly
- Sponsor companies have challenges understanding the true fully loaded costs of drug development
- There is a duplication of roles and responsibilities on sponsor side and vendor side
- Managing multiple vendors on a single protocol is challenging
- Perception of a high need for control leads to micromanagement of vendors
- Change orders and amendments to contracts create management distraction and increase costs
- Preferred provider lists limit vendor choice, sometimes inappropriately
- Clinical Trial Leaders express dissatisfaction with CRO or their own contract management group
- Switching partners is difficult and challenging, reducing flexibility
- Adherence to sponsor processes is not always a cost effective use of CROs
- Holding vendors accountable for outcomes they cannot control is problematic

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Introduction

Can metrics strengthen vendor relationships?

Part 1

- Industries and companies tend towards organisation based on specialised subunits
- Therefore standardisation of outputs makes management easier
- Metrics and KPIs simplify communication of, and adherence to standards

Part 2

- An approach to choosing a metric
- Performance assessment on process capability
- Considering the voice of the business
- KPIs in the management of outsourcing groups

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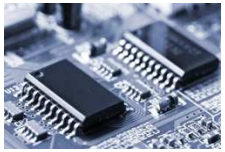
Managing Suppliers as a Strategic Capability

Historical precedent for an ecosystem of suppliers

Integration and disintegration occurs predictably in industries:

Regulation

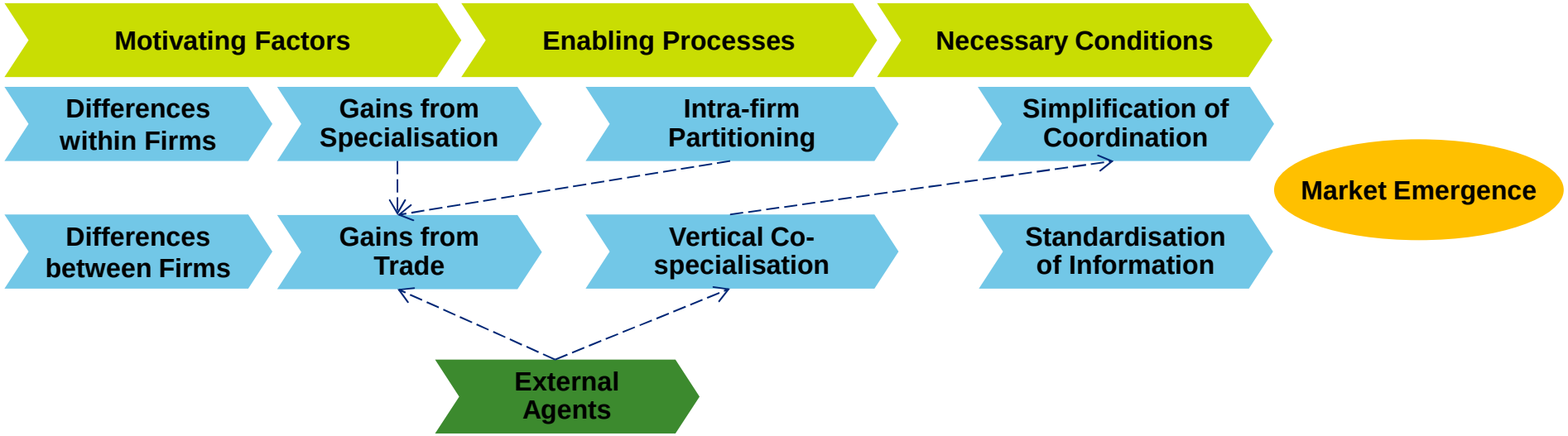
Increasing Modularity



Disruptive Innovation

Vertically Specialised Entrepreneurs

Reduction in Transaction Costs



Adapted from Jacobides, M.G., 2005. "Industry Change Through Vertical Disintegration……."Academy of Management Journal 48, 465–498.

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Organising on Outputs

Knowing what you do helps get what you want

- Companies (and industries) tend towards organisation based on small, relatively autonomous units
- These can be inside or outside the firm
- The organisational choice is deciding what is the optimal mix
- Which depends on an ability to govern the hierarchical elements and the market elements

Managing Departments Inside the Firm:

Identify on Outputs → Measure and Benchmark → Reward and incentivise

Managing Suppliers:

Advanced monitoring and communication → Advanced Administration → Cooperative Incentives

Can be achieved through the use of metrics and KPIs

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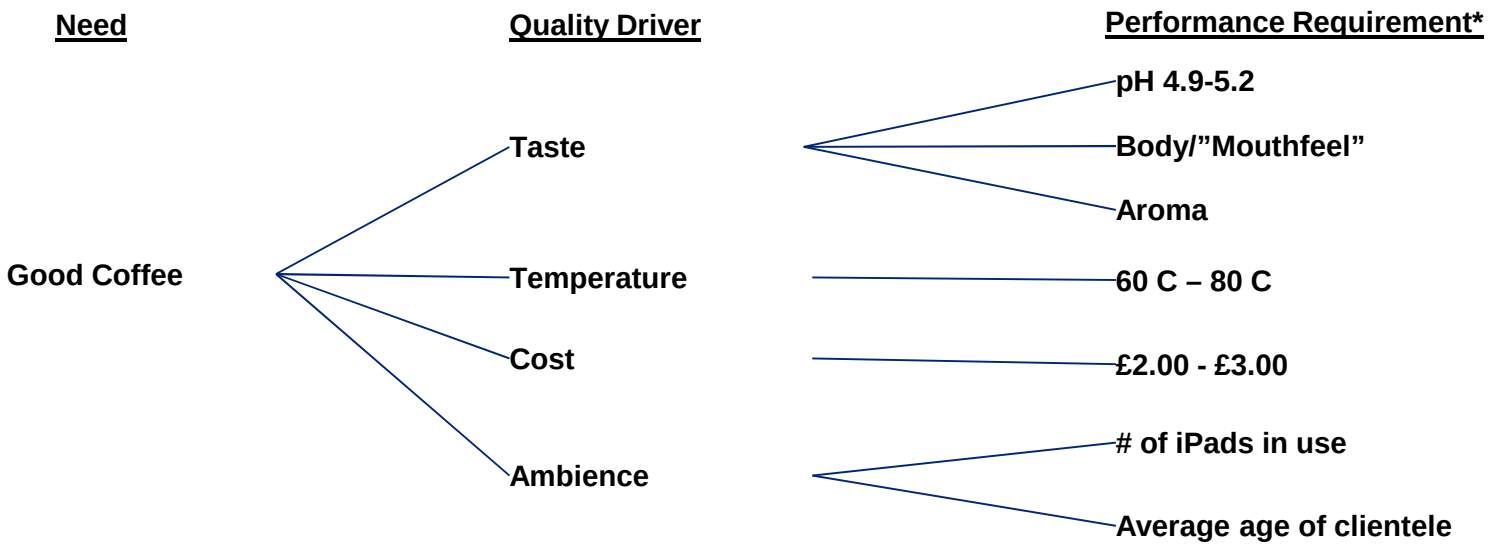
Choosing the Right Metric

What do I measure?

Certain outputs from a process will be critical to customer satisfaction CTCC

Goal is to translate these broad needs into specific actionable measureable performance requirements.

1. Identify Critical Needs
2. Identify the (Quality) Drivers that have to be in place to meet those needs
3. Identify measurable performance requirements that each driver must satisfy



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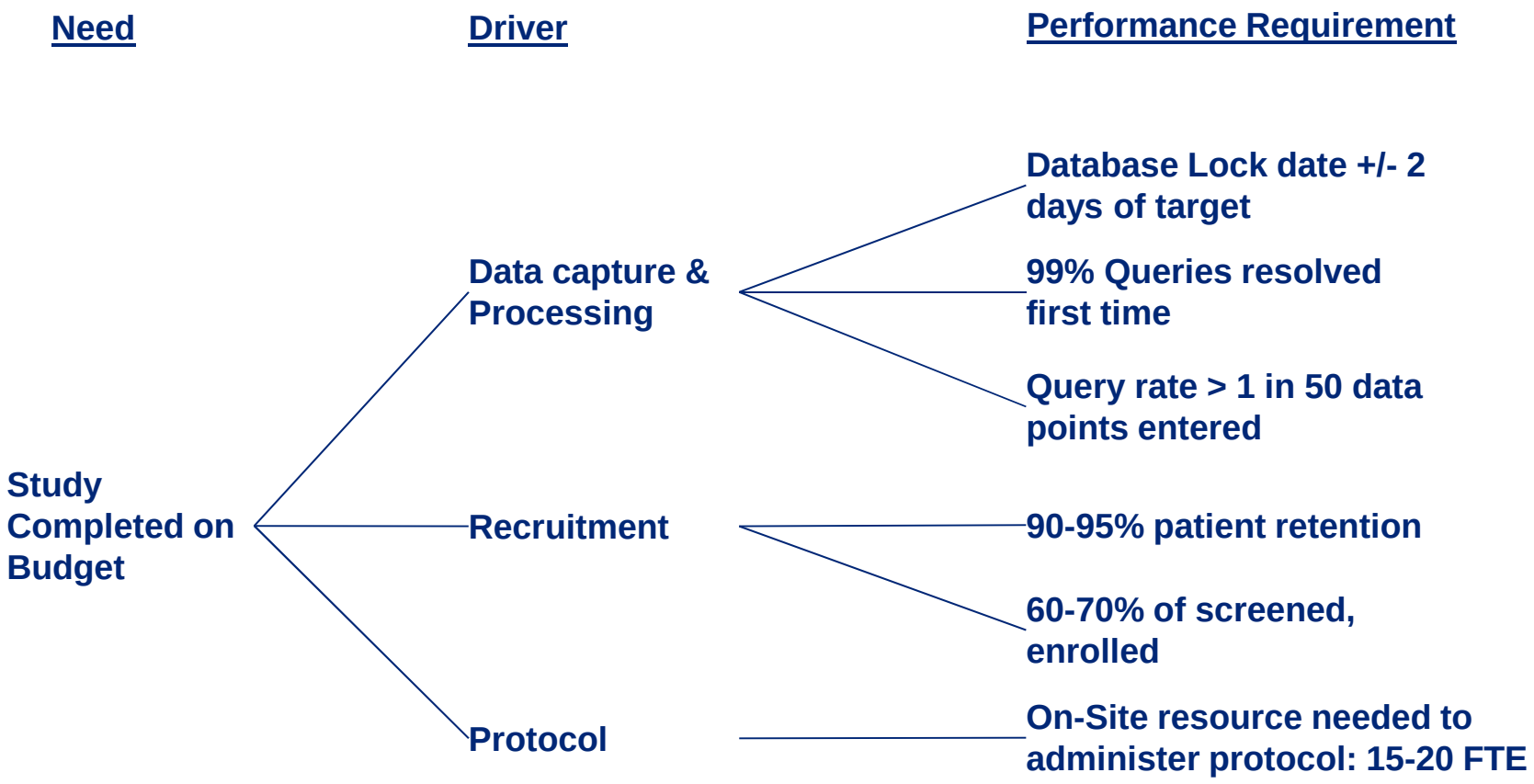
Critical to Customer Trees

Translating the KPI to functions



N.B. data is required to perform correlation analysis

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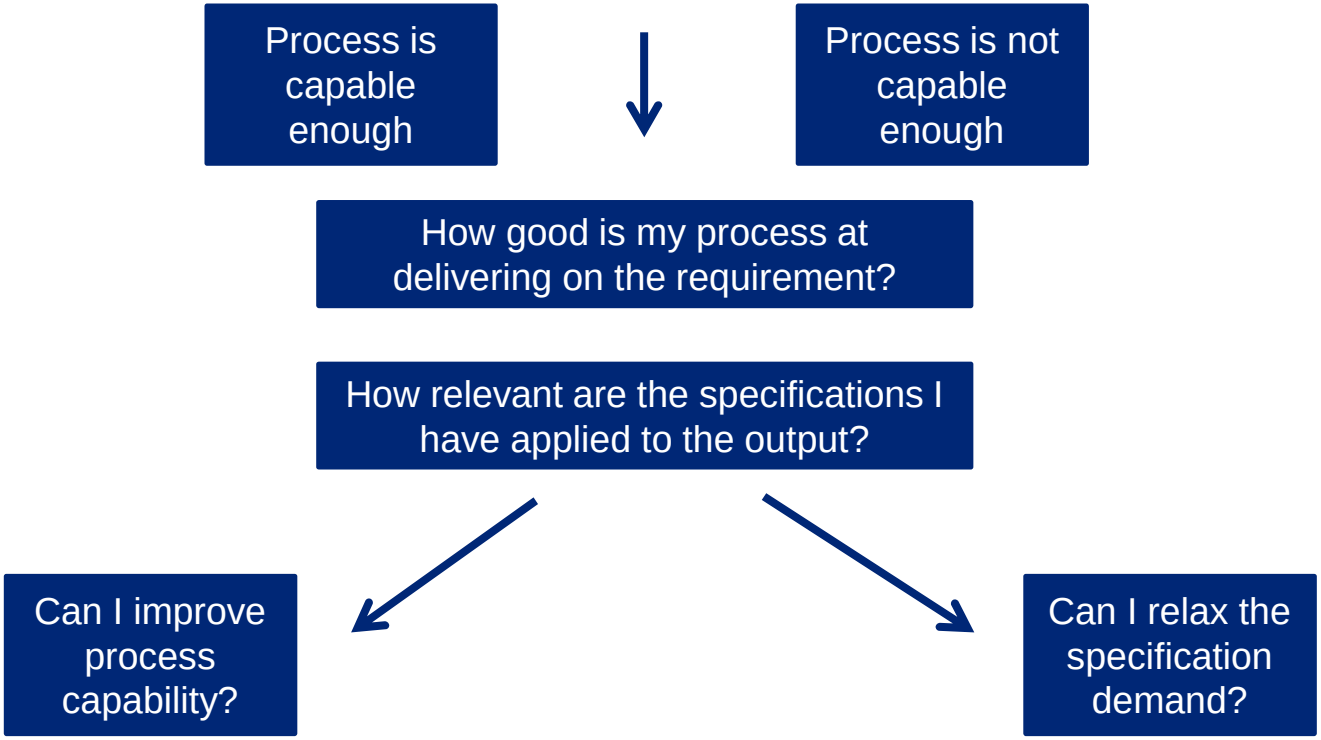
Measuring the Performance of a Process

How good is a process at delivering on requirements?

By now we should know:

1. What we are measuring?
2. What the specification limits are?

Next Question: How capable is my process of delivering to these requirements?



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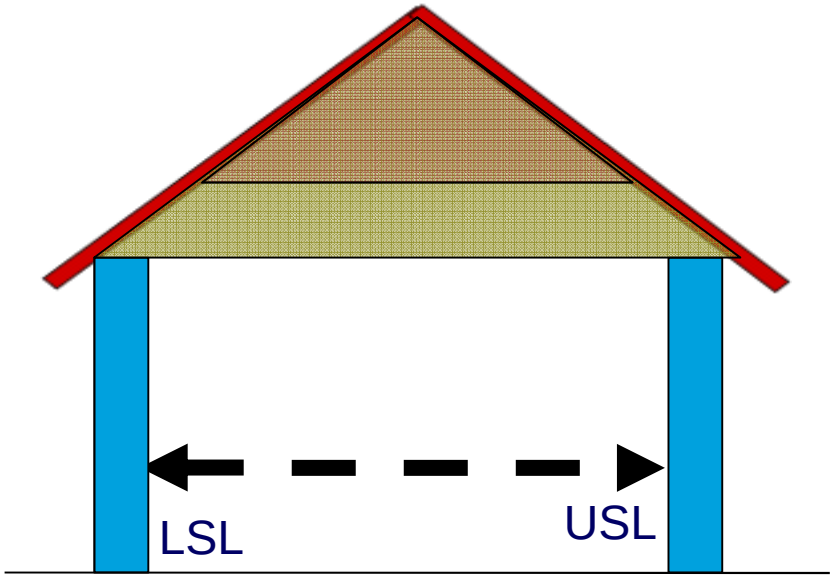
Process Capability

"Voice of the Process" versus "Voice of the Customer"

VOICE of the PROCESS

Control limits for 'the process'

VOICE of the CUSTOMER



Customer specification limits

Will the "process" fit the customer requirements?

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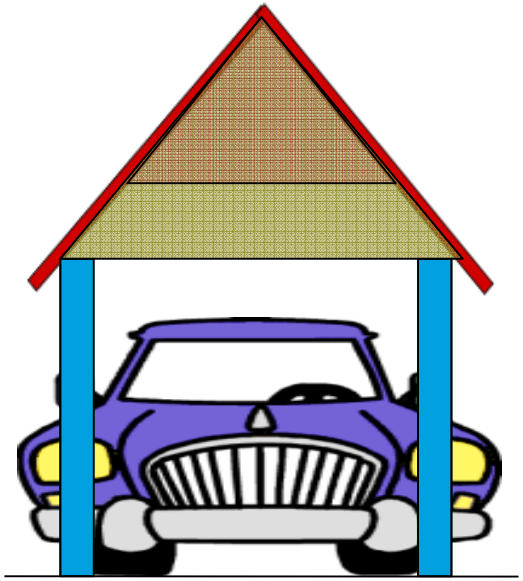
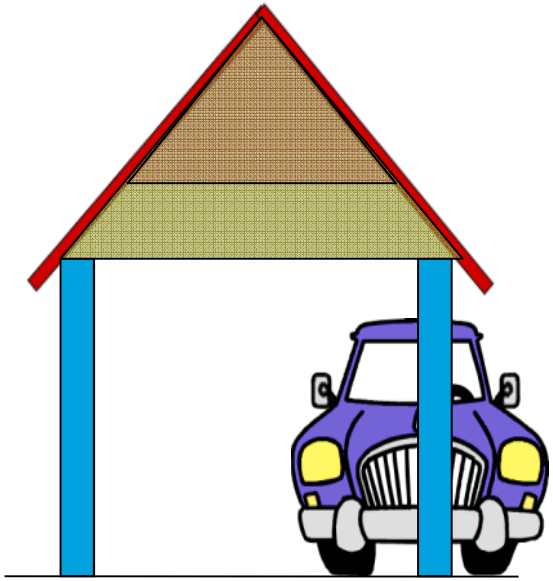
Process Capability

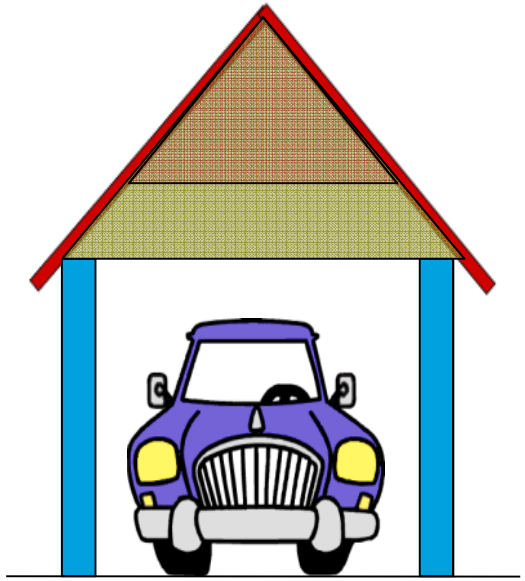
Setting the improvement strategy



Need to change the process
(or the customer specs)



Need to shift the process
(or the customer specs)



Everybody Happy

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Validate Process Requirements

Balancing the voice of the customer with the voice of the business & process

CRO Finance

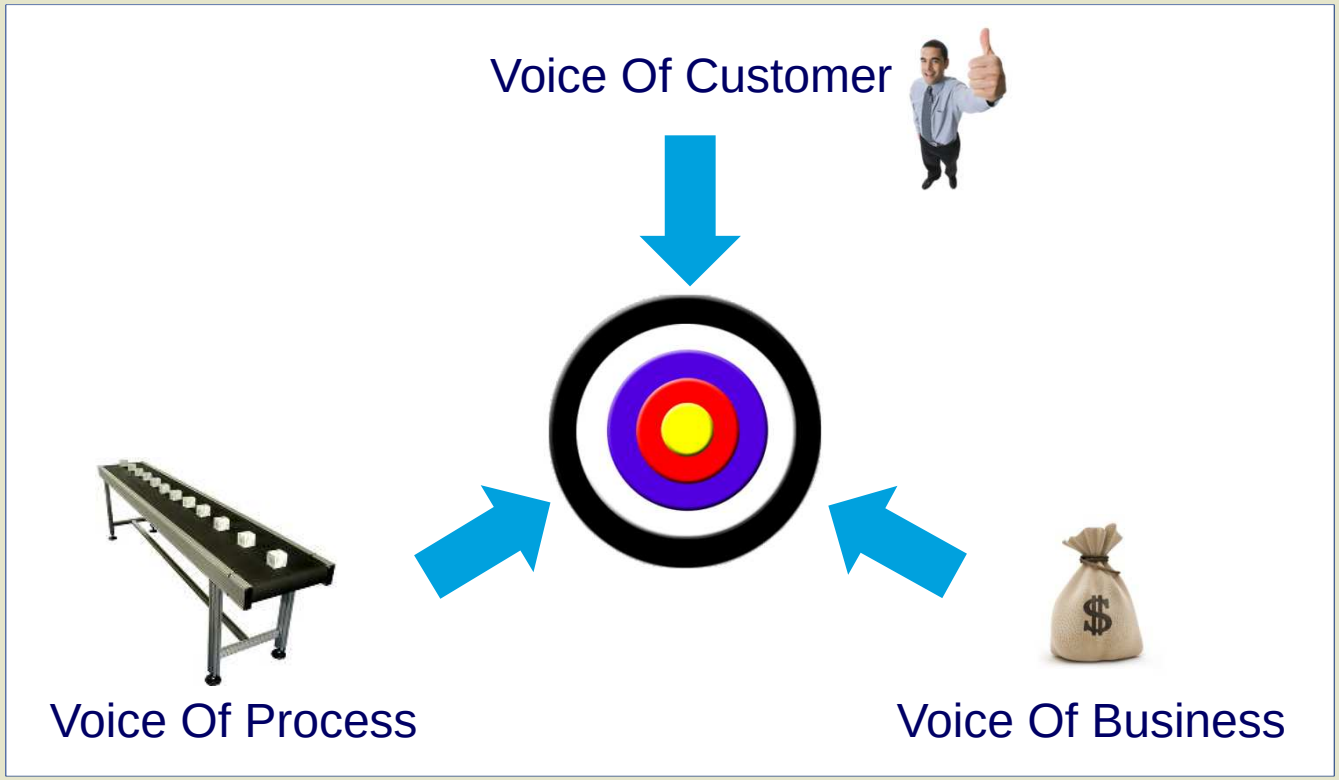
CRO Business Development

CRO Operations functions

Regulator compliance

Regulator approval

Payer



Product Dev. Team

Finance/ Procurement

Clinical Operations

Clinical Sourcing

Patients

Investigators

- Pharma development has a complex matrix of customers and suppliers
- There is a need to recognise business needs and current process capabilities to set realistic performance targets to ensure on-going profitable business

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Contracting for Clinical Services

How well do commonly used KPIs fit this view for clinical outsourcing?

Financial | Sourcing | Procurement Operations | Customer | People | Risk

Voice of the customer

Delivery
Cost Avoidance
Procurement Cycle Time

Voice of the Process

Quality
Contract Compliance

Voice of the Business

Total Cost Savings
Implemented Cost Reduction Savings
% of Active Suppliers Accounting for 80% of Total Spend
Departmental ROI
Managed spend as % of total spend

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Summary

Recap

- As businesses specialise, it may help to think in terms of a series of inputs and outputs of an end-to-end process
- Measuring and rewarding on this basis can have powerful effects on trust and transparency
- Decide what to measure
- Design appropriate specifications in line with your objectives
- Measuring process capability can change the conversation
- Consider the “Voices”

What has been the performance management experience of your organisation as a customer or as a vendor?

Could using metrics and KPIs provide a way to think about the problem differently?

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