



improving processes

Keith's Question Corner

The first question: “KPIs for vendor/CRO oversight – why bother?”
27-Apr-2023

Note: this webinar is being recorded

Keith Dorricott



- Lean Sigma Master Black Belt with 17 years' industry experience
- Formed DMPI in 2016. Engagements with vendors, CROs and Pharma including:
 - Development of KPIs for Sponsor-CRO collaboration
 - Process mapping and identification / prioritization of improvements
 - Senior RBQM Trainer for Cyntegrity
 - Senior Consultant for AQC leading work groups on metric development & use e.g. DCT
 - Critical thinking training on RBQM, root cause analysis, data interpretation
- Member of Scientific Advisory Board for King's College, London – Centre for Pharmaceutical Medicine Research



What do you want to learn?

Learning experience

What is the industry standard?

What KPIs do others use?

Move to actionable KPIs

Sponsor oversight on CRO

Using KPIs to evaluate performance

Building Vendor Management with KPIs

Are KPIs a good use of resources?

Measuring KPIs whether in- or out-sourced

Helping people who are not used to KPIs

Help in educating sponsors – you can't leave it all up to the CRO

What to report and why

KPIs: Why Bother?

- Evidence-based – not just swayed by latest issue
- Measure against expectations
- Quantitative versus Qualitative

5.2. Contract Research Organization (CRO)

5.2.1.

A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control.

5.2.2.

Any trial-related duty and function that is transferred to and assumed by a CRO should be specified in writing.

ADDENDUM

The sponsor should ensure oversight of any trial-related duties and functions carried out on its behalf, including trial-related duties and functions that are subcontracted to another party by the sponsor's contracted CRO(s).

ICH E6 (R2)

Use KPIs to Add Value

Typical Approach	Better Approach
Effort complete once KPIs are reported	KPIs have to be used to add value
Unclear what KPIs actually measure	Clear definitions for each KPI
Unclear on the purpose of the KPIs	Each KPI answers an important question
KPIs launched without training	Launch with training
KPIs used to keep CRO in line	KPIs used collaboratively – to understand and improve

No Blame

“ 94% of the results we experience in the workplace, both good or poor, are **a function of the systems and processes** in which people work, not the efforts of people



W. Edwards Deming

Context Matters

No data have meaning apart from their context

- Do not trust data from anyone who cannot, or will not, provide the context for their figures
- Stop reporting comparisons between pairs of values except as part of a broader comparison
- Start using graphs to present current values in context

Donald J. Wheeler – “Understanding Variation: The Key To Managing Chaos”

Context Matters

% deliverables right first time

Nov	Dec	Jan	Feb	Mar
95%	96%	100%	98%	75%

What happened in March?

- A. Number of deliverables dropped to 4. And the one where there was an issue was not a significant deliverable. Not a concern. Or...
- B. Resource issues meant CRAs were pulled in from another study. They are new to this study and didn't all understand the MVR template. Additional training has been given and there is a temporary higher level of QC applied.

Those compiling the report should provide the context – don't wait to be asked!

Measure What Matters

“

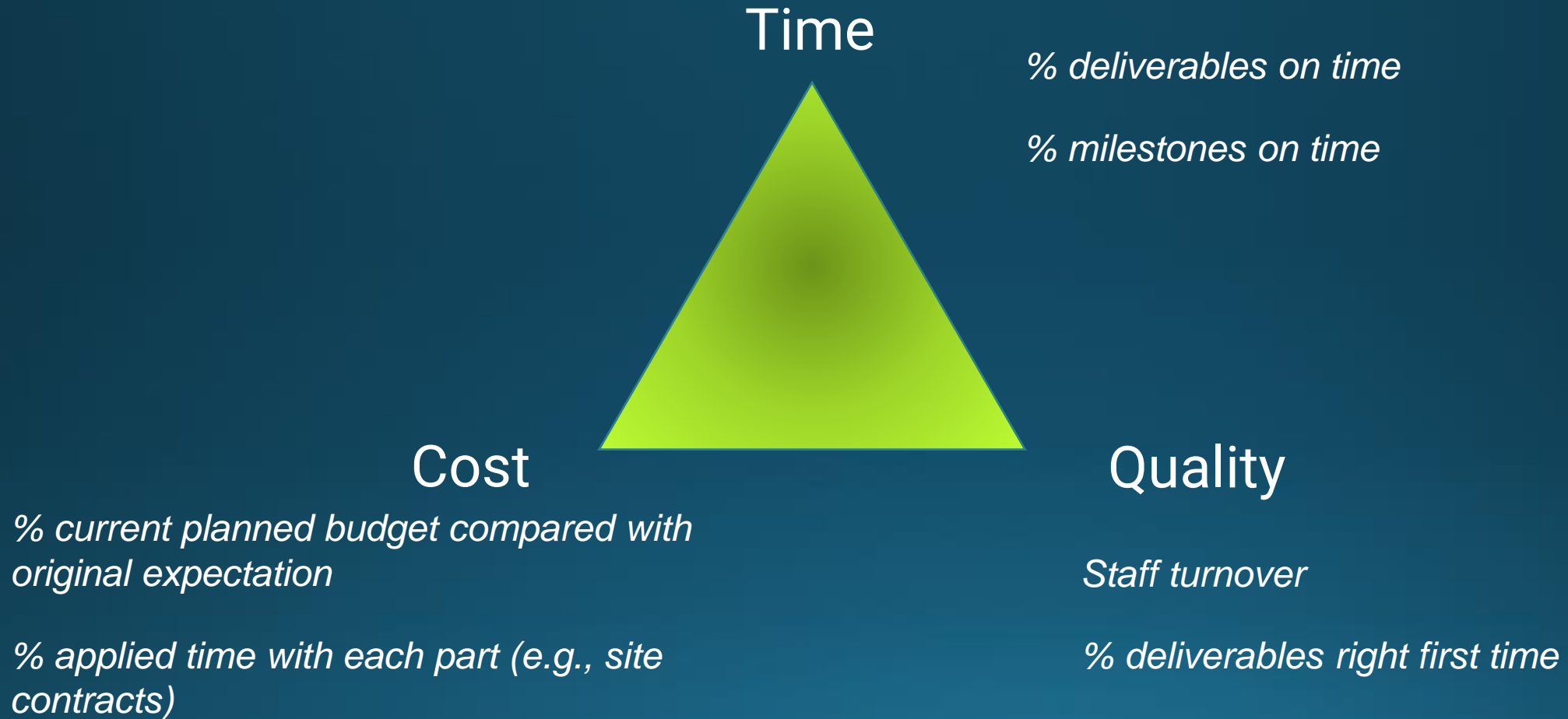
What gets measured gets managed

- Even when it's pointless to measure and manage it, and even if it harms the purpose of the organisation to do so



Simon Caulkin
based on V.F. Ridgway
(Not Peter Drucker!)

Measure What Matters



Measure What Matters

Your KPIs should answer an **important question**
For example...

Are deliverables on time and to quality?

- % deliverables on time
- % deliverables right first time

How accurate are the cost estimates?

- % current planned budget compared with original expectation



Start Small



KPIs are just one part of the picture of CRO/vendor oversight

Summary...

KPIs for vendor/CRO oversight – Why Bother?

- Quantitative versus Qualitative...and GCP
- Tips:
 - Use KPIs to add value
 - No blame
 - Context
 - Measure what matters
 - Start small

Questions?





improving processes

Keith's Question Corner

June 8th @ 12pm EDT, 5pm UK

Next Question: “How can we use KPIs to add value?”

Visit my blog at www.dorricottmpi.com

Drop me a line at keith@dorricottmpi.com