

Performance Metrics Fundamentals

Roger Joby

- **Visiting Research Fellow Liverpool JM University**
- **PCMG Lifetime Fellowship 2019**

Keith Dorricott

- **Metrics Champion Consortium Ambassador**
- **Master Black Belt in Lean Six Sigma**

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Performance Metrics Fundamentals

Keith Dorricott
Ambassador, Metrics Champion Consortium

kdorricott@metricschampion.org



Companies “...measure **too much** or **too little**, or the **wrong things**, and they don’t use their metrics **effectively**.”

Michael Hammer
 Founder of Business Process Reengineering

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Metrics Champion Consortium

Mission: Bring clinical research stakeholders together, including sponsors, CROs, partners and investigational sites, to collaboratively develop standardized performance metrics and associated tools that help organizations oversee, manage and optimize clinical trial execution.

>80 Member Companies
 e.g. Abbott, AZ, Covance, Gilead, Merck, Novartis, Pfizer, PPD, Roche, Sunovion



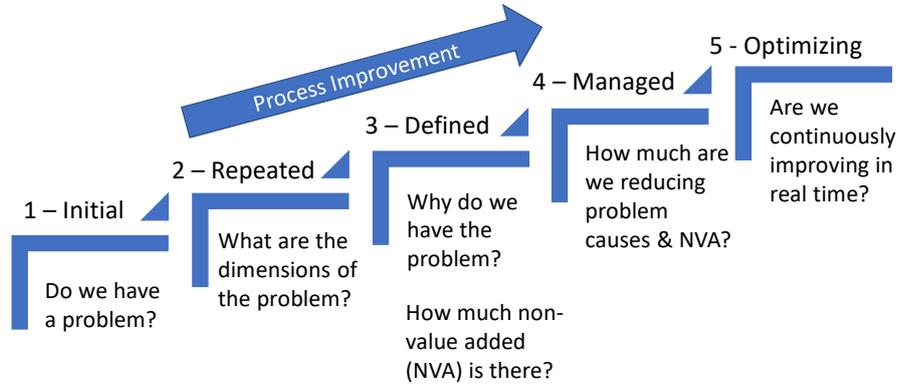
MCC is the place to meet industry peers,
 exchange ideas, collaborate, and think.



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Metric Maturity Model



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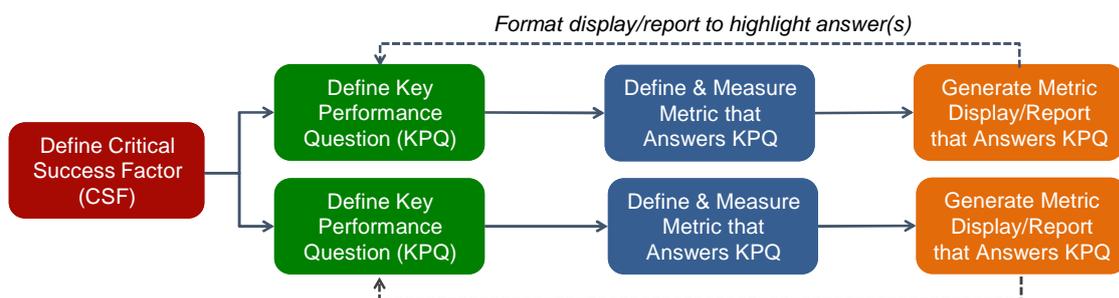
What you measure depends on many factors

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Source: Sullivan L. *Measure the Right Things at the Right Time: Using A Metric Maturity Model to Optimize Performance Measurement*. February 2020. Available at: <https://www.wgclinical.com/insights/mcc/measure-the-right-things-at-the-right-time-using-a-metric-maturity-model-to-optimize-performance-measurement>



The MCC Metrics Development Framework



- CRO Oversight Metrics
- Functional Metric Sets e.g. Central Lab, eCOA, Imaging

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Lagging and Leading Metrics

	Lagging Metrics	Leading Metrics
Definition	Provide information that can be used for future studies	Provides information that can be used to bring the study / process back on track

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Lagging and Leading Metrics

	Lagging Metrics	Leading Metrics
Definition	Provide information that can be used for future studies	Provides information that can be used to bring the study / process back on track
Uses	<ul style="list-style-type: none"> Benchmarking & Baseline Monitoring over time Process understanding & improvement Planning 	<ul style="list-style-type: none"> Indicator of risk e.g. Key Risk Indicator Evidence on assumptions and planning accuracy
Challenges	<ul style="list-style-type: none"> Long cycle times mean changes are difficult to detect Difficult to interpret if large spread of data Impact of outliers (hence use of median) 	<ul style="list-style-type: none"> Is target "allowed" to be updated? Might encourage items that are going to be late to be ignored Doesn't tell you if the target was wrong or the performance
Examples	<ul style="list-style-type: none"> % final cost / original cost Cycle time from investigator payment trigger to payment 	<ul style="list-style-type: none"> Rate of direct costs incurred % staff turnover

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Metric Levels

(P) Portfolio

- Measures across multiple studies e.g. % site payments within target across studies
- Useful for vendor oversight

(S) Study

- Measures across a study e.g. % site payments within target for the study
- Useful for oversight of a study and drill-down of portfolio-level metrics

(C) Country

- Measures across a country e.g. % site payments within target for the country
- Useful for oversight at a country level

(I) Investigative Site

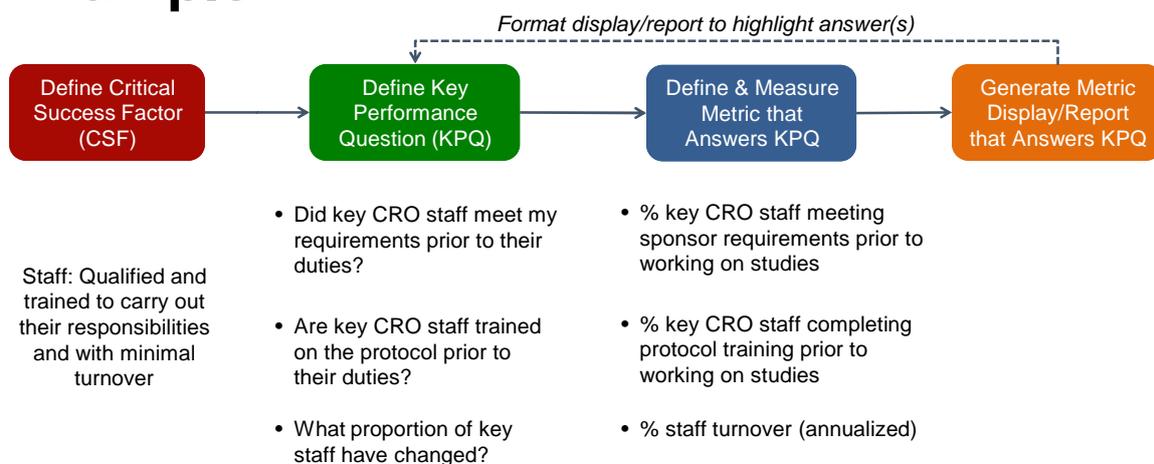
- Measures for one site
- Not applicable for vendor oversight metrics

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MCC Metrics Development Framework - Example

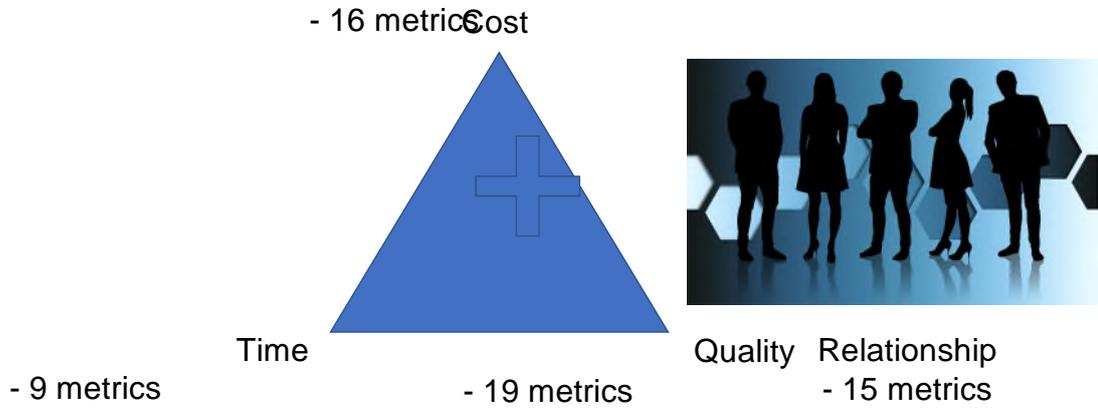


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Dimensions of CRO Oversight



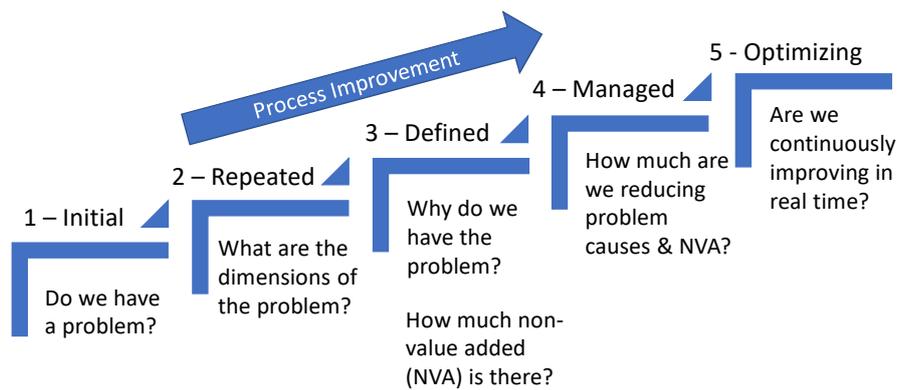
Use as few metrics as you need! The metrics YOU select will depend on YOUR circumstances

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Metric Maturity Model



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As you improve the process your metrics will evolve and expectations change

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Source: Sullivan L. *Measure the Right Things at the Right Time: Using A Metric Maturity Model to Optimize Performance Measurement*. February 2020. Available at: <https://www.wgclinical.com/insights/mcc/measure-the-right-things-at-the-right-time-using-a-metric-maturity-model-to-optimize-performance-measurement>



Takeaways

- Start with the questions that matter – not with what you *can* measure
- There are different dimensions of metrics: cost, quality, timeliness & relationship
- And different levels: portfolio, study, country & site
- Leading and lagging metrics both have uses
- The set of metrics you use will not be identical to others'

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Project performance metrics

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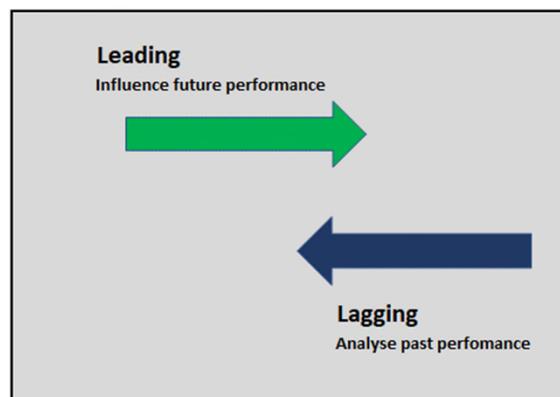


Step 1 - Defining project success

- Performance in terms of time, cost and quality
- Stakeholder satisfaction
 - Sponsor
 - Team
 - Supplier
 - End User
 - Regulators
- Sponsor/Supplier relationship
- Other self defined criteria

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The use of leading and lagging metrics



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Lagging metrics for planning

Analysing past performance

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Realistic project plans using lagging metric

- A budget and timeline that is based in reality and is agreed by sponsor and supplier
- If these are going to be the baselines that you measure against then they need to be as accurate as possible.



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Realistic project plans lagging metrics

Timeline

- Protocol development
- Essential Documents
- Site initiation
- Recruitment
- Last patient last visit to database lock

Budget

- Project management tools used e.g.
 - Scheduling
 - Risk Management
 - Stakeholder Engagement
 - Earned Value Management
- Monitoring plan
- Site recruitment data
- Contingency and risk reduction plans

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Leading metrics

Influence future performance

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Measuring project progress leading metrics

Early warning of deviation from plan

- The influence that a project manager has to change the course of a project rapidly diminishes with time. The more history a project has the more difficult and expensive it is to put back on track.

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Both positive and negative deviations can be threats or opportunities

- Recruitment is faster than planned – do you have sufficient CRA and Data Monitor resource take full advantage of this opportunity.
- Recruitment is slower than planned – potential issues for the timeline and the budget



Earned value the ultimate leading metric

Based on a Deliverable Budget

Deliverables

‘The end products of a project or the measurable results of intermediate activities within the project’

APM BODY OF KNOWLEDGE 5th EDITION

Earned Value = % Complete x Budget

•Bryde, D.J. & Joby, R. (2007) "Product-based planning: the importance of project and project management deliverables in the management of clinical trials" *R & D Management* Vol 37 No 4 pp 363-377

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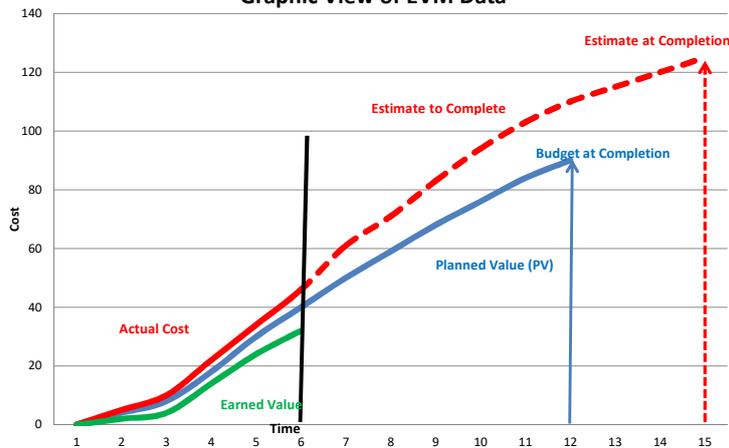
Earned Value -the ultimate leading metric (calculated using key outcomes/deliverables)

% Complete and Earned value		Jun 04				Actual Units	Total planned units	Planned Budget in EURO	Earned Value EURO	% complete
	1st Draft	2nd draft	Final draft	Signed off						
Final Protocol	YES	YES	YES	YES	4	4	6,414.32	6,414.32	100%	
Final CRF	YES	YES	YES	YES	4	4	2,069.04	2,069.04	100%	
Initial Project Plan	YES	YES	YES	YES	4	4	3,885.00	3,885.00	100%	
Final Analysis plan	YES	YES	YES	YES	4	4	9,513.44	9,513.44	100%	
Final list of Investigators	YES	Complete YES or NO			1	1	6,796.16	6,796.16	100%	
Sites Evaluated	52	Number of Site Evaluated			52	52	59,669.16	59,669.16	100%	
Investigator meeting	YES	Complete YES or NO			1	1	24,933.56	24,933.56	100%	
Sites Initiated	20	Number of sites initiated			20	44	159,266.48	72,402.95	45%	
CRF pages monitored and in house	2200	Number of CRF pages in house			2200	55000	798,738.24	31,949.53	4%	
Sites Closed	2	Number of site closed			2	44	50,487.24	2,294.87	5%	
Audit reports	4	Number of completed audit reports			4	7	54,563.16	31,178.95	57%	
Database Built and Tested	YES	Tested			2	2	21,277.96	21,277.96	100%	
CRF pages entered	1500	CRF pages entered			1500	55000	113,184.48	3,086.85	3%	
CRF pages cleaned	100	CRF pages cleaned			100	55000	143,006.48	260.01	0%	
Locked Database	NO	Hard Lock			0	2	80,939.72	-	0%	
Tables Listing and Figures approved	0				0	56	65,473.72	-	0%	
Final Study Report	NO	2nd draft	Final draft	Signed off	0	4	61,485.12	-	0%	
Sub Total							1,661,723.28	275,731.80	17% Overall % Complete	
Project Management							664,726.68	110,299.25	17%	
Grand Total							2,326,451.96	386,031.05	17% Overall % complete	

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Graphic View of EVM Data



Metrics are like signposts

“Signposts don’t walk in the direction they point.
It is we humble mortals who must choose which way to go.
The signpost is not responsible for our decision.”



John Le Carre



All of the above is pointless if it does not instigate action

- A course of action to bring the project back on plan or realising the opportunity to exceed plan



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Case History 1 Haemophilia Project

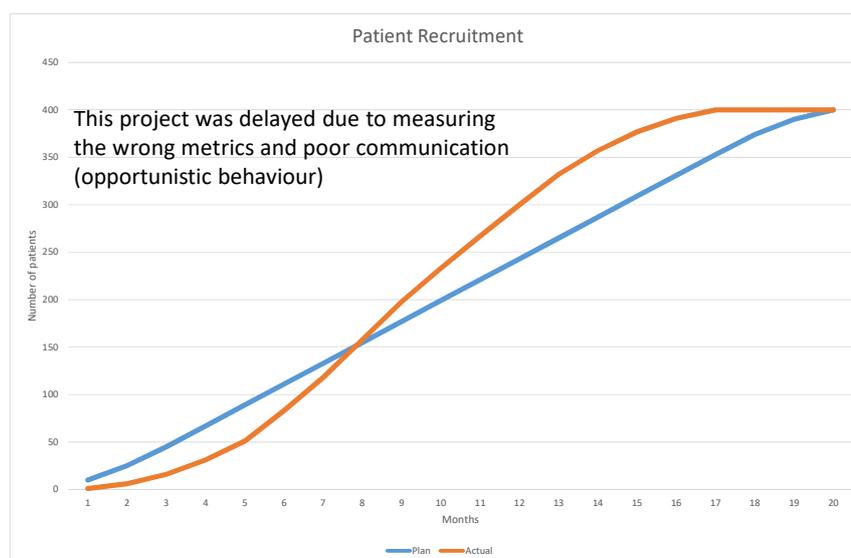
This project failed initially due to bad planning and subsequently to lack of corrective action :

1. The original budget was underbid, this was recognised by Pharma, but still accepted, ignoring lagging metrics from previous studies.
2. EV was used a leading metric and soon showed a negative variance to plan. Was this poor performance or poor plan.

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Case History 2



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Conclusion

- Lagging metrics for planning.
- Leading metrics for monitoring and control.
- Have a plan of action and instigated it when required.
- Make sure all stakeholders buy into the plan and the monitoring and control measures.
- Communicate deviations from the plan without delay.

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