



Using Quality Metrics to Drive Direction for Process Improvement and Improve the Clinical Drug Development Process

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10 Thing I Wish Lean Practitioners Wouldn't Say in 2010

<http://www.leanblog.org/2010/01/10-lean-things-to-not-say-2010/>

[Matt Millman](#)

7. “If you can't measure it, you can't manage it.”



[Filip Frostemark](#)

Of course you should aim for a few metrics but if you really want to improve on something, finding a relevant metric would help you doing the right things. . . . KPIs could help us going from a set of "nice words" into tangible actions. Measurable goals formulated around KPIs will "force" us to actually do something and it also adds a great deal of transparency. Still I agree that not everything could get measured and you need to be careful in identifying the relevant metrics and also when interpreting the data.



[Mark Jones](#)

I have to say that a passion of mine this year has been to try to gauge the 'people impact' of Lean Sigma projects. It is hard to measure (granted) but so important. . . . the Lean work I have been involved in this year has most notably increased motivation and focus for the scientists on the clinic and the patients. This in turn has brought about improvements in the metrics - not the other way round.



[Terry Barnhart](#)

The thing that worries me about metrics is that defining what is important simultaneously defines what is not important, hence not seen. In a complex, non-linear universe, anything can prove important, which was the point of Ohno's observation circle - with narrow vision, you will miss the important, but barely detectable thing.

Today's Discussion

How a group of pharmaceutical, biotechnology and CROs are collaborating to define and implement a standardized set of clinical trial performance metrics with the intent to *drive improvement of the drug development process.*

Joint, Collaborative Process Improvement

Industry Metrics

- Every extra day spent in clinical trials can translate into a loss of \$600,000 in sales for niche drugs, and up to \$8 million for a blockbuster (Source: Datamonitor)
- 45% of studies finish late (Source: Business Insights Ltd)
- The average number of exclusion/inclusion criteria has increased 20% over 5 years (Source: Business Insights Ltd)
- 30% of sites enrol 70% eligible subjects (Source: McKinsey)



Discussion Questions

- Can focus on a fixed set of metrics detract from process improvement discovery?
- How can we use metrics for process improvement and avoid potential pitfalls (like sub-optimization)
- Is the metrics collection cost / benefit favorable?
- What controls are needed to avoid gaming a blinded database ? (rationalizing outlier exclusions)
- What other areas deserve focus to establish industry quality standards?

Rethinking Metrics

- The sad truth:
 - We measure too much
 - We measure too little
 - We measure the wrong things
 - We do not understand *cause and effect*
 - We have no idea why we measure what we do
 - We do not know what to do with what we measure
- The goal of measurement is not simply to quantify business performance, but to improve it
- We must move away from autopsy to treatment; away from historical accounting to proactive management

Building Partnerships Around Standardised Performance Metrics

The Metrics Champion Consortium (MCC) is a not-for-profit organisation comprised of biotechnology, pharmaceutical and service provider organisations who work collaboratively to develop and implement standardised performance metrics with the intent of *jointly improving the efficiency and effectiveness* of managing and tracking resources needed to successfully run clinical trials.

MCC Member Organisations

Abbott Laboratories

AstraZeneca

BARC Global Central Lab

BioClinica

Biogen Idec

Biomedical Systems

Cardio Analytics

Cardiocare

Carefusion

Cerexa

CHDI

Clinsys Clinical Research

Covance

**Duke Clinical Research
Institute**

ERT

**Esoterix Clinical Trial
Services**

Eurofins Medinet

ExecuPharm

Genentech

Genzyme

i3

ICON

Imaging Endpoints

INC Research

Incyte

Lilly

M2S

MacroGenics

Medidata Solutions

Medtronic

Merck

New England Research Institute

Novartis

Paragon Biomedical

Perceptive Informatics

Pfizer

PharmaNet

PPD

Quest Diagnostics

RadMD

RadPharm

Regeneron

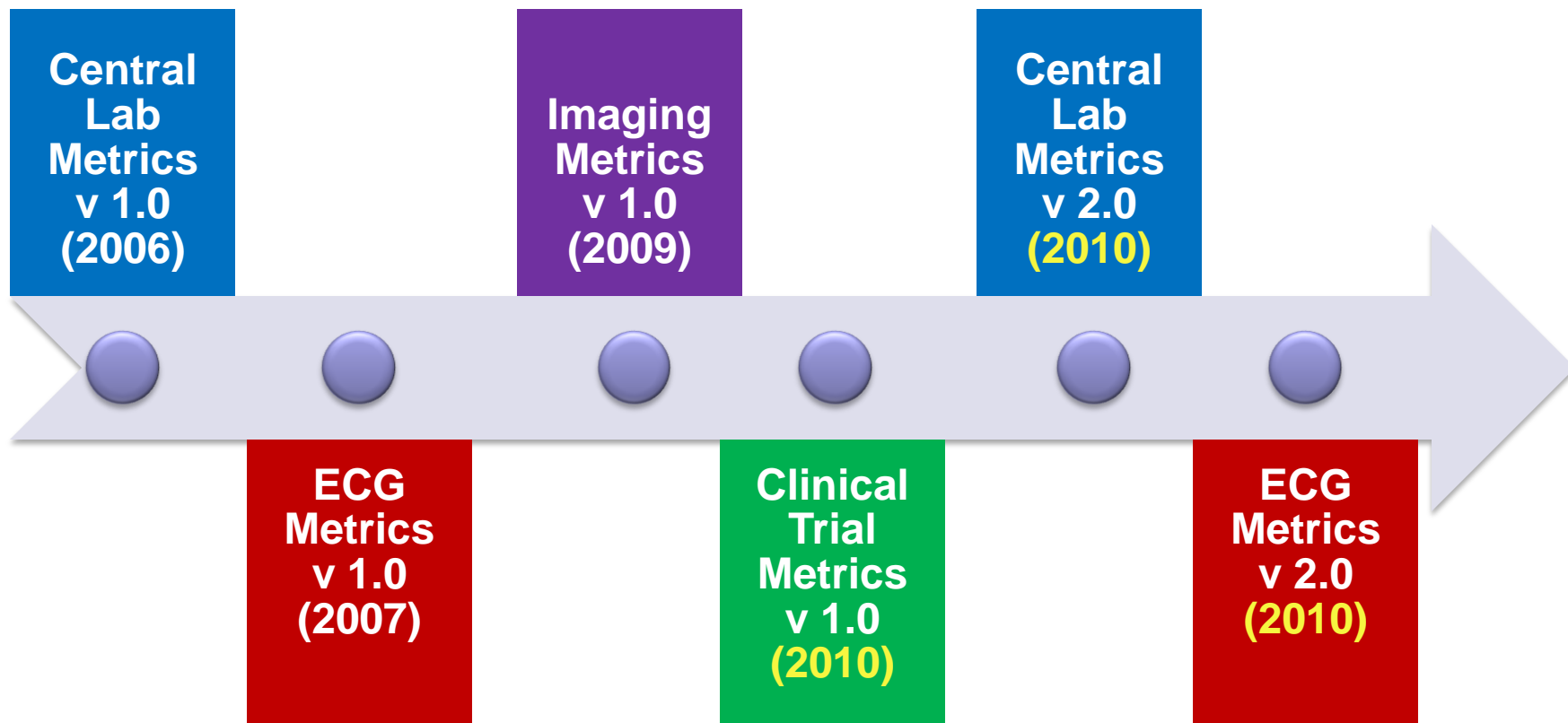
Research Point

Synarc

Virtual Scopics

WorldCare Clinical

Metrics Development Timeline

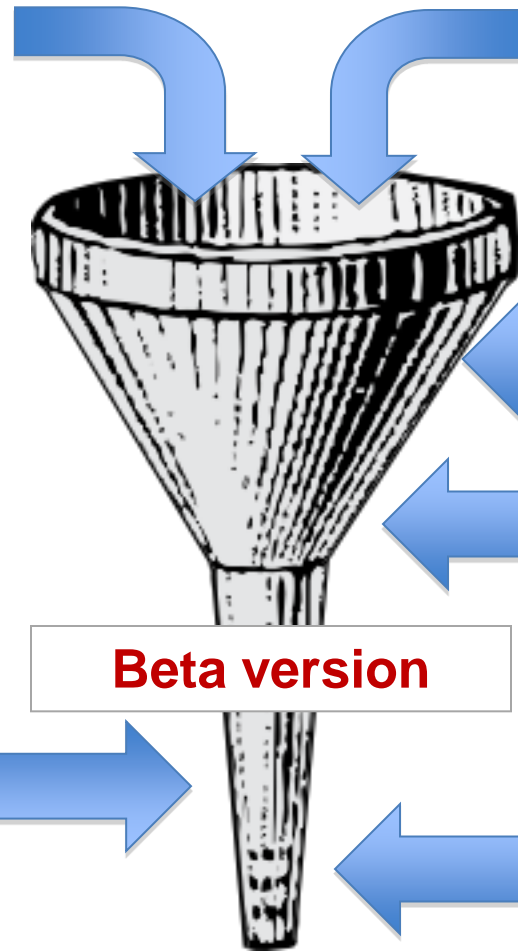


MCC Metrics Development Process

Brainstorm Metrics Lists

- Industry meetings
- Surveys

Gather Existing Metrics
MCC SC & WG members



Create Process Maps
MCC SC & WG members

Screen Metrics With
Mapping Tool
MCC SC & WG members

Beta version

Solicit Industry
Feedback

Revise Metrics
MCC SC & WG members

Metrics version 1.0

Types of Performance Metrics

- Cycle Time (CT)
 - How long it takes
- Timeliness (T)
 - Whether milestone achieved on time
- Quality (Q)
 - Errors or other quality characteristic
- Efficiency / Cost (E)
 - Resources needed

And What About the Metrics' Quality?

Properly defined metrics should be:

S = Specific: clear and focused to avoid misinterpretation. Should include assumptions and definitions and be easily interpreted.

M = Measurable: can be quantified and compared to other data. It should allow for meaningful statistical analysis.

A = Attainable: achievable, reasonable, and credible under conditions expected.

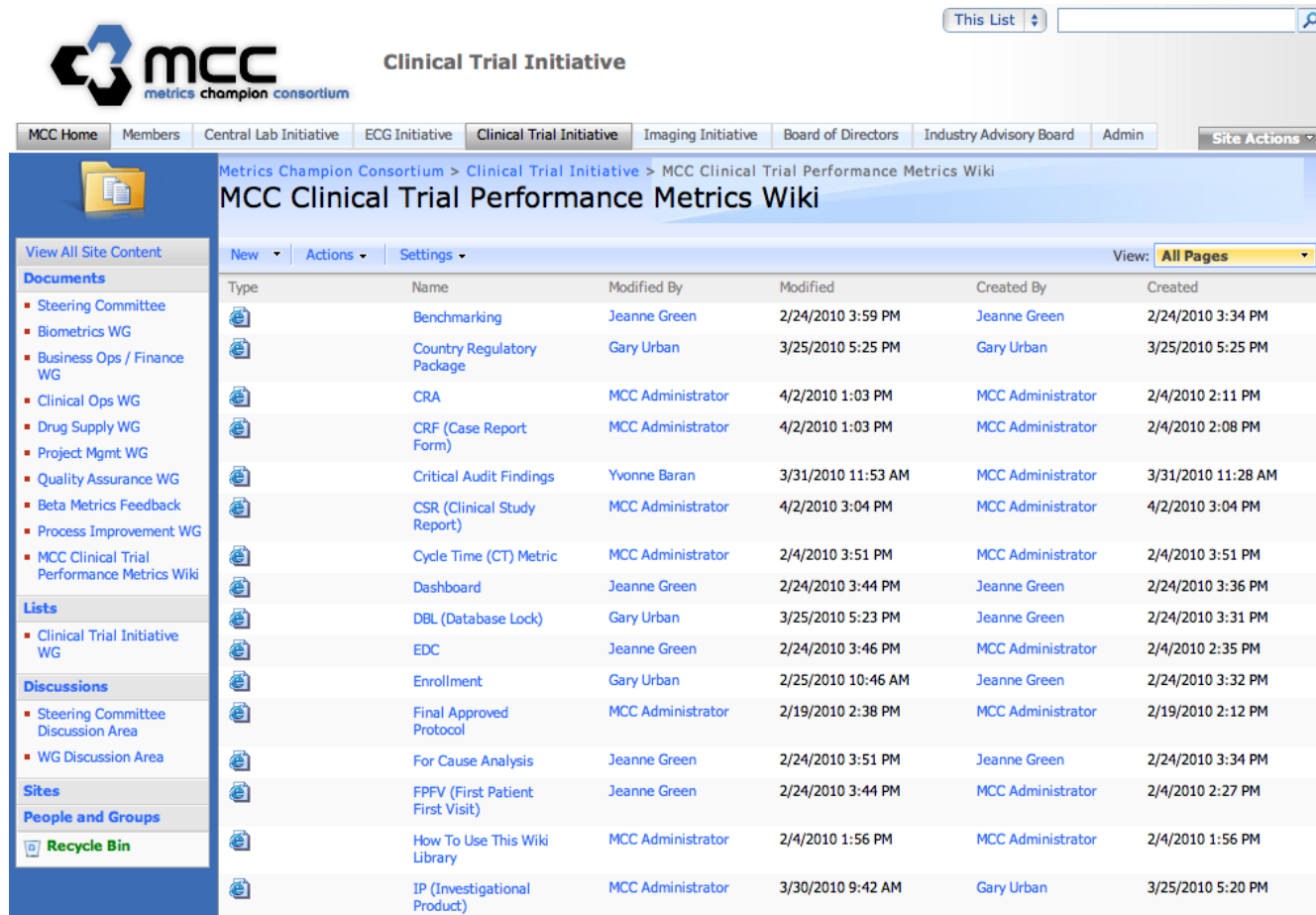
R = Realistic: fits into the organisation's constraints and is cost-effective.

T = Timely: achievable within a time frame given.

Example of MCC Metric

Metric #	Metric Type	Metric Title	Category	Metric Indicator	Part of Study
25	T	% subjects enrolled	Patient Screening and Retention	LEADING Indicator	Study Conduct
Definition (see Wiki for detailed definitions)		Formula / Example		Reporting Detail	
% subjects enrolled at point in time (actual date of 25, 50, 75%) vs. target date See MCC Wiki for definitions		Formula: $X/Y (100) = \% \text{ subjects enrolled}$ $X = \# \text{ of subjects enrolled}$ $Y = \text{total } \# \text{ of subjects anticipated to be enrolled}$ Example: A total of 35 subjects are enrolled at point time vs. an expected 32 enrolled subjects at point in time. $35/32 \times 100 = 109\%$		Study / Country / Region / Therapeutic Area / Portfolio levels Unit of Measure %	
Business Driver(s) / Benefit Statement		Additional Analysis on a "for cause" basis		Reporting Frequency	Target
Meeting or exceeding enrollment targets ensures trial timelines are met. It may be acceptable for the metric to trend toward the lower end of the target early in the enrollment period. Below target metrics indicate the need for risk management/intervention. A trend toward the upper end of the target may indicate a need to mitigate the risk of over-enrollment.		% of sites activated; Screen failure rate vs. expected; Actual vs. Planned Enrollment once LPLV is achieved. Formula: $(\# \text{ Months for Actual Enrollment} - \# \text{ Months Planned for Enrollment}) / \# \text{ Months Planned for Enrollment} \times 100 = \% \text{ additional time required for enrollment.}$ $18-12=6/12 \times 100 = 50\%$		Weekly or monthly, dependent upon planned enrollment period	> = 90% (Green) 75%-90% (Yellow) < 75% (Red)
Companion Metrics		MCC metrics # 3, 5, 11, 14, 17, 24, 34			

MCC Clinical Trial Metrics Wiki



mcc
metrics champion consortium

Clinical Trial Initiative

MCC Home Members Central Lab Initiative ECG Initiative **Clinical Trial Initiative** Imaging Initiative Board of Directors Industry Advisory Board Admin Site Actions

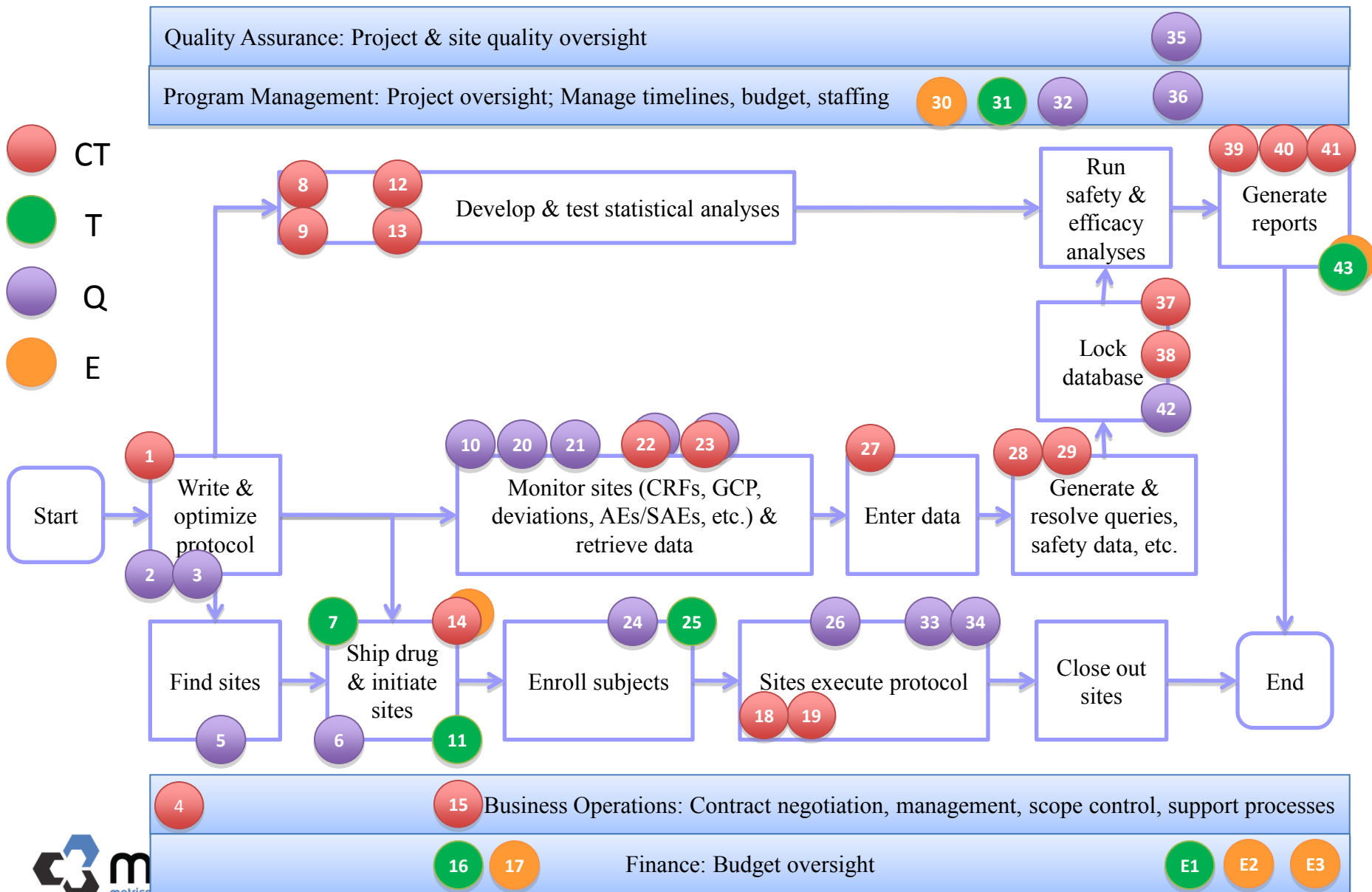
Metrics Champion Consortium > Clinical Trial Initiative > MCC Clinical Trial Performance Metrics Wiki

MCC Clinical Trial Performance Metrics Wiki

New Actions Settings View: **All Pages**

Type	Name	Modified By	Modified	Created By	Created
	Benchmarking	Jeanne Green	2/24/2010 3:59 PM	Jeanne Green	2/24/2010 3:34 PM
	Country Regulatory Package	Gary Urban	3/25/2010 5:25 PM	Gary Urban	3/25/2010 5:25 PM
	CRA	MCC Administrator	4/2/2010 1:03 PM	MCC Administrator	2/4/2010 2:11 PM
	CRF (Case Report Form)	MCC Administrator	4/2/2010 1:03 PM	MCC Administrator	2/4/2010 2:08 PM
	Critical Audit Findings	Yvonne Baran	3/31/2010 11:53 AM	MCC Administrator	3/31/2010 11:28 AM
	CSR (Clinical Study Report)	MCC Administrator	4/2/2010 3:04 PM	MCC Administrator	4/2/2010 3:04 PM
	Cycle Time (CT) Metric	MCC Administrator	2/4/2010 3:51 PM	MCC Administrator	2/4/2010 3:51 PM
	Dashboard	Jeanne Green	2/24/2010 3:44 PM	Jeanne Green	2/24/2010 3:36 PM
	DBL (Database Lock)	Gary Urban	3/25/2010 5:23 PM	Jeanne Green	2/24/2010 3:31 PM
	EDC	Jeanne Green	2/24/2010 3:46 PM	MCC Administrator	2/4/2010 2:35 PM
	Enrollment	Gary Urban	2/25/2010 10:46 AM	Jeanne Green	2/24/2010 3:32 PM
	Final Approved Protocol	MCC Administrator	2/19/2010 2:38 PM	MCC Administrator	2/19/2010 2:12 PM
	For Cause Analysis	Jeanne Green	2/24/2010 3:51 PM	Jeanne Green	2/24/2010 3:34 PM
	FPFV (First Patient First Visit)	Jeanne Green	2/24/2010 3:44 PM	MCC Administrator	2/4/2010 2:27 PM
	How To Use This Wiki Library	MCC Administrator	2/4/2010 1:56 PM	MCC Administrator	2/4/2010 1:56 PM
	IP (Investigational Product)	MCC Administrator	3/30/2010 9:42 AM	Gary Urban	3/25/2010 5:20 PM

MCC Clinical Trial Performance Metrics v 1.0



MCC Clinical Trial Metrics v 1.0



REGISTER NOW FOR A SPECIAL MCC MEMBER WEBINAR!!

The MCC Clinical Trial Performance Metrics Steering Committee invites you and your colleagues to the:

Official Launch of the MCC Clinical Trial Performance Metrics version 1.0.

During this 90 minute session, Steering Committee members will review the complete set of metrics and discuss MCC plans to support member implementation of the metrics.

Topic: MCC Clinical Trial Performance Metrics v1.0 Launch
Date: Thursday, September 16, 2010
Time: 11:00 am, Eastern Daylight Time (New York, GMT-04:00)
Session Number: 716 512 747

[CLICK HERE TO REGISTER](#) for the free session. Once you have registered, you will receive a confirmation email with instructions for joining the session.

MCC Member Blinded Database



- MCC Board of Directors established an alliance partnership with CMR International, a Thomson Reuters business
- The Alliance Partnership, with guidance from MCC Members, is developing the database repository reporting platform utilizing Spotfire Analytics software
- MCC Member organisations must contribute data in order to access database reports



Using Metrics to Drive Process Improvement

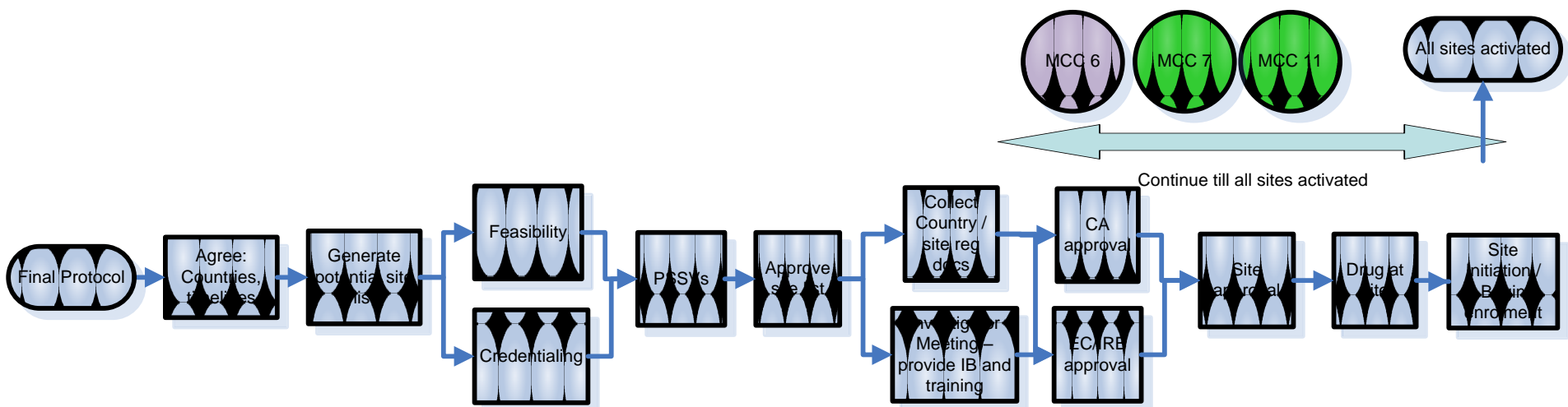
Keith Dorricott

MCC Process Improvement Work Group

■ Initial Purpose:

- Identify significant gaps in coverage of the clinical trial process
- Assess each proposed metric to:
 - determine how it could be used for process improvement
 - ensure data formats support process improvement activities
- Create *How to use metrics for process improvement* guidance paper

Site Selection and Activation



■ PIWG Considered:

- Purpose – “To activate the right number of high quality sites as soon as possible and at lowest cost”
- Factors in this process that drive cost & cycle-time *throughout the trial*
- Supplier issues
- Lack of leading quality indicators

Site Selection and Activation

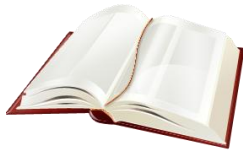
**High Quality
Protocol**

+

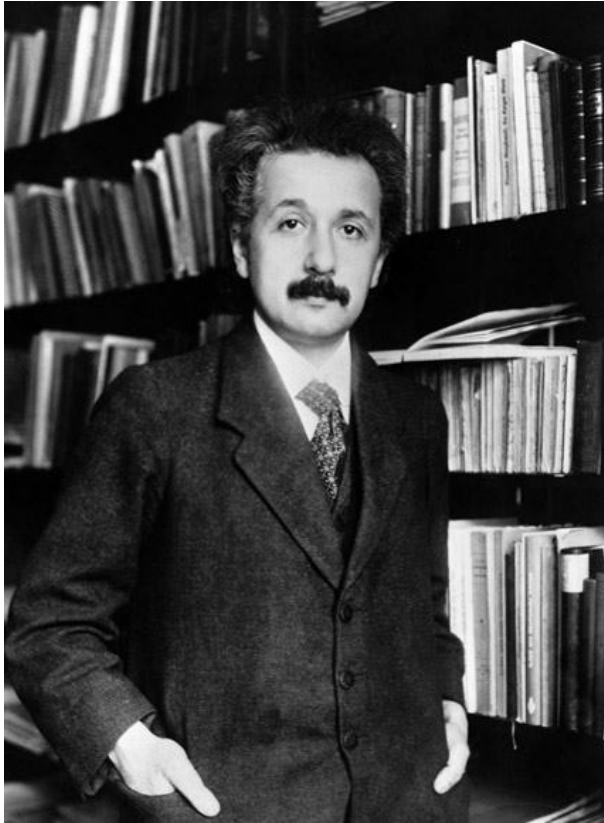
**Good Site
Selection**

=

**High Chance of
Successful Trial**



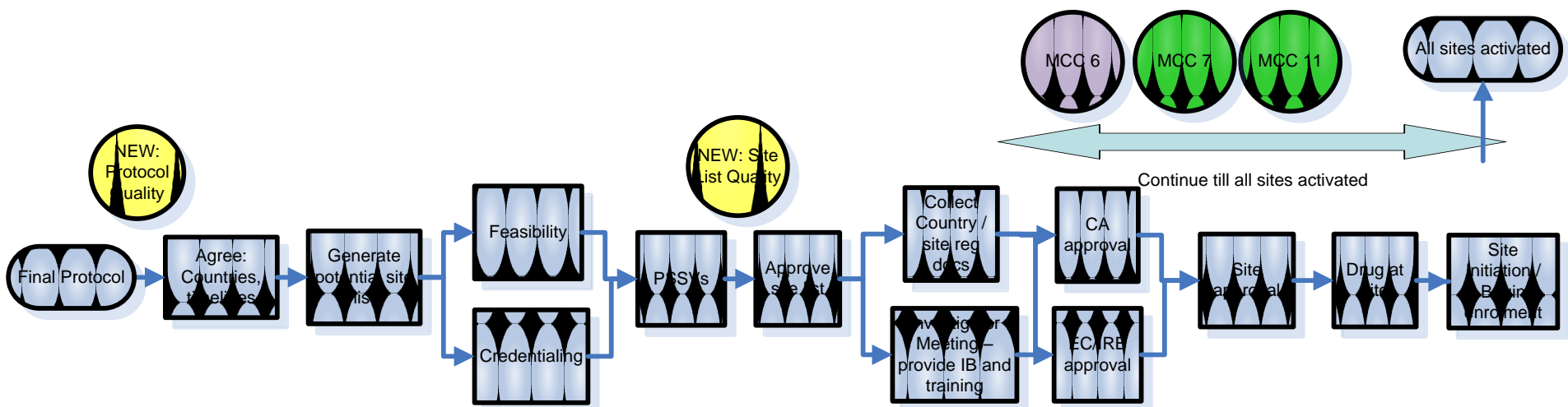
- Timeliness is easy to measure
- Quality is difficult to measure: but critical
- Measuring Timeliness but not Quality is risky



“Not everything that can be counted counts and not everything that counts can be counted.”

Albert Einstein

Site Selection and Activation



- Two new Quality Metrics proposed:
 - Protocol Quality Score
 - Site List Quality (“Site Assessment Score”)

New MCC Quality Tools

- Measuring quality of diverse outputs is not easy: PIWG focused on process
 - Teams use the Quality Tools as part of the process
 - Assesses whether best practice approach is being used
 - Encourages teams to question their approach
 - Output from tools is a score – although the score is secondary

New MCC Quality Tools – Key Features

- For use by Protocol Development and Site Selection teams – self assessment
- Team completes quality survey to determine how the protocol or sites selected score against the appropriate quality criteria
- If the quality score is below expectations team should review root cause with aim of a higher score

MCC Quality Scoring Approach

- Quality is difficult to measure – but important for success
- The act of measuring should modify behaviour:
 - Is the team doing what is needed to produce the best protocol?
 - Does a site lack skills and need specific training?
 - Are there enough high quality sites selected in country X?
- Interest in developing additional Quality Scoring Approach for Site Performance, CRFs and CSRs

Companion Metrics – Protocol Quality

- Cycle Time measured alone can sub-optimize
- MCC developed “companion metric” approach
- Each of the 43 metrics has associated metrics listed



Companion Metrics – Site Assessment Score



- Pilots of these metrics have started
- Retrospective study of Site Assessment Score underway
- Can we predict performance and use this to improve current process?

In Summary

- MCC metrics support joint collaborative process improvement
- Common metrics language and definitions enable collaboration
- Metrics should drive desired behaviour and minimise undesired short-sightedness
- Embed quality tools in the service process to support first pass quality performance instead of only measuring it after the fact
- ‘The most expensive study is the one you do twice’

How can my company get involved?

For additional information about joining the MCC, visit

<http://www.metricschampion.org>

or

contact Linda Sullivan (lsullivan@metricschampion.org)

MCC Clinical Trial Metrics v 1.0



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