Updates on Metrics Champion Consortium Activities: Measuring Effectiveness of Core Labs & Sites for Better Overall Quality

Steve Asbury, Global ECG Coordinator
Eli Lilly & Company

Linda Sullivan, VP Operations
Metrics Champion Consortium

9th Annual IIR Central Labs Conference - Boston, MA - September 20, 2011

http://www.metricschampion.org

Agenda

- MCC Mission & Goals
- MCC Performance Metrics, Quality Tools & Other New Program Features
- MCC ECG Performance Metrics v 2.0
- Q&A

MCC Mission (Updated)

The Metrics Champion Consortium (MCC) is an open, multidisciplinary, non-profit organization comprised of biotechnology, pharmaceutical, medical device and service provider organizations.

Our mission is to help sponsor and service provider organizations involved in the pharmaceutical, biotechnology and medical device industries improve their overall clinical trial development processes through the utilization of MCC standardized clinical trial performance metrics (time, cost & quality) by:

- Supporting the ongoing collaborative development of standardized performance metrics and process improvement tools
- Encouraging the continuous implementation of the metrics and tools among MCC members
- Providing a collaborative learning environment for members to share best practices, discuss challenges and industry trends
- Offering live and online educational opportunities to support the use of performance metrics and tools in member organizations

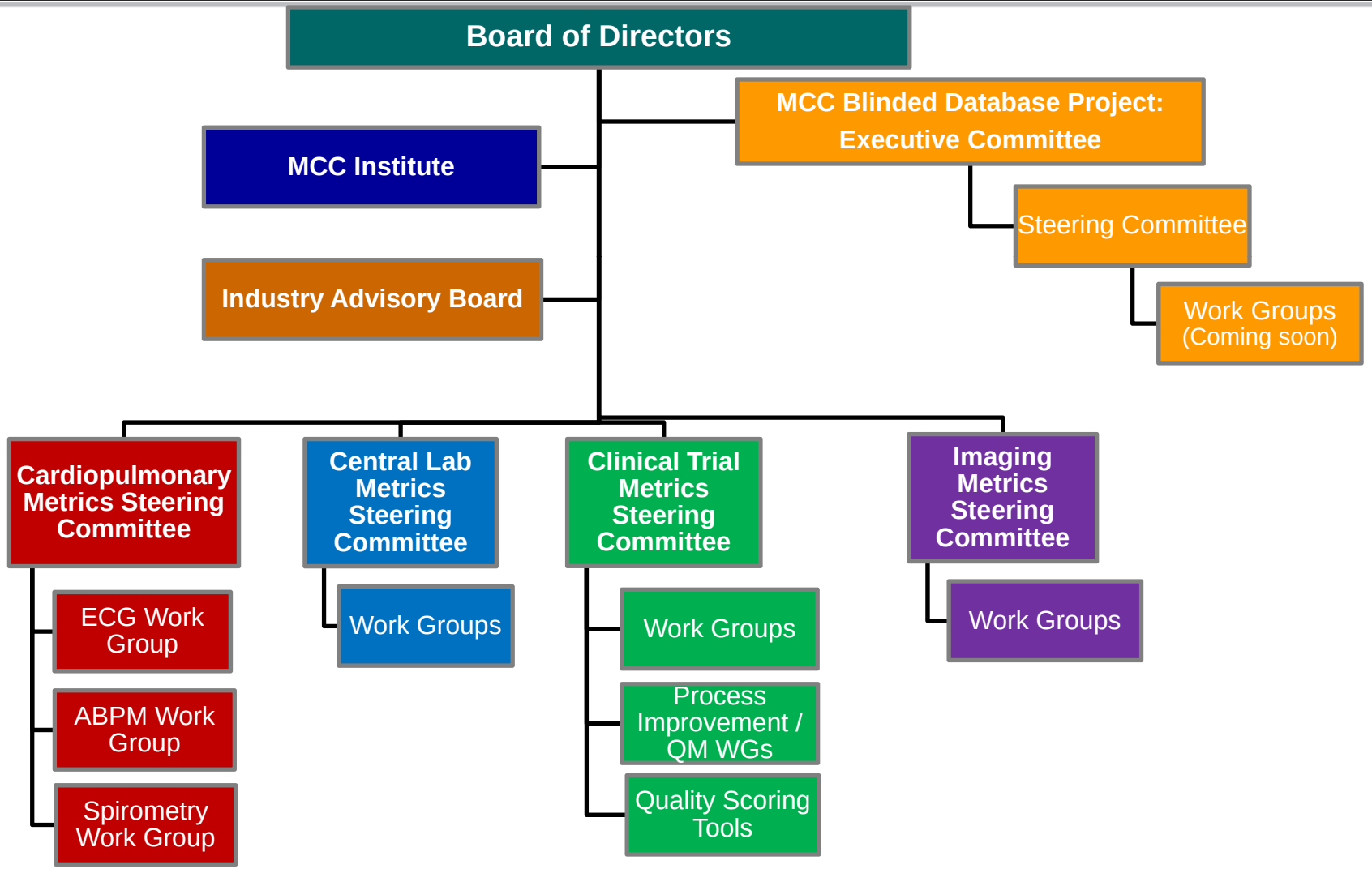
MCC Members

Abbott Laboratories
Actelion Pharma
Acorda Therapeutics
AG Mednet
AstraZeneca*
BARC Global Central Lab
Bayer Healthcare
Beaufort CRO
BioClinica
Biogen Idec
BioMarin Pharmaceutical Inc
Biomedical Systems
CardiaBase
Cardio Analytics
Cardiocore
Celgene
Cerexa
CHDI
Clinical Reference Laboratory
Clinical Systems Ltd.
Clinsys Clinical Research
Cognizant
Corelab Partners
Covance
Covidien
CSL Limited
Customized Improvement Strategies
DecisionView
Duke Clinical Research Institute
ERT*
Esoterix Clinical Trial Services
Eurofins Medinet
ExecuPharm
Forte Research Systems
GE Healthcare
Genentech
Genzyme
Halloran Consulting Group
i3
iCardiac Technologies
ICON
Imaging Endpoints
INC Research
Incyte
Intrinsic Imaging
Ixico
Lilly*
M2S
MEDIDATA GmbH
Medidata Solutions
Medtronic
Merck
MLM Labs
New England Research Institute
Novartis
Novella Clinical
Paragon Biomedical
Parexel / Perceptive Informatics
Pfizer*
PharmaNet*
PPD*
PRA International
QD-Quality & Training Solutions
Quest Diagnostics
Quintiles*
RadMD
Regeneron
Roche*
Seattle Genetics
Sunovion Pharmaceuticals
Synarc
Virtual Scopics
WorldCare Clinical

* MCC Board of Directors

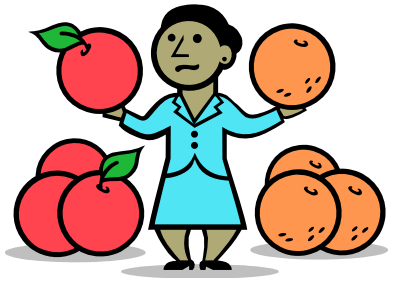
70+ members and growing!

Organizational Structure (Updated)

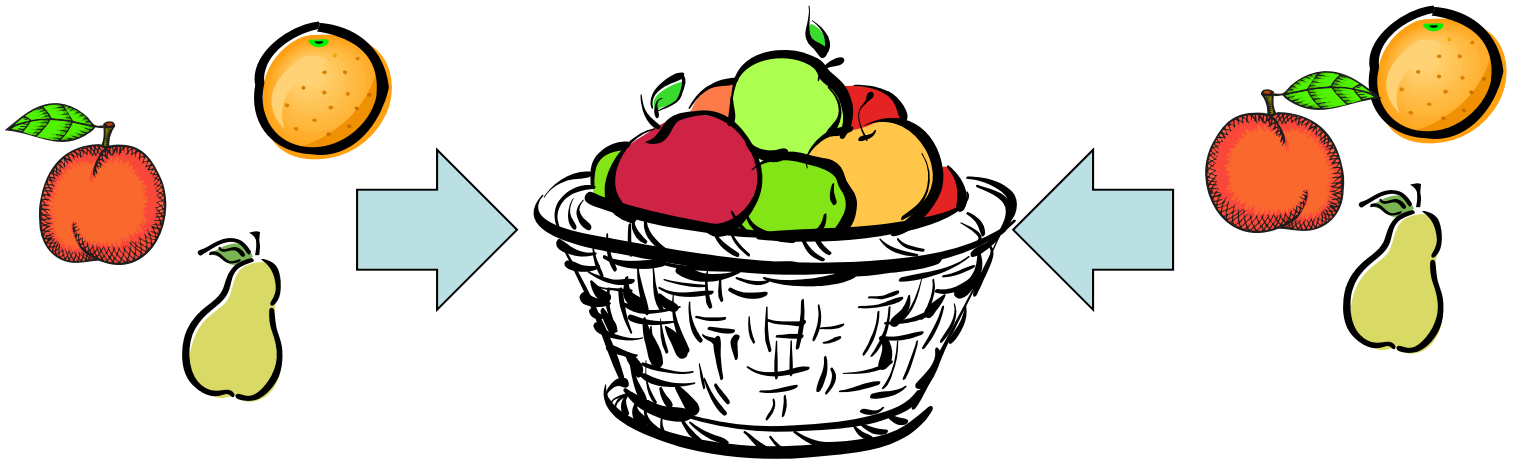


Lack of Standardized Performance Metric Definitions Creates Challenges

- Sponsors use different service providers
  - ➢ Managing metrics across portfolios across service providers is a challenge

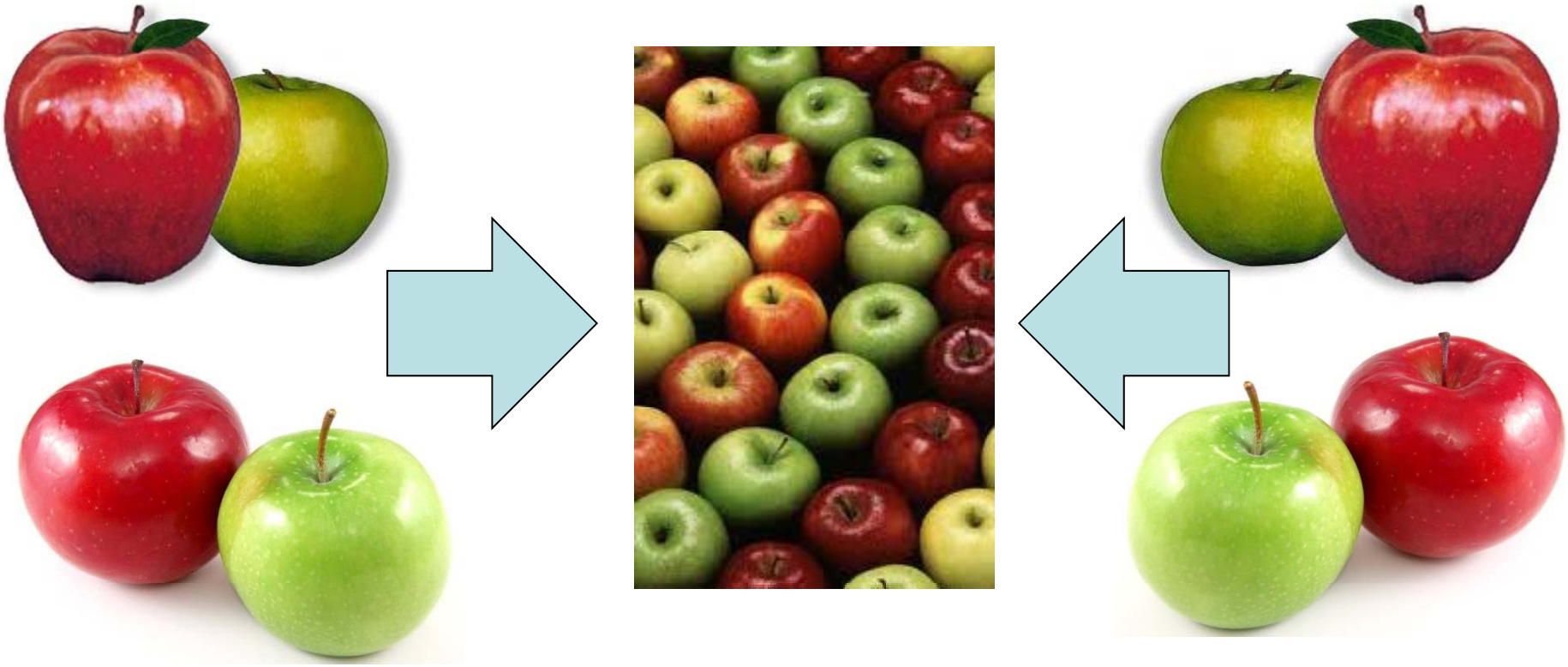


- Service providers are faced with managing varying performance based metrics from Sponsors

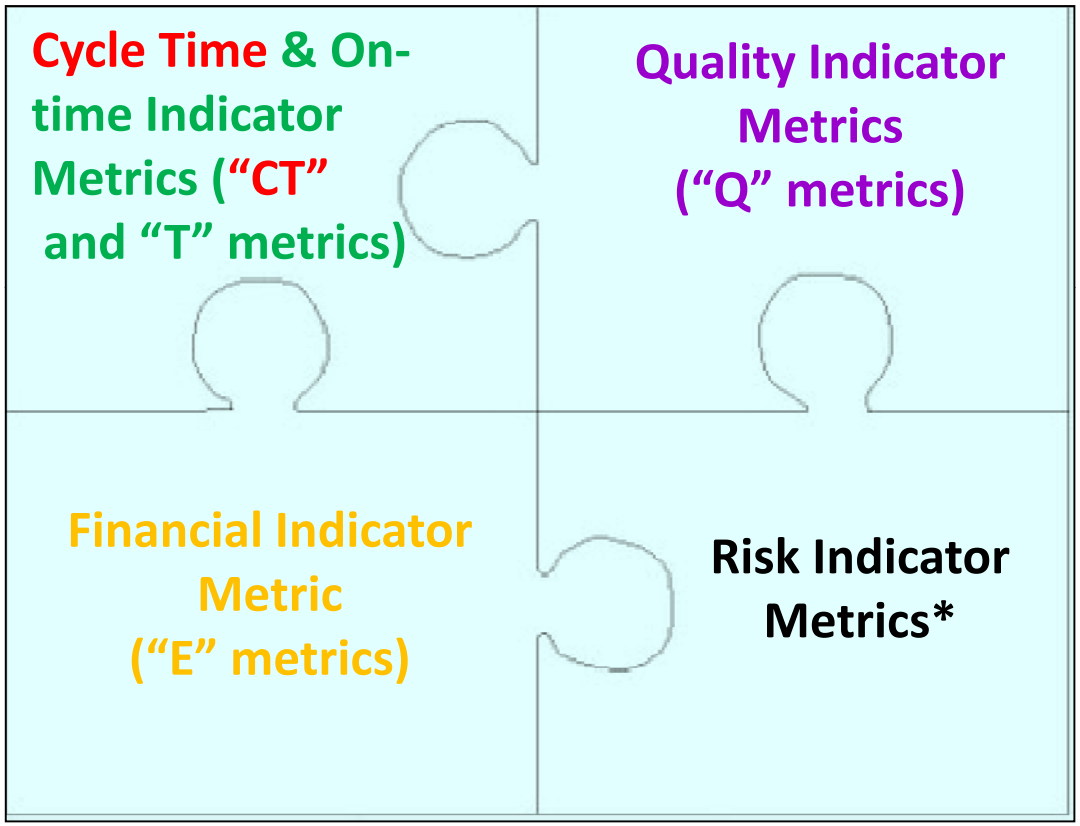


Standardized Performance Metric Definitions Creates Opportunities

Mutually beneficial standardized performance metrics can be achieved and fruitful for all parties



MCC Performance Metric Types



* Some MCC metrics can be used as Risk Indicator Metrics – this designation is determined by an organization.

MCC Metrics Include Sub-Metrics

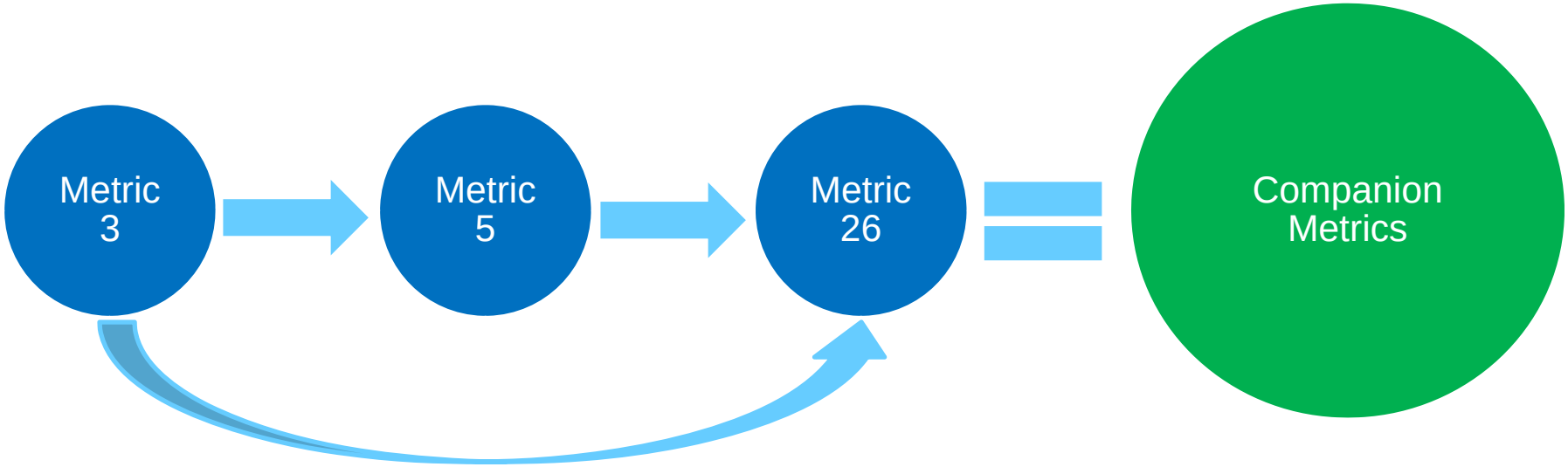
Each set of MCC performance metrics provides a metrics hierarchy:

- MCC metrics are performance indicators
- Most metrics include sub-metrics that should be reviewed when performance does not meet target expectations

Thus reducing the number of metrics that need to be reviewed on a quarterly/monthly basis

Companion Metric Mapping (New Feature)

Provide guidance on which MCC metrics should be reviewed together to understand the combined performance of related tasks…..



MCC Standardized Performance Metrics

- Central Lab Performance Metrics (2006, *2011**)
- Cardiopulmonary Performance Metrics
  - ECG Performance Metrics (2007, 2011)
  - Ambulatory Blood Pressure Monitoring Performance Metrics (*2011**)
  - Spirometry Performance Metrics (*2011**)
- Imaging Performance Metrics (2009, *new metric 2011*)
  - New Metric #20: % Images Acquired within Protocol Window
- Clinical Trial Performance Metrics (2010)

New Programs to Support MCC Mission

Quality

MCC Quality Tools

- Protocol Quality Evaluation Tool
- Site Selection Quality Tool
- Site Study Conduct Evaluation Tool

Benchmarking

MCC Metrics Database

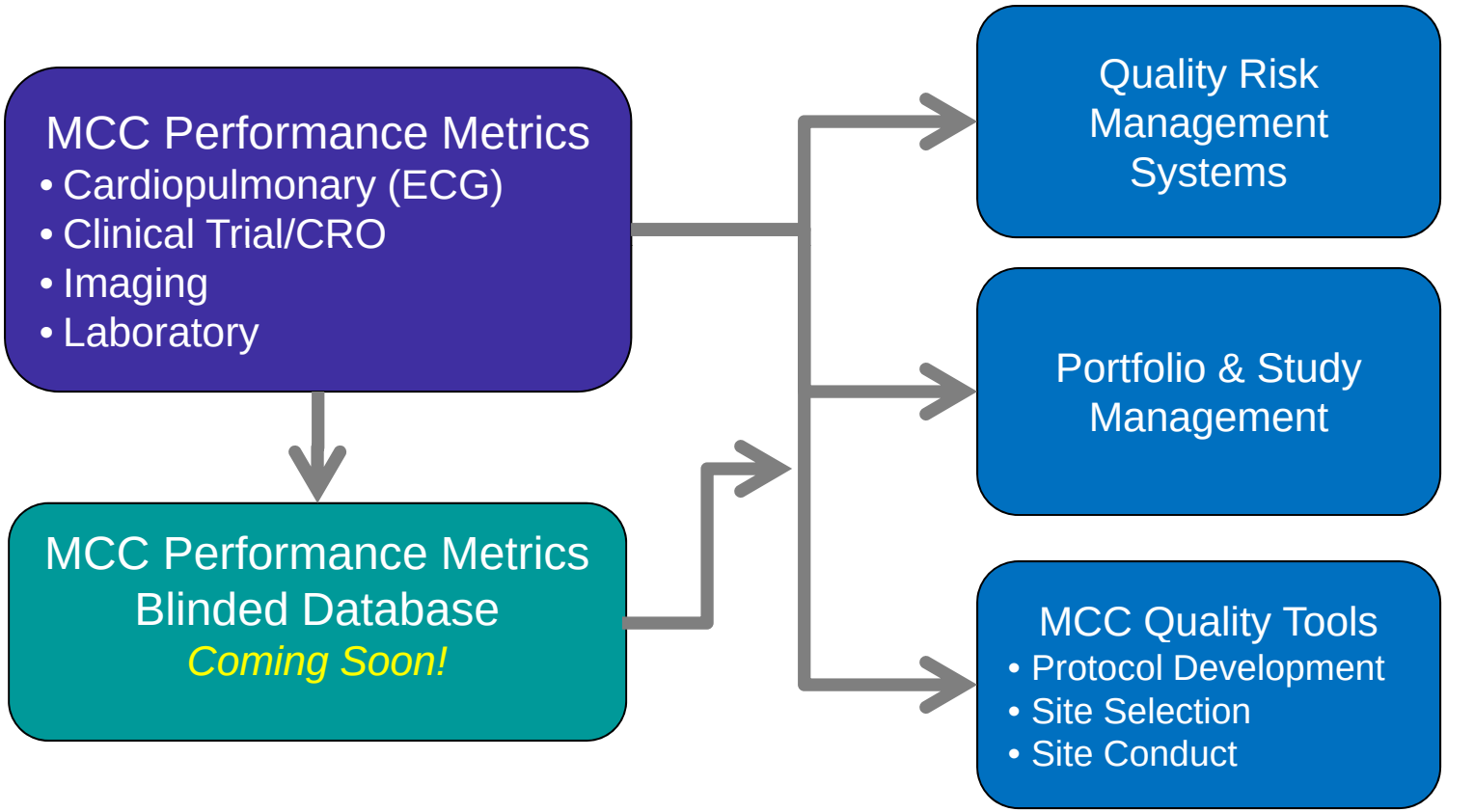
- MCC Members only
- Blinded Comparisons
- Hosted by IBM Clinical Cloud
- *COMING SOON*

Training

MCC Institute

- Member Only Program
- Experienced Faculty
- Live Workshops
- Online Learning Modules
- 100-400 level courses
- *COMING SOON*

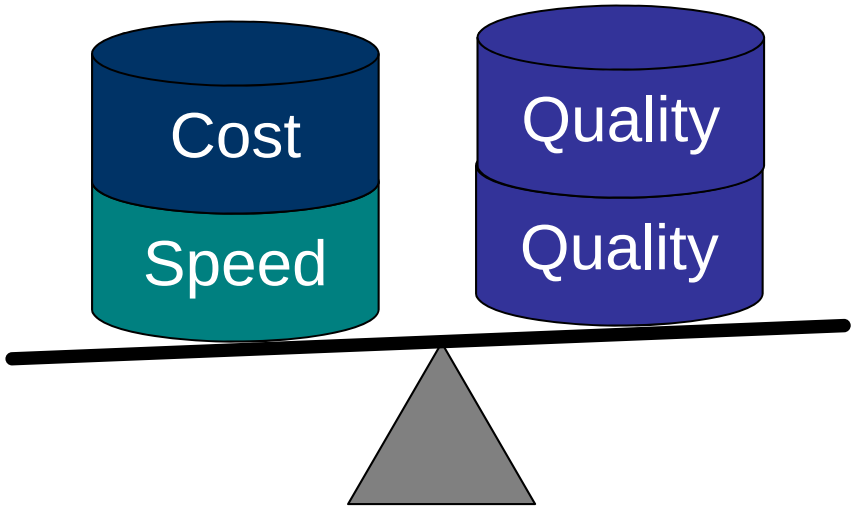
Standardized Performance Metrics Provide Foundation for Management Approaches



MCC Institute – Training Modules *Coming Soon!*

MCC Metrics and Quality Tools Support Balanced Approach to Trial Management

Reducing the time and cost of a task should be balanced with maintaining / improving quality



MCC Performance Metrics and Quality Tools provide sponsors and service providers with the ability to achieve the right balance

MCC ECG Performance Metrics v2.0

Steve Asbury
Eli Lilly and Company

IIR Central Labs Conference
September 20, 2011

CARDIOPULMONARY metrics champion

mcc metrics champion consortium

MCC ECG Performance Metrics Background

MCC ECG Performance Metrics (v1.0) were introduced in 2007. The standardized performance metrics, defined by MCC members (sponsors and ECG core labs), were implemented to be utilized by sponsors and ECG core labs to:

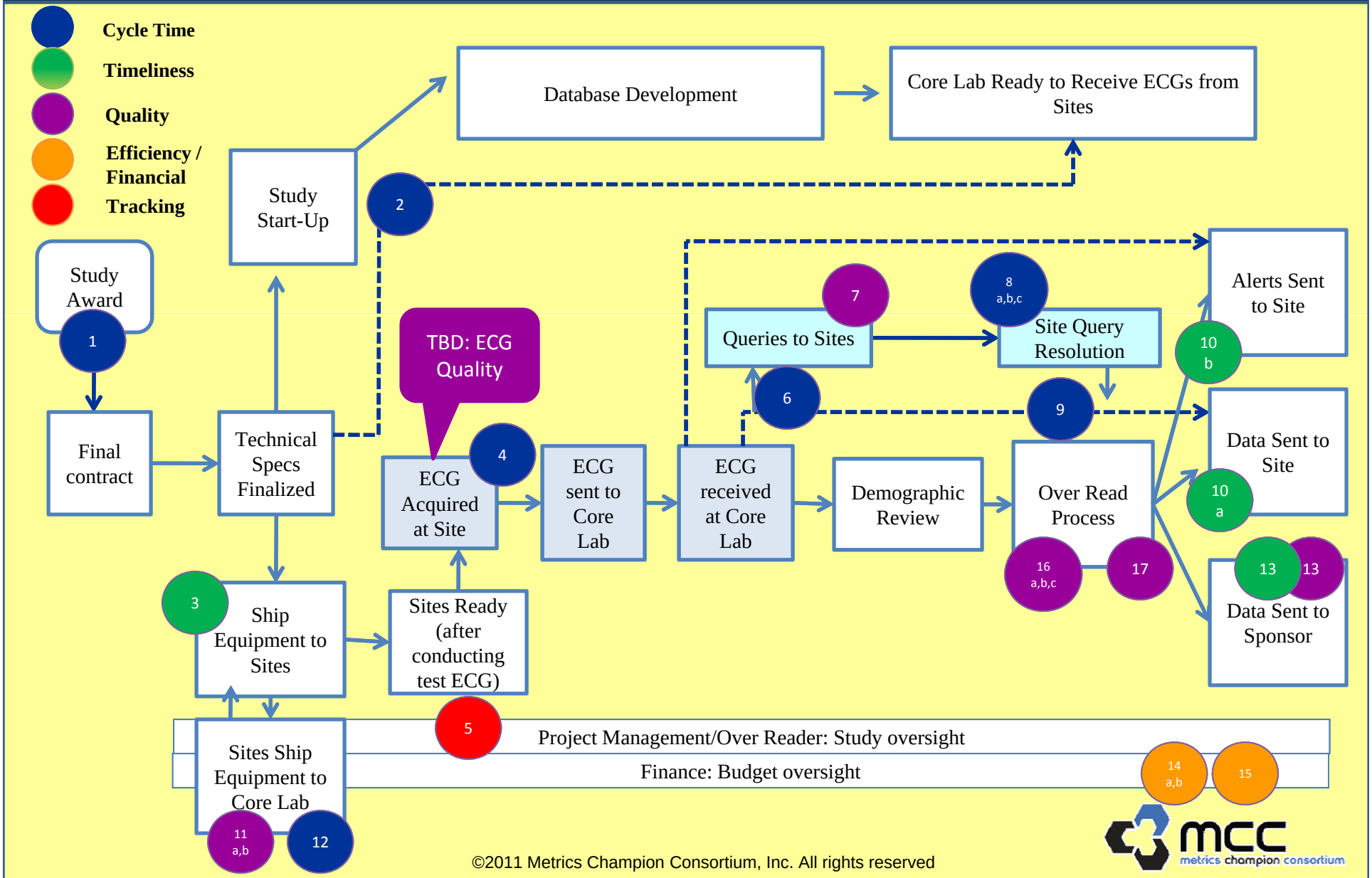
- identify areas where we could improve clinical trials collecting centralized ECGs;
- create better processes at the sponsors, investigative sites and core labs;
- understand how decisions made and processes implemented by the sponsors impact core labs' processes;
- allow common understanding of core lab processes; and
- develop a common understanding of processes between the core labs and sponsors.

MCC ECG Performance Metrics v2.0 Updates

MCC ECG Performance Metrics v2.0 launched June 2011

- Metrics were revised/added to allow a more consistent approach to metric creation
- Metrics were added/removed to address gaps in the process
- Metrics have been broken into two parts:
  - Core Metrics (metrics1-15)
  - ECG-Specific Metrics (metrics16-17)

ECG Clinical Trial Process with MCC ECG Metrics v2.0



MCC ECG Performance Metrics v2.0

Metric	Metric Type	Metric Title
1	Cycle Time	Average number of days from study award to contract signature
2	Cycle Time	Average number of days from signed technical specifications document (TSD) to core lab ready to receive samples
3	Timeliness	Percentage of on-time equipment shipments to sites
4	Cycle Time	Average and median time from collection of sample at the site to receipt at core lab
5	Tracking	Number of Samples Processed within Reporting Period
6	Cycle Time	Average and median time for queries to be raised by the core lab
7	Quality	Percentage of data queries from core lab to site
8	Cycle Time	a. Turnaround time on resolution of site queries from core lab (resolved queries) b. Outlier Analysis of query resolution time (resolved queries) c. Listing of queries outstanding >2 weeks (unresolved queries)
9	Cycle Time	Average and median time for core labs to enter query resolution provided by the site into system
10	Timeliness	a. Percentage of final reports issued to sites within agreed turnaround time b. Percentage of alerts successfully communicated to sites within defined turnaround time
11	Quality	a. Percentage of equipment failure as determined by site b. Percentage of equipment failure as determined by site that is a true failure of equipment
12	Cycle Time	Average turnaround time for replacing faulty equipment
13	Timeliness Quality	Percentage of on-time, accepted file transfers
14	Efficiency / Cost	a. Percent spend with current budget b. Change from initial budgeted amount to current/final budgeted amount
15	Efficiency / Cost	Percentage of invoice payments received by the core lab within the agreed upon turnaround time
16 ECG 1	Quality	a. Percentage of ECGs that have suspect quality as determined by the core lab b. Percentage of ECGs in which no parameters could be assessed c. Percentage of ECGs in which only the interval duration measurements could not be assessed
17 ECG 2	Quality	Percentage of manual adjustments of automated annotations for all intervals

MCC Members Developed Detailed Metric Definitions & Robust Descriptions

Anatomy of a MCC ECG Performance Metric				
Metric #	**Metric Type**	**Metric Title**	**Definition (see Wiki for detailed definitions)**	**Formula / Example**
	CT, T, Q, E, TR			**Formula:** **Specific Example:**
Additional Analysis on a "for cause" basis			**Who's Being Measured?**	**Business Driver(s) / Benefit Statement**
List of "drill down" metrics that should be reviewed when the metric is not within established target			CORE LAB, SITE, SPONSOR	Statement about why this metric is important /the reason for utilizing metric.
Unit of Measure	**Target**		**Reporting Frequency**	**Companion Metrics**
Calendar days, % etc.	Threshold target or acceptable range. Exceeding target triggers additional analysis on a "for cause" basis		Monthly, Quarterly, etc.	The term "companion metrics" refers to the concept that many MCC metrics should be examined in combination with other MCC metrics … together they give you a more complete picture of performance

Note to MCC Members: The detailed descriptions of the metrics are posted on the MCC website's Member Homepage .

ECG Metrics v2.0 – Added Median Data

- Many of the metrics now include both the mean value for a metric as well as the median value for the metric.
  - mean value could be misleading as only one or a few results could greatly skew the data reported.
  - median values provide users the ability to ascertain if the result is skewed by a few disparate data points.

ECG Metrics v2.0 – New Metrics

Metric #4 - Average and Median Time from Collection of the Sample at the Site to Receipt at the Core Lab

Metric #5 - Number of Samples Processed with Reporting Period (Tracking Metric)

Metric #6 - Average and Median Time for Queries to be Raised by the Core Lab

Metric #8b - Outlier Analysis of Query Resolution Time

ECG Metrics v2.0 – New Metrics

Metric #8c - Listing of Queries Outstanding >2 Weeks

Metric #9 - Average and Median Time for Core Lab to Enter Query Resolution Provided by Site into System

Metric #11b - Percentage of Equipment Failure as Determined by Site that is True Failure of Equipment

Metric #14b - Percent Spend within Current Budget

ECG Metrics v2.0 – New Metrics

Metric #15 - Percentage of Invoice Payments Received by the Core Lab Within the Agreed Upon Turnaround Time

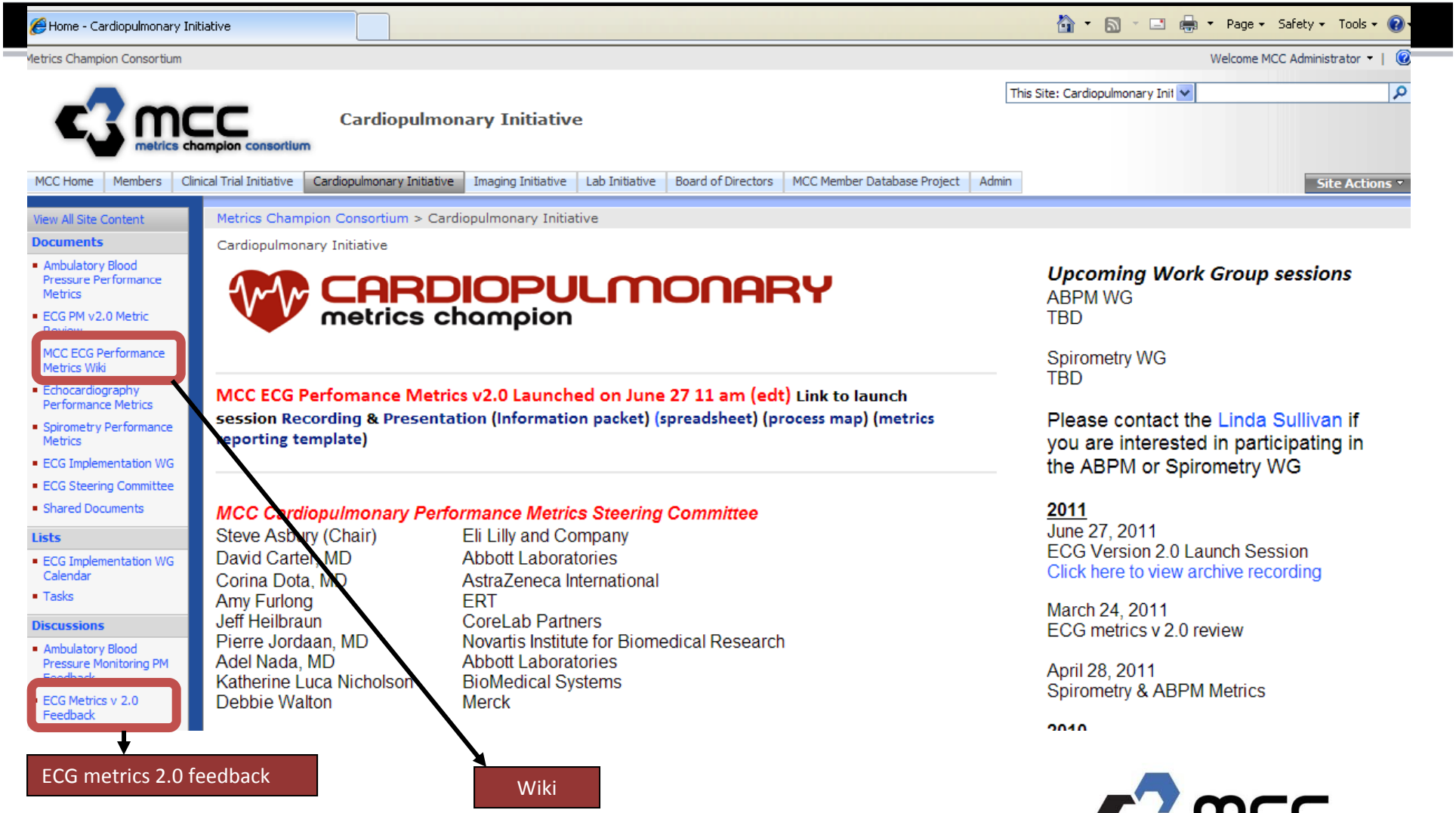
Metric #16b - Percentage of ECGs in which No Parameters (Morphology or Intervals) Could be Assessed

Metric #16c - Percentage of ECGs in which *Only the Morphology* Could be Assessed

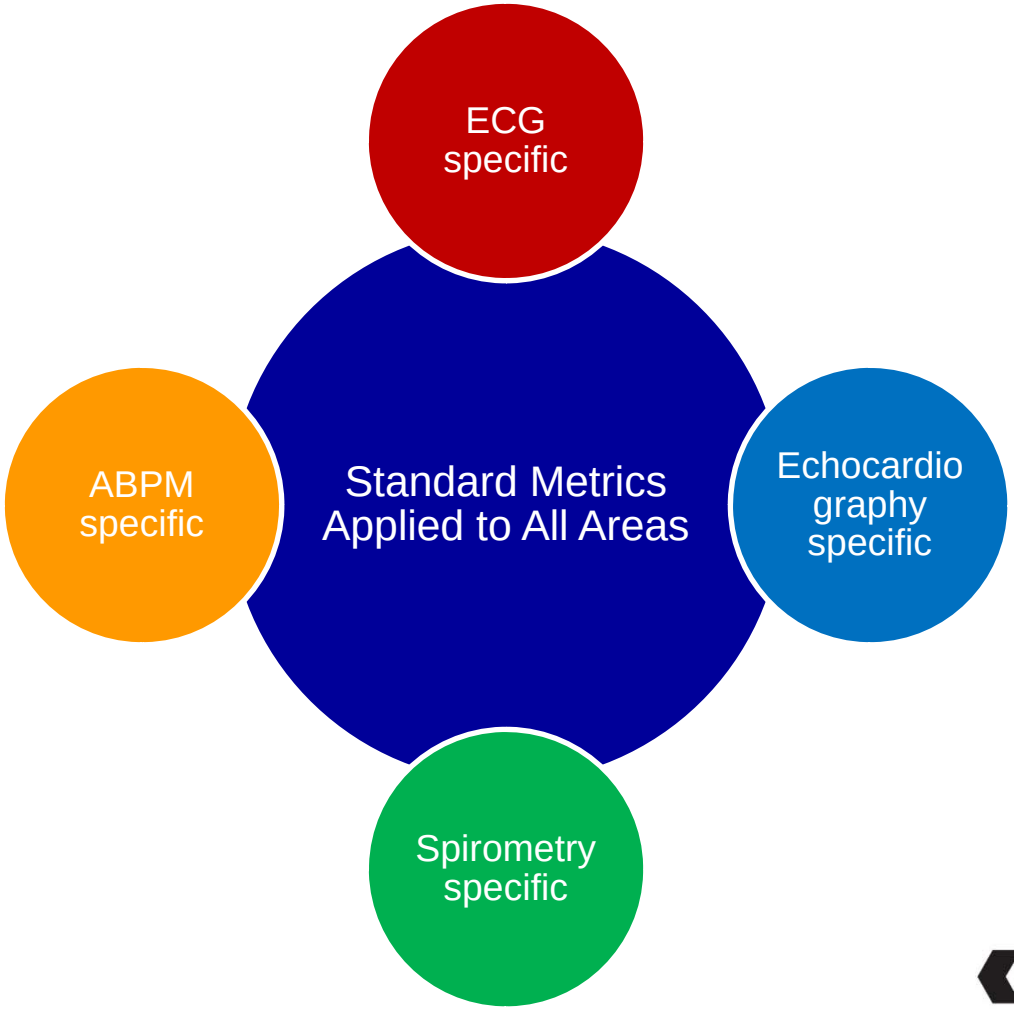
ECG Metrics v2.0 – Revised Metrics Reporting Tool

						Total Hours	96	783	85	4832	3			
9	na	Average and Median Time for Core Lab to Enter Query Resolution Provided by Site into System	Hours	Monthly	<8	# Samples with Queries	5	638	15	1576	2			
						Metric Value: Average	19	1	6	3	2	6	2	One of the query resolutions in study 1 took 32 hours to enter due to it being misplaced within the core lab.
						Comparison to Last Period	↑	↓	⇔	⇔	↓	⇔		
						Metric Value: Median	3	1	5	3	2	3	2	
						Comparison to Last Period	⇔	↓	⇔	⇔	↓	⇔		

Resources on the MCC website - Initiative Collaborative Workspace



Expand Use of "ECG" Metrics To Related Service Areas



MCC Plans to Expand Use of Metrics To Other Services Areas – Coming Soon!

Core Metrics	ECG Metrics	ABPM Metrics	Spirometry Metrics
Metric 1	X	??	??
Metric 2	X		
Metric 3	X		
Metric 4	X		
Metric 5	X		
Metric 6	X		
Metric 7	X		
Metric 8	X		
Metric 9	X		
Metric 10	X		
Metric 11	X		
Metric 12	X		
Metric 13	X		
Metric 14	X		
Metric 15	X		
	ECG – specific metrics Metrics 16 & 17	ABPM – specific metrics	Spirometry – specific metrics

Need More Information?

- MCC Roundtable discussion in the Exhibit Hall (4pm)
- MCC Members can participate in the next online meetings:
  - Lab WG: Sept 26, 2011
  - ECG WG: Sept 28, 2011
  - ABPM WG: Oct 11, 2011
  - Imaging WG: Oct 12, 2011
  - Spirometry WG: TBD
- Visit http://www.metricschampion.org for additional information about the MCC.