

Overview and Update on the Metrics Champion Consortium (MCC): A Collaborative Effort to Jointly Improve Performance

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Agenda

- Industry Overview
- MCC Organization
- Current MCC Initiatives
- Value of Participating in the MCC
- Q&A

Industry Under Pressure to Improve R&D Productivity

Today's drug development industry is under increased pressure to improve R&D development performance / strategies by reducing drug development times and costs, while at the same time increasing productivity and maintaining quality.

Industry Under Pressure to Improve R&D Productivity

Biotech & pharma organizations that are currently achieving efficient clinical trial cycle times attribute their success to the following “best practices”[†]:

- focusing on core competencies
- prioritizing utilization of resources
- outsourcing services

[†] Kaitin Kl. “Pushing the Innovation Envelope: Drug Development Metrics and the Changing Dynamics of Pharmaceutical R&D.” Presented at the 6th Annual Pharmaceutical Metrics Event: Driving Quality, Cost, & Time; October 16-18, 2007; Cambridge, Massachusetts.

Building Partnerships Around Standardized Performance Metrics

A group of biotechnology, pharmaceutical and service provider organizations helped form a not-for-profit organization, the Metrics Champion Consortium (MCC), where member organizations work collaboratively to develop and implement standardized performance metrics aimed at improving the efficiency and effectiveness of managing and tracking resources needed to successfully run clinical trials.

MCC Mission

The mission of MCC is to develop, through a collaborative process, performance metrics within the Biotechnology and Pharmaceutical industry with the intent to ***jointly*** encourage performance improvement, effectiveness, efficiency, and appropriate levels of controls for both Sponsors and Service Providers.

Participating Organizations

- Abbott
- Amgen
- AstraZeneca
- Bio-Imaging Technology
- Biomedical Systems
- Bristol Myers Squibb
- Cardiocore
- Cordium Links
- Covance
- CRL.Medinet
- Eli Lilly
- eResearch Technology
- Esoterix
- Eurofins Medinet
- Genzyme
- ICON Central Labs
- ICON Medical Imaging
- M2S
- Mayo Clinical Trial Services
- MDS Pharma
- Medarex
- Merck
- Perceptive Informatics
- Pfizer
- PharmaNet
- Quintiles
- Rad-MD
- RadPharm
- Schering-Plough
- Spacelabs
- Synarc
- Valeant
- Vertex
- Viasys Clinical Services
- Virtual Scopics
- Wyeth

MCC Goals

- Key service areas (e.g. Labs, ECG, CRO, Imaging) will have defined sets of performance metrics that are utilized by sponsor/service provider partnerships to manage clinical trial performance
- Entire industry actively participates in metrics creation and change management processes
- Constructive conversations are generated between all parties because of metrics
- Sponsors and service providers grow more productive as a direct result of MCC initiatives

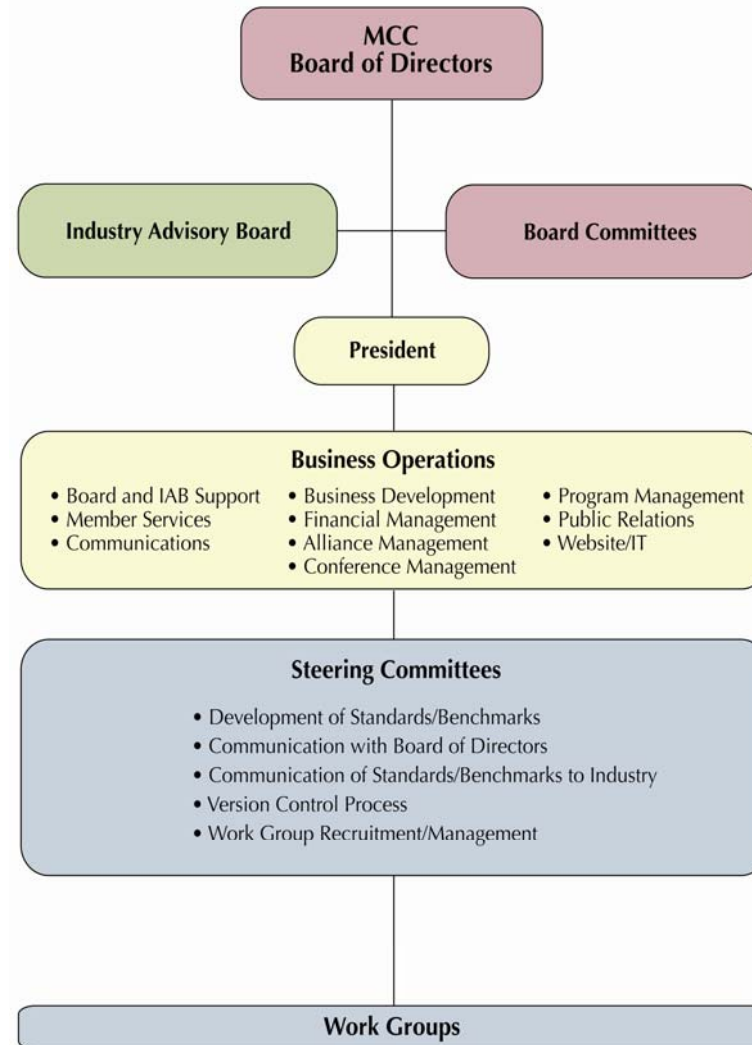
MCC Value Proposition

- MCC organizations work collaboratively to develop standardized performance metrics which aim to improve the efficiency and effectiveness of clinical trial operations *for each* sponsor/supplier relationship.
- Organizations use the standardized performance metrics to identify opportunities to improve performance within their own sponsor / supplier relationship where results do not meet expectations within a study or across a group of studies.

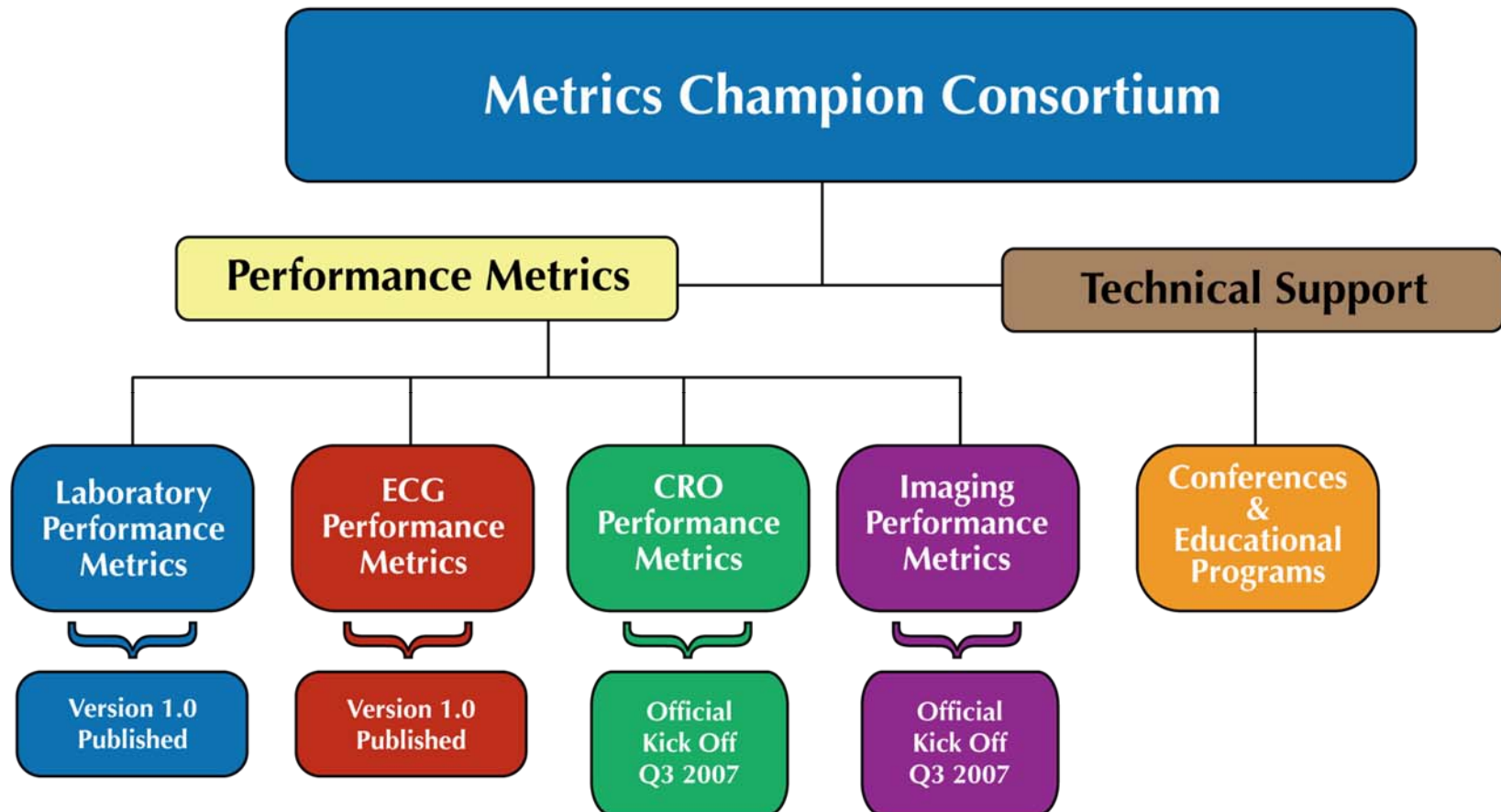
MCC Value Proposition

- After identifying opportunities for improvement, sponsor/service provider partners work together to determine how best to enhance the process in order to ***improve performance and strengthen their partnership.***
- The MCC provides an environment for biotechnology, pharmaceutical and service provider organizations to share “best practices” and learn from each other through participation in MCC learning forums and collaborative work groups.

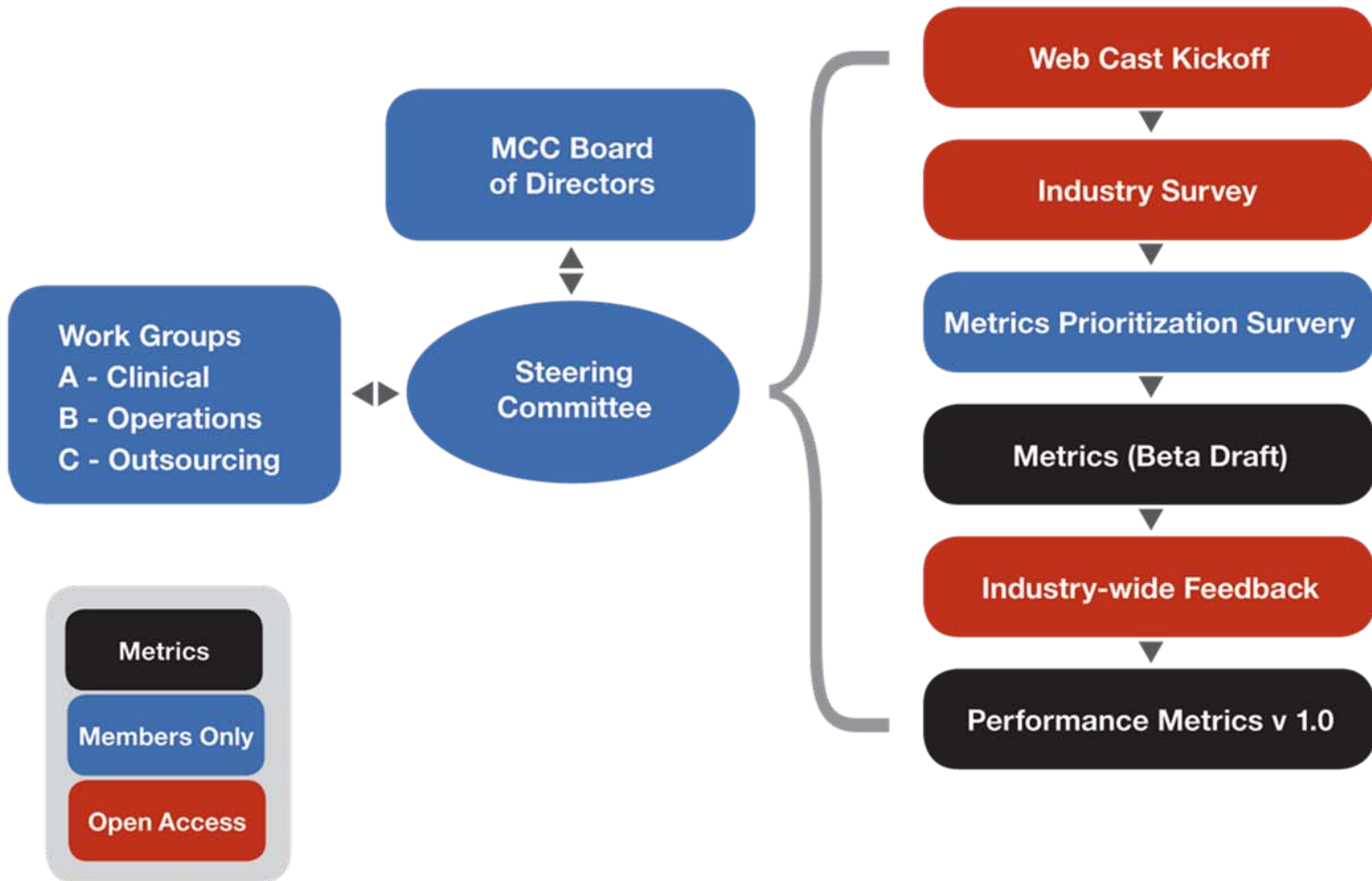
MCC Organization



Overview of MCC Activities



Metrics Development Process



Central Laboratory Performance Metrics v1.1

Metric	Category	Metric Title
1	General Operations	Project management turnover
2	Protocol Initiation	Percentage first supplies shipped on time to the first site for first patient
3	Site Initiation	Percentage first supplies shipped on time for all sites (all regions)
4	Data Cleaning	Percentage of queries from central laboratory to site based upon requisitions received
5	Data Cleaning	Average turnaround for resolution of queries from central laboratory to site
6	Site Support Services	Percentage of queries from site to central laboratory based upon requisitions received
7	Site Support Services	Average turnaround time on queries from site to central laboratory
8	Safety	Percentage of panics that had both 1 st attempt made and were successfully communicated to the sites within the defined turn around times

Metric	Category	Metric Title
9	Laboratory Operations	Percentage specific test(s) reported within expected turnaround time
10	Laboratory Operations	Percentage tests not reportable
11	Data Management	Percentage on time accepted file transfers
12	Financial Management	Plan, Forecast and Actual Financial Report
13	Financial Management	Comparison of budgeted and actual transportation costs by region and/or country
14	Quality Assurance	Percentage of audit findings closed within sponsor and central laboratory agreed upon timeframe

Central Laboratory Performance Metric #3

Metric	Category	Metric Title	Definition*	Formula/Example	Unit of Measure	Reporting Frequency	Target
3	Site Initiation	Percentage first supplies shipped on time for all sites (all regions)	<p>Minimum: The percentage of protocols that have the first supplies shipped date met based on the defined expectations between sponsor and central laboratory.</p> <p>Additional analysis on a “for cause” basis: A listing of protocols that did not meet the first supply ship date based upon the defined expectations between sponsor and central laboratory per business unit and per protocol.</p>	<p>Formula: (Total N of protocols with first supplies shipped date / Total N of protocols with first supplies required) x 100</p> <p>Specific Example: 10 protocols initiated; 9 received first supplies as expected (1 did not) Result: (9/10) x 100 = 90% received first supplies within expectations</p>	Total N and Percentage	Quarterly	>95%
			<p>General Benefit Statement</p>	<p>You will be informed regarding a service provider's ability to finalize the predefined database, prepare and/or ship kits and deliver what is required for the site to achieve first patient visit from a central laboratory requirement perspective per your contractual agreement. In addition, you can extrapolate that if the service provider can provide the required start-up supplies per the timeline; resupply will occur in the same timely manner thus a resupply metric was not defined at this time.</p>			

Metric	Metric Title
1	Average number of days from ECG study award to contract signature Note: For stand-alone ECG projects
2	Average number of days from signed ECG technical specifications document (TSD) signature to vendor ready to receive ECGs
3	Percentage of on-time ECG equipment shipments to sites
4	Percentage of sites who conduct a successful test ECG transmission prior to 1st subject visit
5	Percentage of ECGs reported to Investigator Sites within agreed turnaround time
6	Percentage of ECG data queries from vendor to site
7	Turnaround time on resolution of ECG site queries from central vendor
8	Percentage of ECG alerts successfully communicated to sites within defined turnaround time

Metric	Metric Title
9	Percentage of ECGs received from one study that were interpretable by the core lab
10	Percentage of manual adjustments of automated QT annotations from one study (semi-automatic "computer assisted" method with visual inspection and manual adjustment whenever necessary)
11	Percentage of ECG equipment failure
12	Average turnaround time on replacing faulty ECG equipment
13	Percentage of on-time, accepted ECG file transfers
14	Key ECG core lab personnel turnover during protocol
15	Percentage of ECG core lab audit/assessment findings closed within agreed timelines
16	Average percent of variance maintained in the ECG budget

Central Lab & ECG Groups

2008 Activities

The Central Lab and ECG initiatives are launching Shared Learning / Implementation Work Groups:

- Sponsors & service providers
- Lessons learned
- Sharing ideas
- Case studies
- Data collection tools / templates
- Meet on a monthly basis

CRO & Imaging Groups

2008 Activities

Launching CRO & Imaging metrics initiatives:

- Steering Committees established in late 2007
- Work groups launching March 2008
- Work groups plan to meet throughout 2008
- Expect to release beta version of metrics in early 2009:
 - Imaging metrics - January 2009
 - CRO metrics - April 2009

MCC CRO Metrics Development Process

CRO Steering Committee

- Cory Gutterman / Abbott
- Ed Cannon / AstraZeneca
- Beenu Kapoor / Covance
- Holly Hankins / Eli Lilly
- Kathe Balinski / Medarex
- Magaly Woolard / Merck
- Kate Trainor / Perceptive Informatics
- Scott Treiber / PharmaNet
- Kristy Morgan / Quintiles
- Paul Shin / Valeant

MCC CRO Metrics Development Process

CRO Work Groups

1. Business Operations
2. Finance
3. Clinical Operations
4. Drug Supply
5. Project Management
6. Data Management
7. Biostatistics
8. Medical Writing
9. Quality Assurance
10. Safety
11. Regulatory Affairs

- Work groups will be chaired by CRO Steering Committee members
- All MCC organizations are entitled to have multiple representatives on the CRO work groups
- Work groups will be launched April 2008

MCC CRO Metrics Development Process

In Scope:

- Develop a list of key metrics
- Create metrics that can be key indicators of performance
- Clearly define measurement criteria

Out of Scope:

- Determining pass/fail criteria
- Assigning accountability

Value of Participating in Consortium Activities

Industry benefits from participating in the MCC:

- Industry shared learning and problem solving
- Increased productivity
- Richer dialogue between sponsor and service providers - less debate about what you have and more time focused on solving problems and celebrating successes in relationship
- Simplified review and analysis of metrics data
- Strengthened sponsor/service provider relationships

Questions?



Please contact Guy Mascaro or Linda Sullivan at 317.848.2908 for additional information about participating in MCC activities.

www.metricschampion.org