

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

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- Industry Overview
- MCC Organization
- Current MCC Initiatives
- Value of Participating in the MCC
- Clinical Trial Metrics Initiative

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.

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.

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 in support of the drug development process.

Participating Organizations

- Abbott
- ACRMetrix
- Amgen
- AstraZeneca
- Bio-Imaging Technology
- Biomedical Systems
- Cardialysis
- Cardioanalytics
- Cardiacore
- CHDI Foundations
- ClearTrial
- Cordium Links
- Covance
- CRL Medinet
- Eli Lilly
- eResearch Technology
- Esoterix
- Eurofins Medinet
- Facet Biotech
- Genzyme
- Genentech
- i3
- ICON
- Inc Research
- Incyte
- M2S
- Macrogenics
- MDS Pharma
- Medarex
- Merck
- NERI
- Novartis
- Paragon Biomedical
- Perceptive Informatics
- Pfizer
- PharmaNet
- Quest Diagnostics
- Quintiles
- Rad-MD
- RadPharm
- Regeneron
- Social & Scientific Systems, Inc.
- Spacelabs
- Synarc
- Valeant
- Vertex
- Viasys Clinical Services
- Virtual Scopics
- WorldCareClinical
- Wyeth

Collaboration with Other Industry Groups

- ACRO representation to the MCC Board of Directors
 - Sean Larkin, PharmaNet
 - Paul Colvin, PPD
- CDISC
- FDA
- PhRMA
- Research Initiatives Foundation for the NIH
- eClinical Forum
- SCDM

- 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

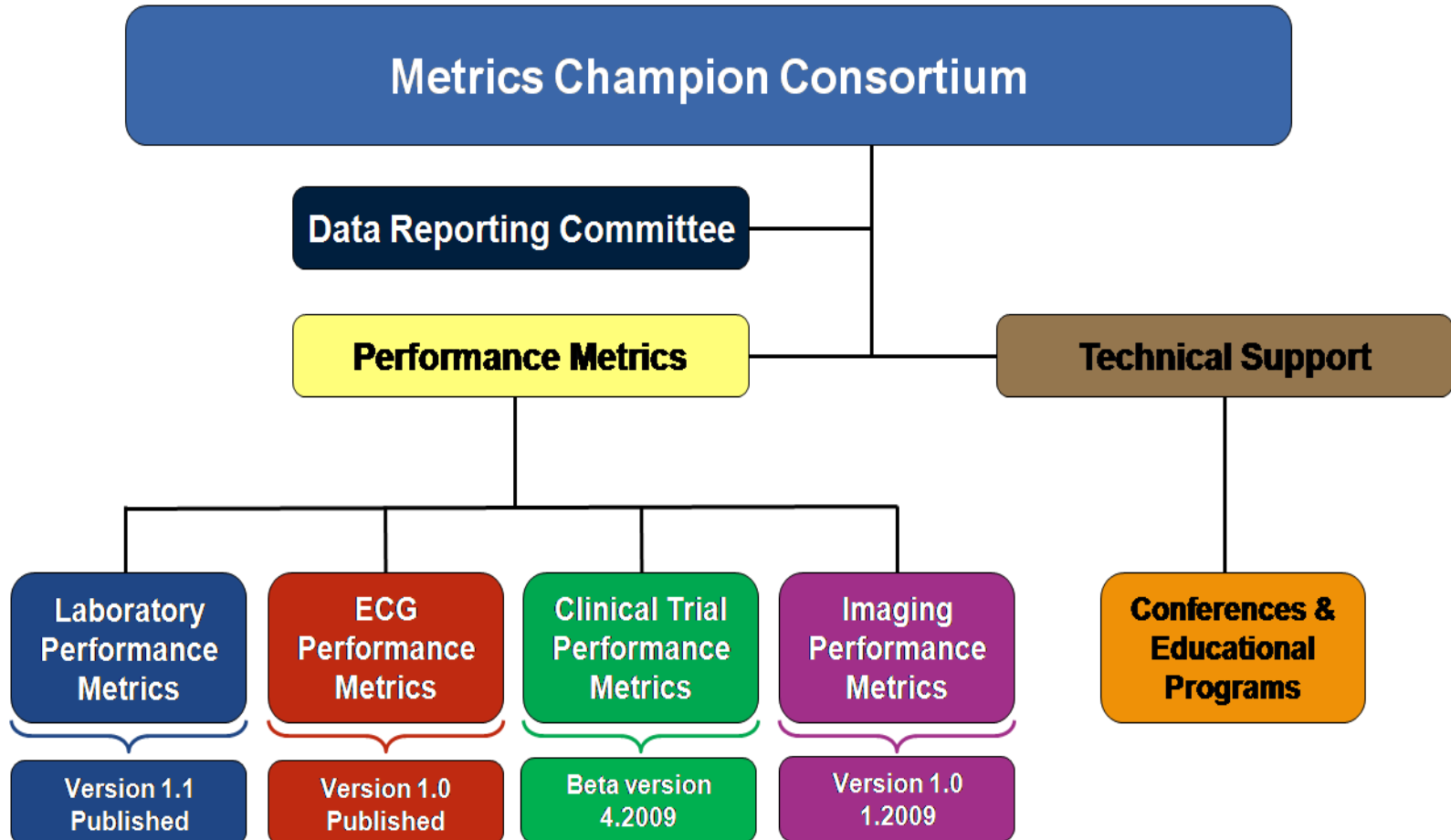
- MCC organizations work collaboratively to develop standardized performance metrics which aim to improve the efficiency and effectiveness of clinical trial operations *for each* sponsor/supplier relationship.
- Organizations use the standardized performance metrics to identify opportunities to improve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

- 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.

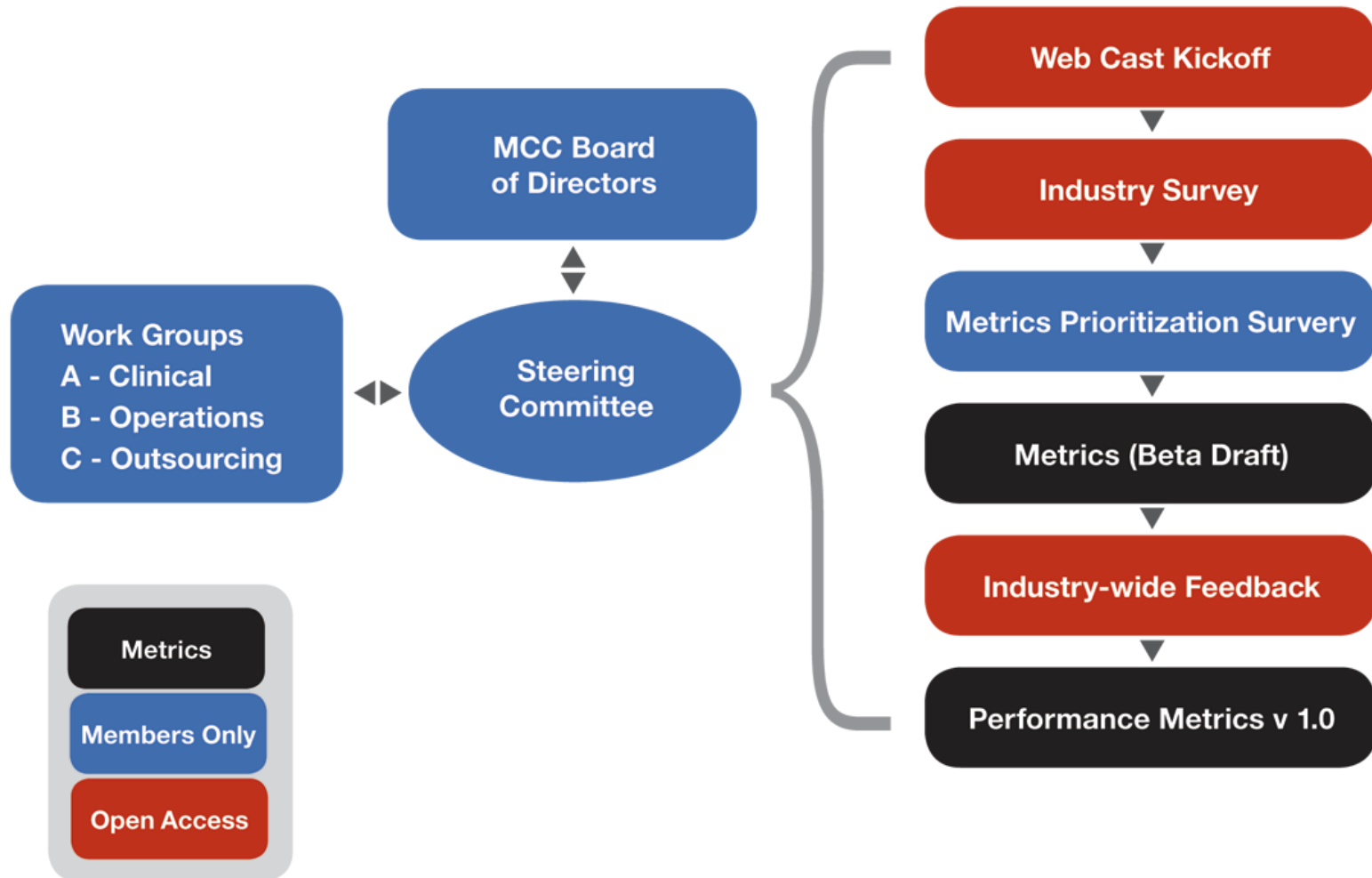
Value of Participating in Consortium Activities

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



Metrics Development Process



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

Metric	Category	Metric Title
8	Safety	Percentage of panics that had both 1st attempt made and were successfully communicated to the sites within the defined turn around times
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	<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

Metric	Category	Metric Title
1	Financial	Average percentage of variance in the imaging budget
2	Contract Signature	Average number of calendar days from imaging study award to contract signature
3	Site Start-Up	Percentage of sites qualified vs. actual
4	Site Start-Up	Average number of calendar days from site designated ready to first date of image receipt
5	Image Acquisition	Average number of calendar days from image acquisition to image receipt
6	Image Acquisition	Average number of calendar days from image receipt to initial feedback to site
7	Image Processing	Average number of calendar days from image QC complete to reporting of eligibility results
8	Image Processing	Average number of calendar days from image receipt to ready for independent review
9	Image Processing	Average number of calendar days from when the image is designated for review to completion of the review

Metric	Category	Metric Title
10	Image Quality	Percentage of suboptimal (but evaluable) images
11	Image Quality	Percentage of non-evaluable images versus total received
12	Image Quality	Percentage of non-evaluable baseline images
13	Missing Imaging	Percentages of missing imaging visits
14	Image Queries	Percentage of site queries
15	Image Queries	Average number of calendar days an imaging query is outstanding
16	Export Submission	Average number of calendar days from last patient reviewed to delivery of dataset
17	Export Submission	Average number calendar days from original estimate to actual for export submission
18	Independent Review Charter	Number of weeks to develop and write independent review charter
19	Acquisition Protocol Robustness	Number of image acquisition technique-related amendments per modality per protocol

Launching Implementation/Shared Learning Work Groups:

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

- 2009 will be an important year:
 - Release Clinical Trial metrics
 - Develop additional case studies
 - Support metrics implementation among sponsor/service provider partnerships
 - Explore developing data reporting templates across MCC metrics initiatives
- No plans to launch new metrics initiatives in 2009
- Future metrics initiatives may include biomarkers



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

www.metricschampion.org