

# *Metrics Champion Consortium ECG Performance Metrics*

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IIR 5<sup>th</sup> Annual Partnering with Central Labs, ECG and Imaging Labs  
January 19, 2007



- Metrics Champion Consortium
- ECG Performance Metrics
  - Where We've Been
  - Where We Hope to Go
- General Structure of ECG Performance Metrics
- ECG Performance Metrics Examples

# MCC Overview

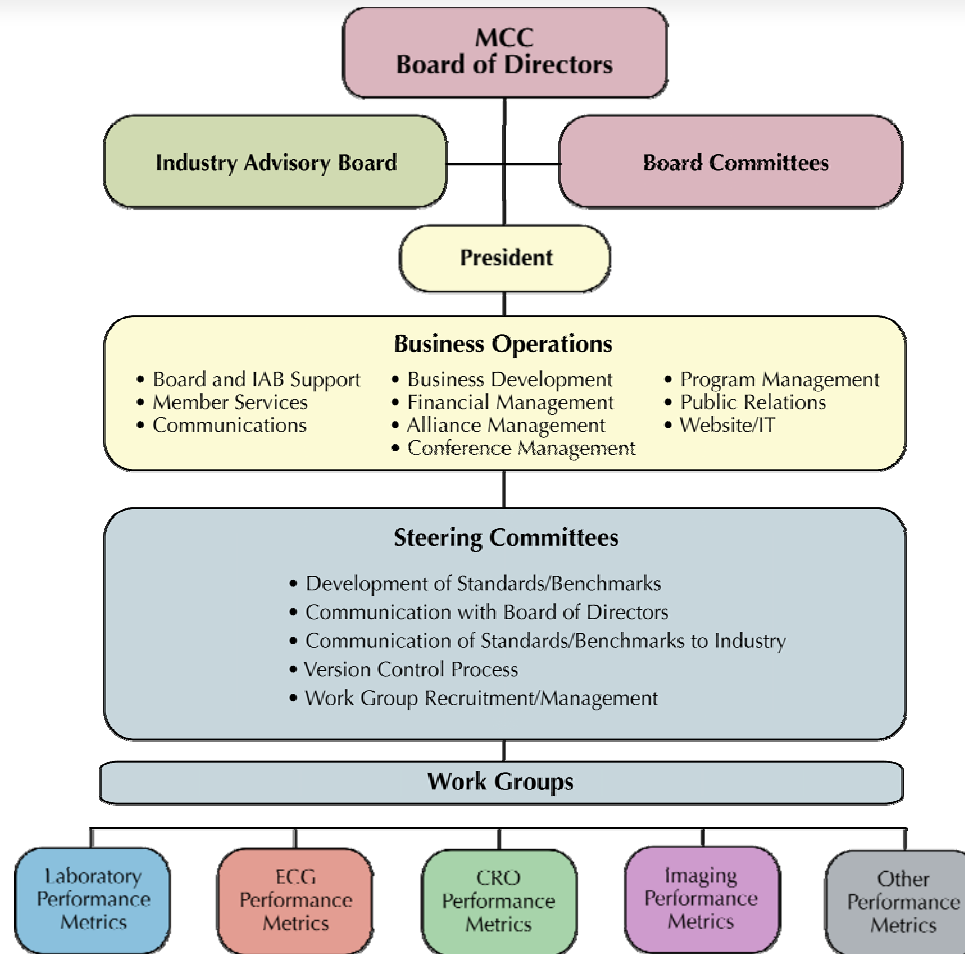
The Metrics Champion Consortium (MCC) is an open, multidisciplinary, non-profit organization committed to the development of worldwide industry standards to measure the performance of biotechnology and pharmaceutical service providers.

Industry must become more productive!

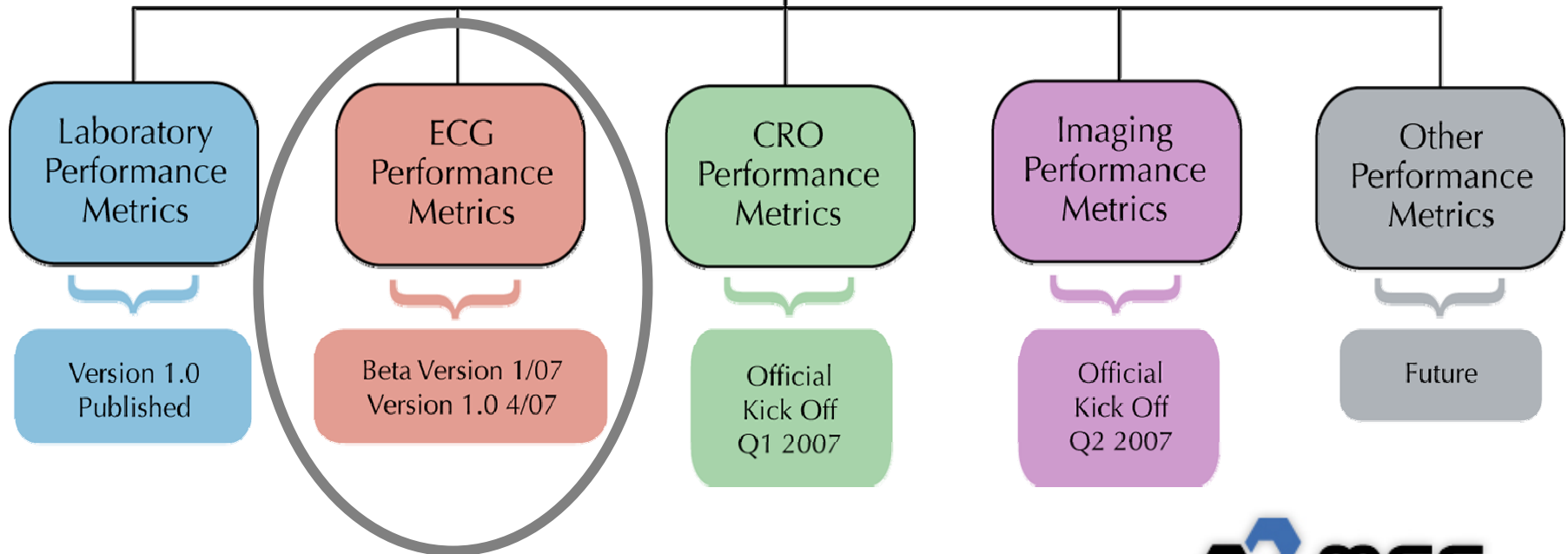
*“Businesses that succeed and make money constantly assess themselves and improve in all dimensions of their business; metrics are the cornerstone of their assessment, and the foundation for any business improvement.”*

Source: Reengineering and Process Metrics, Dave Trimble - Senior Partner, ProSci – [www.prosci.com](http://www.prosci.com)

# MCC Organization



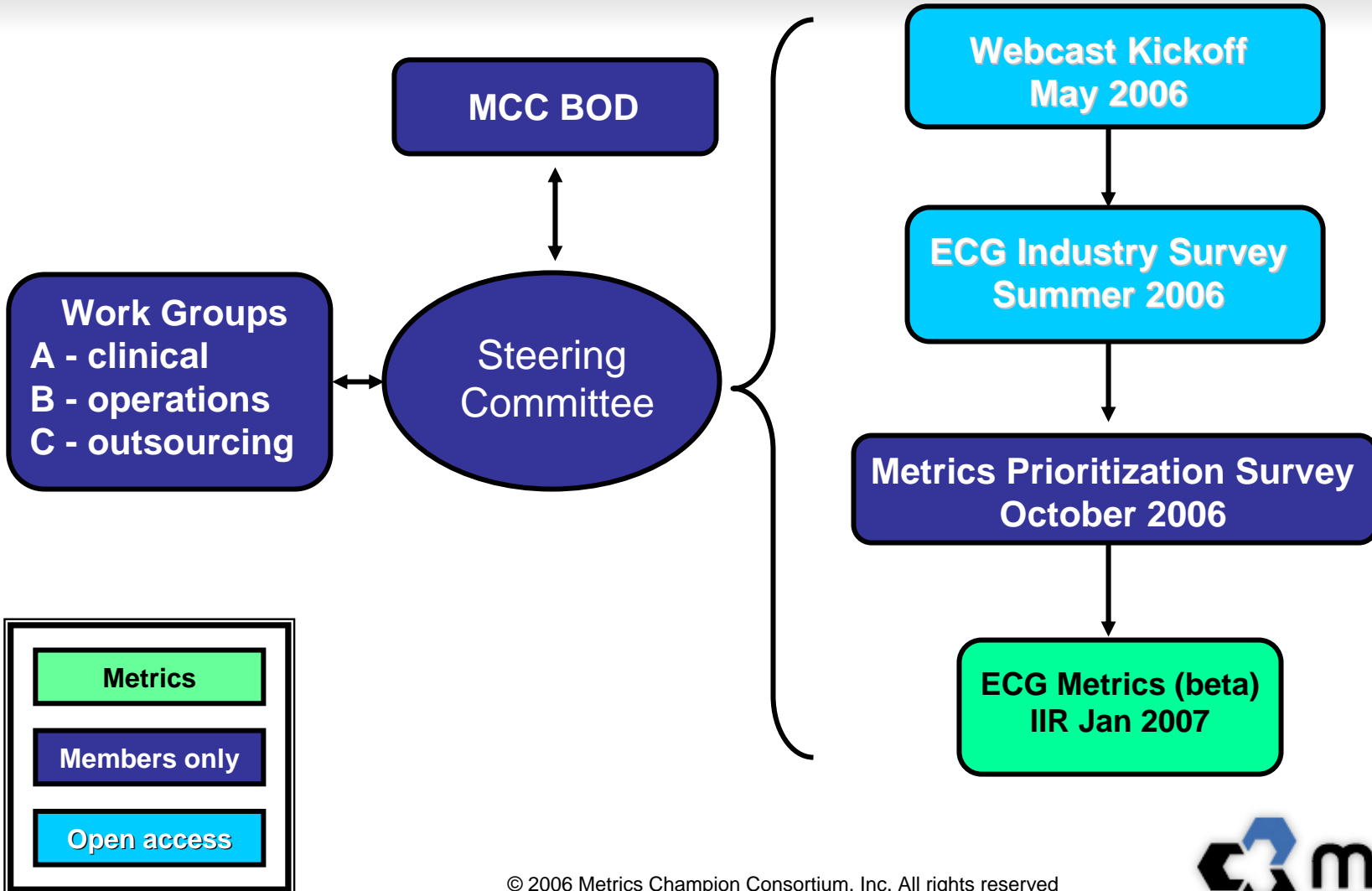
## Metrics Champion Consortium



# ECG Metrics – Mission Statement

Develop and support a baseline set of ECG service provider performance metrics within the biotechnology and pharmaceutical industry with the intent to ***jointly*** encourage the sponsors, service providers and investigative sites in gaining performance improvement, effectiveness, efficiency, and appropriate levels of controls.

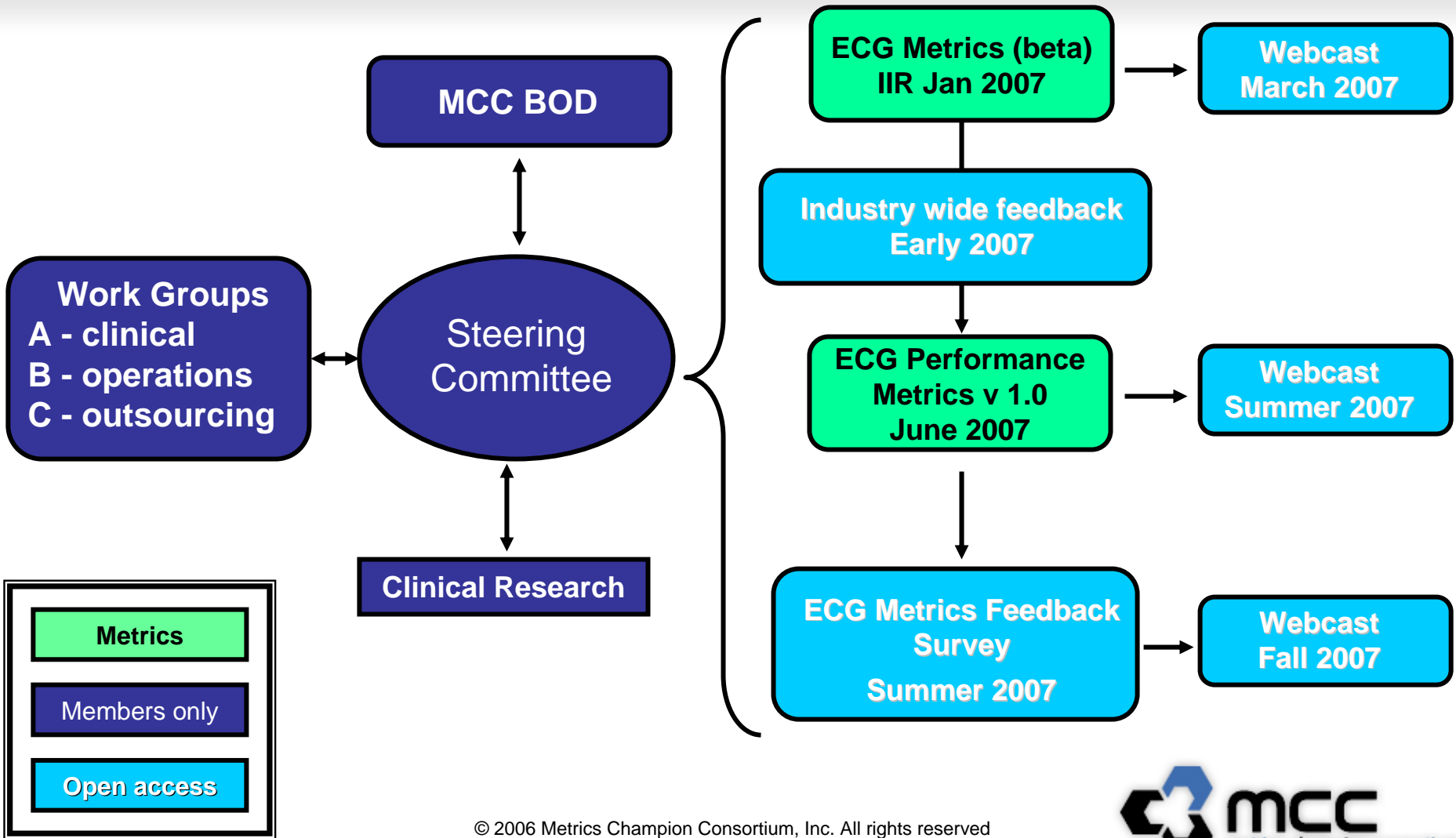
# ECG Metrics Development



# ECG Metrics – Historical Aspects

- Provided an open forum for open discussion of processes and understanding across industry
- Open to anyone with an interest (biotech/pharma, core labs, manufacturers and consultants)
- Expectations of developing “best practices” and industry standards

# ECG Metrics – The Future



## Other Projects in 2007??

- Refining ECG Metrics
  - Lessons learned on rollout
- Benchmarking
- Pilot run of ECG Metrics version 1.0
- Best Practices
- Symposiums
- Publications

- Standardized reporting across industry
- Metrics for investigative site, core lab and sponsor performance improvements
- Understanding various aspects of industry work
- Development of best practices
- Open communication lines to allow understanding of industry and possibly standardization
- Develop better metrics to ensure quality processes across all aspects of ECGs in clinical research

## 25 ECG Performance Metrics (beta version)

1 financial/budget metric

15 operations/clinical metrics

9 FDA ECG warehouse metrics

- Metrics agreed upon and built by the vendor and the FDA
  - Metrics not derived from MCC input
- Free of charge to FDA during NDA review
  - Sponsors must purchase the ability to utilize metrics from the vendor
  - Metrics not provided free of charge to members of the MCC
- Metrics not automatically available for change
  - Vendor is open to MCC input into new releases

Metric	Category	Metric Title	Definition	Formula/Example	Unit of Measure	Reporting Frequency	Target
2	Site Initiation	Percentage of On-time Equipment Shipment to Sites	<p><b>Minimum:</b> The percentage of sites who received their ECG equipment by the agreed upon receipt date based on defined expectations between the sponsor and core lab. NOTE: Timelines must be discussed, established proactively and agreed to by both parties to make this a meaningful metric.</p> <p><b>Additional analysis on a "for cause" basis:</b> A listing of protocols, countries and sites that did not meet the ECG equipment receipt date based upon the defined expectations between sponsor and core lab.</p>	<p><b>Formula:</b> (Total N of protocols with first equipment shipped date met / Total N of protocols with first equipment required) x 100</p> <p><b>Specific Example:</b> 1000 sites initiated; 990 received machines as expected (10 did not).</p> <p><b>Result:</b> 990/1000 x 100 = 99% received machines within expectations.</p>	Total N and Percentage (%)	Quarterly	>95%
			<p><b>General Benefit Statement</b></p>	<p>You will be informed regarding the service provider's ability to finalize the predefined database, prepare and/or ship ECG supplies and deliver what is required for the site to achieve first patient visit from a core lab's requirement perspective per your contractual agreement. In addition, you can extrapolate if the core lab 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. Lastly, you can assess the sponsor's ability to provide receipt dates to the core lab which is reasonable to accommodate shipping times for countries, which includes addressing Customs/Import concerns associated with countries. This will assist the sponsors and core labs in understanding the caveats in shipping to different regions of the world.</p>			

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# ECG Metrics Structure

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- Percentage of ECGs reported within agreed turnaround time
- Percentage of on-time equipment shipments to sites
- Percentage of queries from vendor to site
- Turnaround time on resolution of site queries
- Percentage of on-time, accepted file transfers

- Key personnel turnover during protocol (Project Management and Over Readers)
- Percentage of alerts successfully communicated to sites within defined turnaround time
- Average number of days from specifications signature ready to receive ECGs

- Percentage of audit findings closed within timelines
- Percentage of sites who conduct test transmission prior to first patient visit
- Average turnaround time on replacing faulty equipment
- Percentage of equipment failure

- Proportion (%) of ECGs received from one study that were interpretable by the core lab
- % of manual adjustments of automatic QT annotations from one study
  - Semi-automatic ‘computer-assisted’ measurement with visual inspection and manual adjustment whenever necessary

## ***Quality of ECG Signal***

- Global low frequency noise content
- Global high frequency noise content
- Do not depend on core lab performance
  - Depend on acquisition by the study site
- Must consider what were the electrocardiograph's filter settings

# Metric Examples – FDA ECG Warehouse

## ***QT Annotation Quality***

- Low frequency noise content around T-offset annotations
- High frequency noise content around T-offset annotations
- T-wave signal strength for beats with T-offset annotations
- Signal-to-noise ratio of T-wave signal to high frequency noise content around T-offset annotations

# Metric Examples – FDA ECG Warehouse

## ***Compliance with the QT Annotation Protocol***

- % ECGs without annotations
- % ECGs without annotations on the expected number of QTs in primary lead
- % ECGs with annotations in multiple leads

- Average days from study award to contract signature
- Average percentage of variance maintained in budget

- Metrics can be used to improve the performance of core labs, sponsors and sites
- Creating metrics has initiated open conversation among the industry
- Global metrics are most beneficial if we get involvement and feedback
- Still work to be done, please join the initiative

***Join us at 4:00 pm today***

Don't miss the second session of this two part series!

This afternoon's session will review the meaning of each metric and the expected utility of the metrics in the eyes of the sponsor, core lab and investigative sites.

## ECG Performance Metrics Steering Committee:

- Steve Asbury  
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- Nenad Sarapa  
(Telephone: 732.590.4363;  
[nsarapa@daiichisankyo-us.com](mailto:nsarapa@daiichisankyo-us.com))
- Rob Kent  
(Telephone: 858.646.2514;  
[robert.kent@quintiles.com](mailto:robert.kent@quintiles.com))

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A screenshot of the Metrics Champion Consortium (MCC) website. The header includes the MCC logo and a navigation bar with the URL "MCCBoardofDirectorsPreparestoFillCentralLaboratoryPerformanceMetricsSteeringCom". The main content area is divided into sections: "our mission" with a photo of four people in lab coats and a "login now" button; "membership information" with a description of the MCC and links for "view membership benefits", "sign up today", and "join our e-mail list"; and "work group information" with a description of workgroups and links for "view workgroups". There are also announcements for "IIR meeting discount for MCC members - Now Available!" and "Laboratory Metrics Survey - Now Available!".

Visit [www.metricschampion.org](http://www.metricschampion.org)



# Questions?

