

Drive Change! Imaging Metrics Discussion Forum

IIR 5th Annual Partnering with Central
Labs, ECG and Imaging Labs
January 19, 2007



- Metrics Champion Consortium (MCC) Overview
- Membership
- Performance Metrics Deliverables:
 - Central Laboratory Metrics
 - Imaging Metrics
- Extracting Value from Consortium
- Q&A

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.

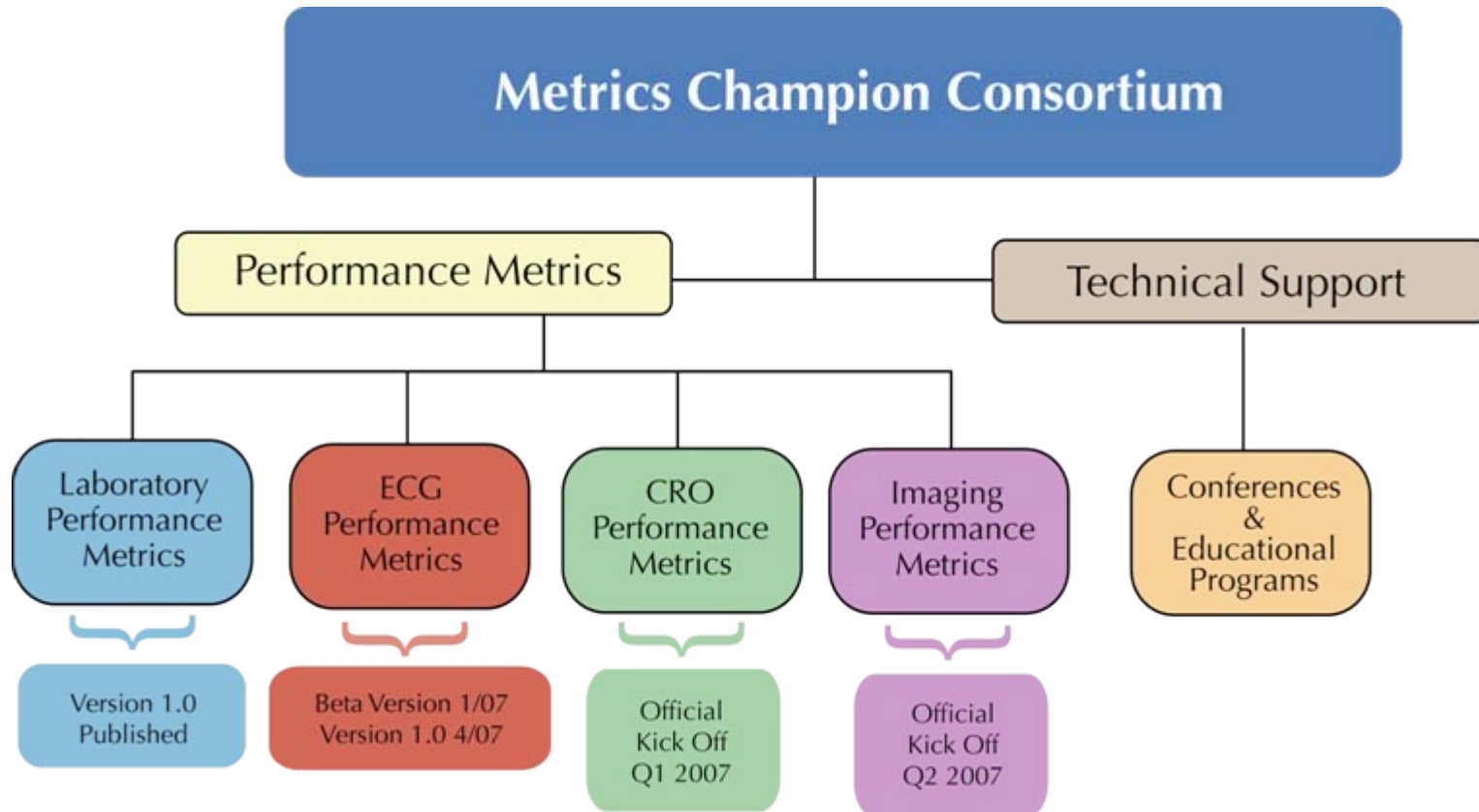
MCC Mission

Develop and support Service Provider Performance Metrics within the Biotechnology and Pharmaceutical industry with the intent to **jointly** encourage performance improvement, effectiveness, efficiency, and appropriate levels of controls.

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



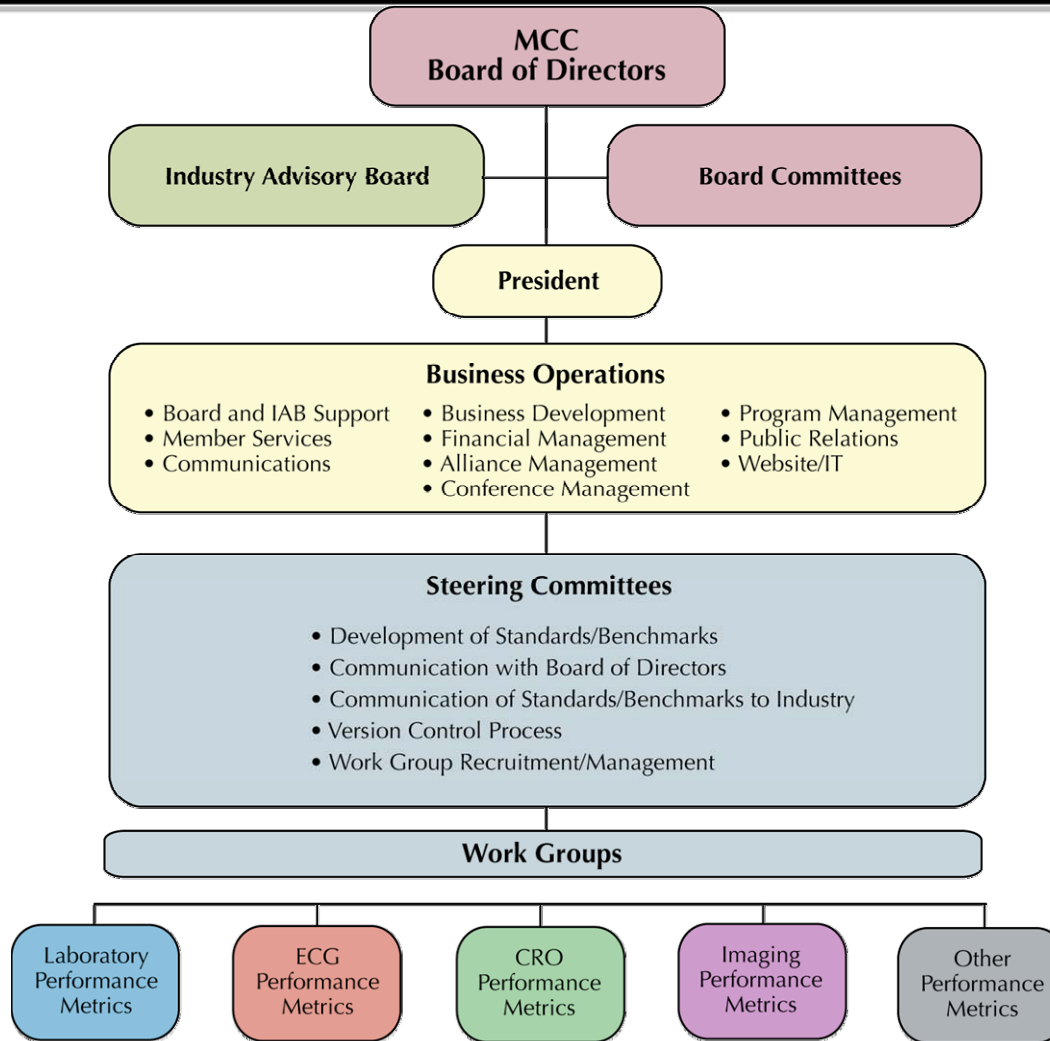
- Every key service area will have a defined set of performance metrics (e.g. Labs, ECG, CRO, Imaging)
- Entire industry actively participate in metrics creation and change management processes
- Constructive conversations are generated between all parties because of metrics
- Sponsors and service providers are growing more productive as a direct result of the MCC initiative.

- Lead the development of standardized performance metrics that improve the quality of process improvement while supporting the scientific nature of clinical research.
- Provide educational programs on MCC performance metrics and the benefits of adopting standardized metrics.
- Work with other professional groups to encourage maximum sharing of information and minimum duplication of efforts.

- Maintain a global, multidisciplinary, cross-functional composition for MCC and its working groups.
- Accomplish the MCC goals and mission without promoting any individual organization.

- Membership open to ALL
- Not-for-Profit (501c6 tax exempt Org)
- Primarily volunteer driven (Board of Directors, Industry Advisory Board, Steering Committee Leads, Working Group Members)
- Dues charged to cover business operation expenses

MCC Organization



Common Questions/ Concerns

- MCC metrics are rigid and inflexible
 - MCC metrics are intended to be foundation metrics and should be used whenever possible
 - Pick and chose which ones are most important between sponsor and service provider – you don't have to use them all
 - May need to add additional metrics to meet needs of unique relationships/events/processes between sponsor & service provider

Common Questions/ Concerns

- MCC will publish service provider metrics
 - Not at this time, data remains between Sponsor and Service Providers
 - Industry Advisory Board will influence future direction

Common Questions/ Concerns

- Performance metrics will reduce or eliminate creativity
 - Metrics change behaviors, help identify opportunities, increase learning, and monitor process performance
 - They are essential for sound business decisions & operations management.

Common Questions/ Concerns

- Data will be used against service providers
 - In isolated situations this is true and sometimes appropriate, but this is not the focus of the Consortium mission and goals,
*“... **jointly** encourage performance improvement, effectiveness, efficiency, and appropriate levels of controls.”*

Common Questions/ Concerns

- Service providers are not being included
 - Not true. Go to website and see all the new service providers joining!

MCC Membership

- Not-for-profit organization – finalized March 2006
- Any company or organization can join
- Three levels of membership:
 - Associate Member – basic privileges (**restricted**)
 - Corporate Member – expanded privileges
 - Corporate Sponsor – full privileges
- Involvement in the consortium builds partnerships between service providers and sponsors
- Involvement **now** allows you to have a greater level of influence on the future direction of the consortium

Benefits of MCC Membership

Benefits	Corp. Sponsor	Corp. Member	Assoc. Member	Work Group Participant	Non-Member
Opportunity to participate as a member of the MCC Board of Directors	*				
Opportunity to participate as a member of a Metrics Initiative Steering Committee	*				
Access to the MCC Board of Directors and Metrics Initiative Steering Committee areas of the Web site	*				
MCC Industry Advisory Board (IAB): Corporate Sponsors are entitled to have one representative on the IAB which provides advice to the MCC Board of Directors on strategic direction	*				
Right to submit changes for consideration to the Metrics Control Review process	*	*			
Right to be registered on the MCC website as participating in the Metrics Champion Consortium	*	*			
Access to MCC Members Only area, including: Current MCC performance metrics and Steering Committee minutes for each metrics initiative	*	*	*		
Access to background & historical documentation of current MCC performance metrics	*	*	*		
Access to MCC educational & training material	*	*	*		
Reduced rates for MCC/IIR events	*	*	*		
Ability to request membership in a specific Work Group related to your area of interest	*	*	*		
Access to MCC Work Group work space, including work group-specific "in development" performance metrics; documentation on the metrics; Work Group communications and meeting minutes				Yes	

MCC Contribution Structure

Company Size	Corporate Sponsorship	Corporate Membership	Associate Membership
>1,000 employees	1st Yr \$35K Annual \$10K	1st Yr \$10K Annual \$10K	N/A
500-999	1st Yr \$15K Annual \$5K	1st Yr \$5K Annual \$5K	N/A
0-499	1st Yr \$10K Annual \$3K	1st Yr \$3K Annual \$3K	N/A
Academic or Non-Profit			1st Yr \$3K Annual \$3K

How are MCC funds used?

- MCC is not-for-profit: If excess revenues are generated they remain in consortium and future dues would be adjusted accordingly.
- MCC estimates that 350K to 400K are required to operate annually with some larger one time expenses the first year (ex. Website development, etc.)
- MCC funds will be used for items such as:
 - web site development and maintenance
 - staff to perform core operational duties /support working groups
 - communication expenses
 - supplies and materials
 - limited travel expenses
 - insurance
- Members have access to annual financial reports accounting for all revenues and expenses via the MCC website.

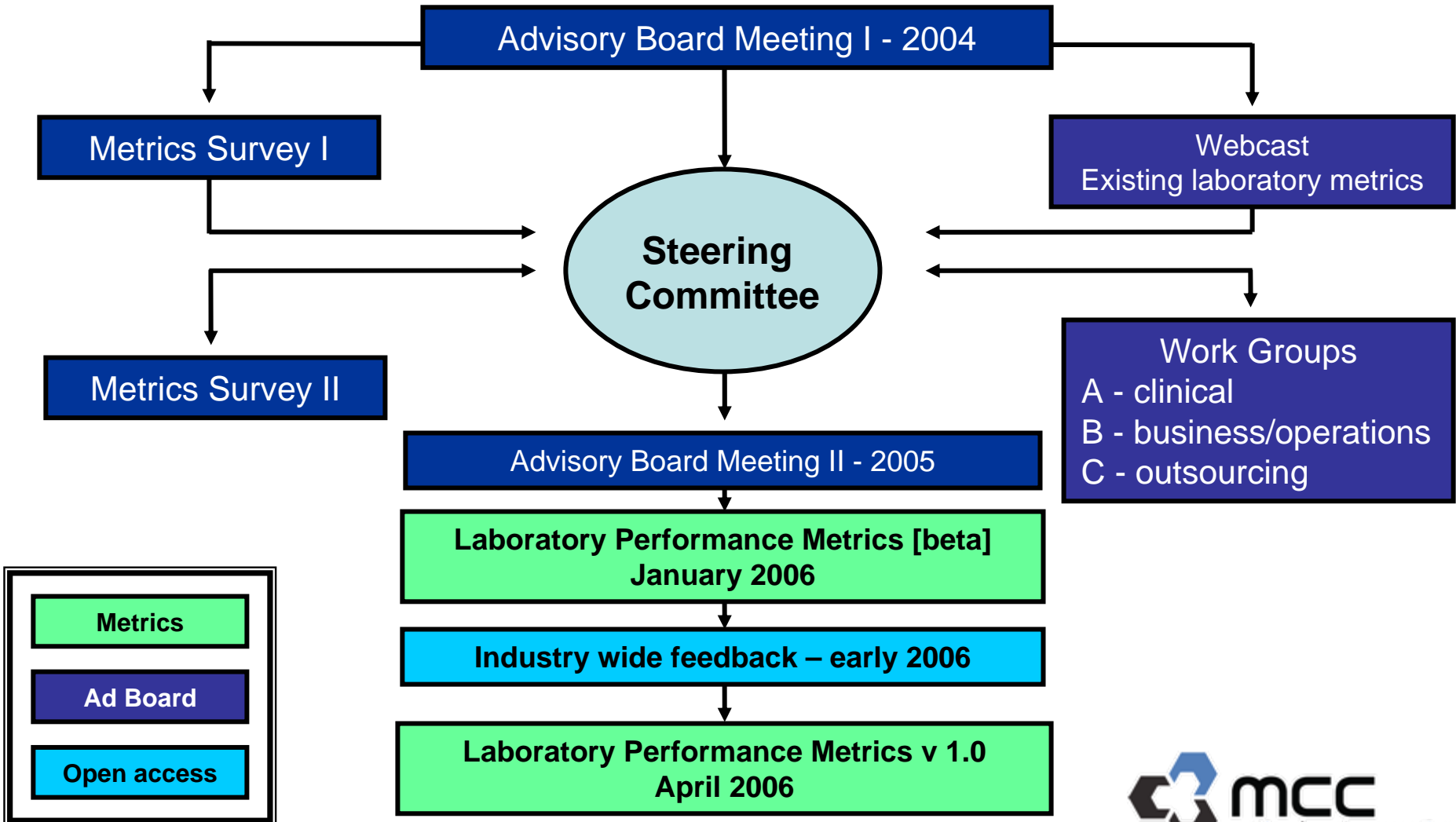
- IIR-related meeting planning, meeting conference space, promotion – our IIR business partnership covers these expenses*
- sponsor and service provider travel expenses**
- monetary compensation for Board members, Industry Advisory Board members, Steering Committee members, and working group members - these are volunteer positions

* When tied to an already existing IIR conference

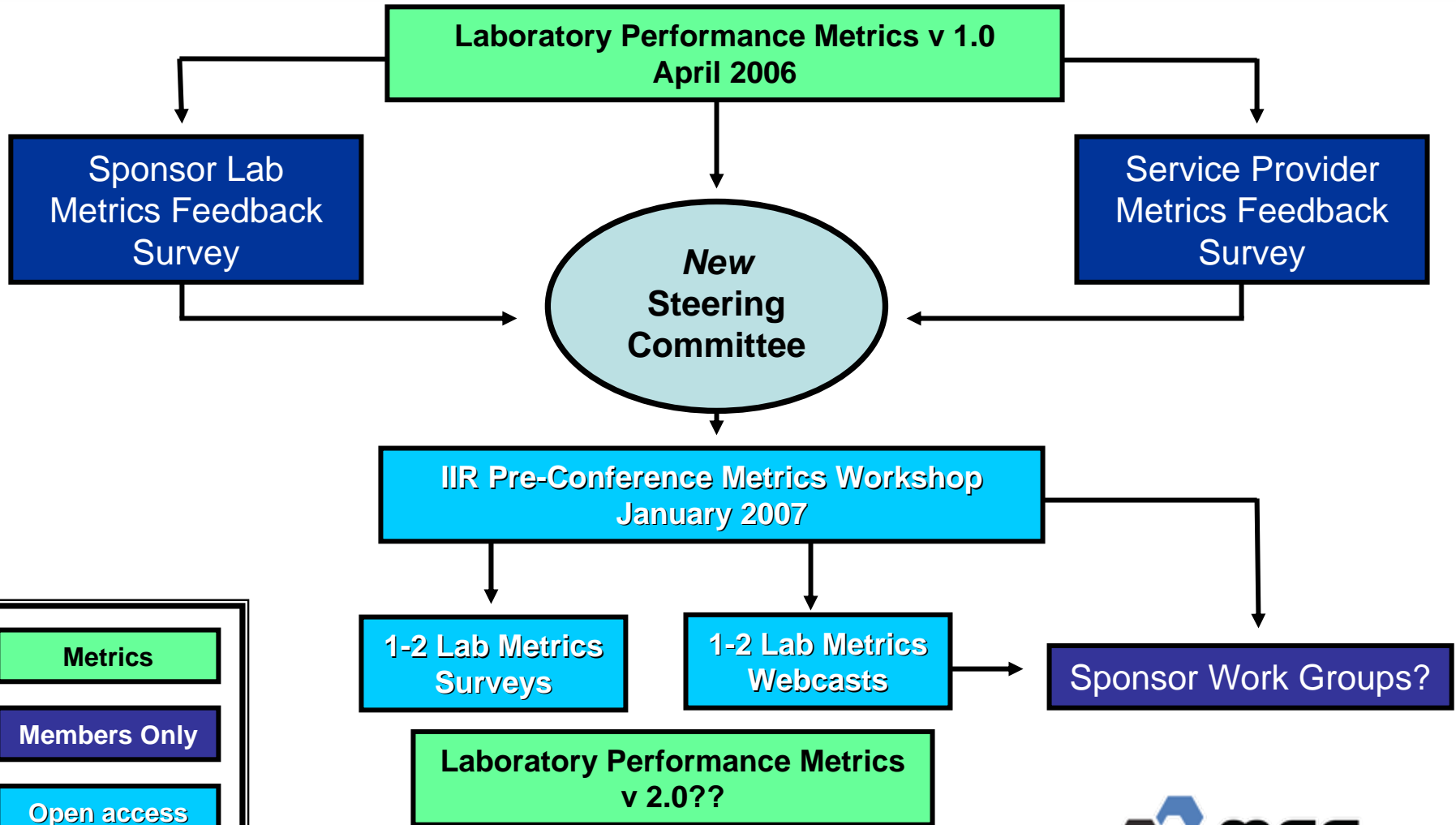
** Exceptions must be reviewed and approved by MCC president prior to travel

Laboratory Performance Metrics Deliverables

Lab Metrics Development Process



Lab Metrics Development Process



Laboratory Performance Metrics v 1.0

Metric	Category	Metric Title
1	General Operations	Project management turnover during protocol
2	Protocol Initiation	Average number of working days from statement of work signature to "database ready"
3	Site Initiation	Percentage first supplies shipped on time
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 successfully communicated to the sites within the defined turnaround time

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

Metric #1: Project management turnover during protocol

Category	Definition*	Formula/Example	Unit of Measure	Reporting Frequency [†]	Target [†]
General Operations	<p>Minimum: The percentage of the project management turnover on the central laboratory team which supports sponsor's protocol, overall per sponsor and central laboratory.</p> <p>Additional analysis on a "for cause" basis: A list of project management turnover by name per protocol and/or by sponsor.</p>	<p>Formula: (Total N project managers who have left the sponsor team / Total N project managers who are on the sponsor team) x 100</p> <p>Specific Example: 1 Project Manager left a team of 5 persons supporting the sponsor Result: $(1/5) \times 100 = 20\%$ turnover on sponsor team</p>	Total N and Percentage	Semi-Annually / Annually	Minimal

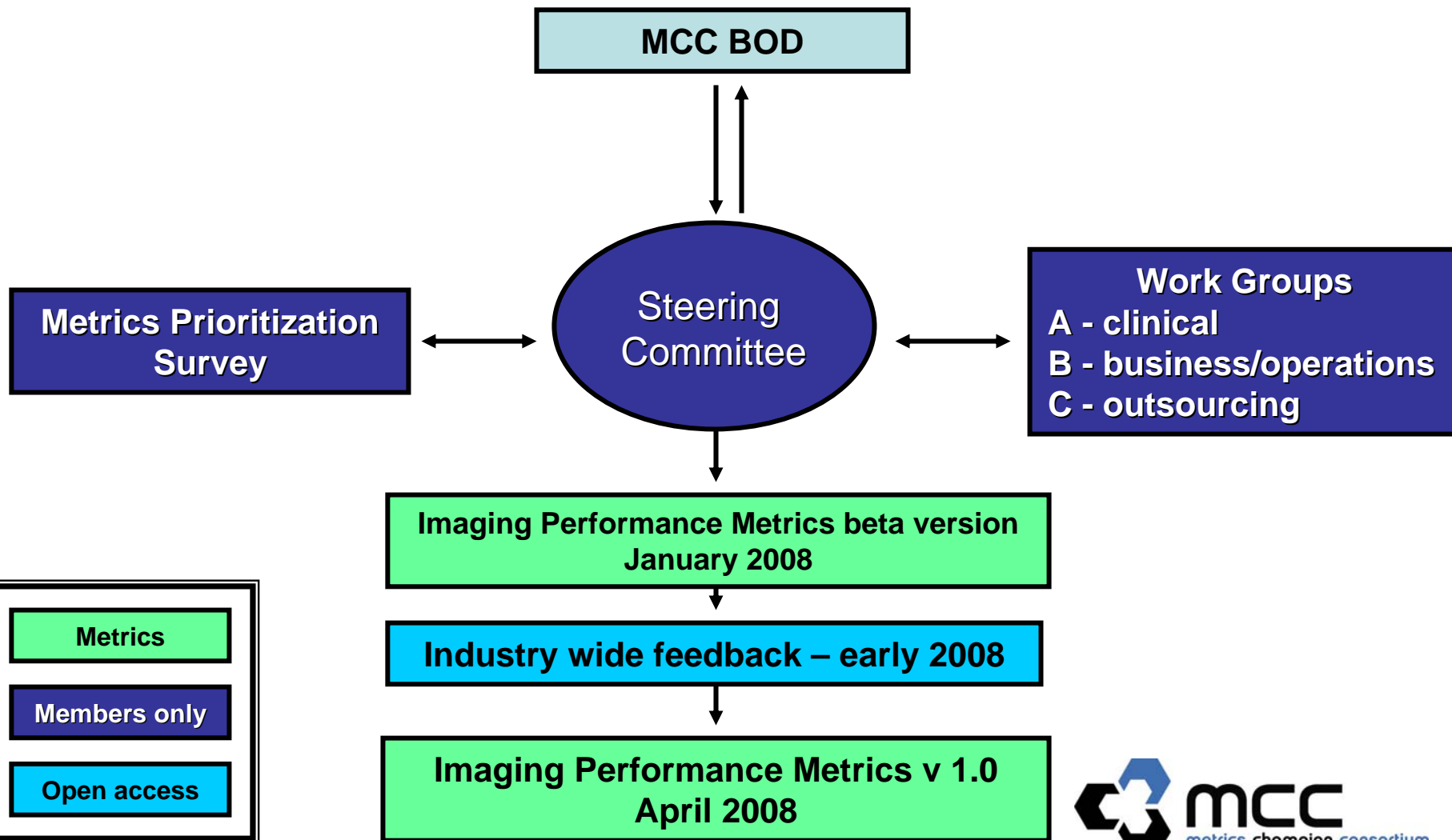
*The definition includes a minimum metric to allow general evaluations and 'additional on a for cause basis' metric(s) to provide additional insight into a general metric which may not be meeting expectations to help assess what actions can be taken to address it.

[†] The reporting frequency and target have been provided as working guidelines and the final definitions should be agreed upon between sponsor and service providers.

Imaging Performance Metrics Deliverables



Imaging Metrics Development Process



Overview of Metrics - Potential Benefit within Imaging Industry

- Increase overall productivity of clinical trial imaging (sponsor, core lab and clinical site)
 - Metrics should be developed for the purpose of identifying “what works” and “what needs improvement”
- Information and discussion tool for sponsor and core lab decision makers
 - Drive change as appropriate

Potential Topics for Imaging Metrics

- Image Receipt
 - % images received versus expected images
 - % images received within expected time frame
- Image Quality
 - % images acceptable for review

Questions/Actions:

- Site training
- Issue with acquisition guidelines

Potential Topics for Imaging Metrics

- Logistical and Technical Site Queries
 - Average # queries per patient and/or site
 - Average site response time to query
 - Most common queries

Questions/Actions:

- Site training
- Issue with imaging requirements/forms development

Potential Topics for Imaging Metrics

- Datalocks
 - % of datalocks completed by target date

Questions/Actions:

- Metric design should include comments/explanation.

Potential Topics for Imaging Metrics

- Financial Metrics
 - Estimated cost vs. amended cost vs. actual cost

Questions/Actions:

- Assess how well sponsor communicated initial study needs
- How many changes sponsor requested
- Assist sponsor and core lab with tracking cost

Key Messages for Development of Imaging Metrics

- We (Imaging Industry) must collectively agree on the benefits of developing and implementing metrics.
- Participation from sponsors and core labs will provide objectivity and ensure a well balanced approach for metric development.
- Our goal should be to improve all aspects of clinical trial imaging including sponsor, core lab and site processes.

Key Success Factors

- Biotechnology & pharmaceutical companies must **adopt and use** these standard metrics
- Service providers must **adopt and produce** these standard metrics
- Both must participate in the change management process
- Both must support the initiative with key talent and funding

Extracting Value from Consortium

Achieving Return on Investment

Performance Metrics

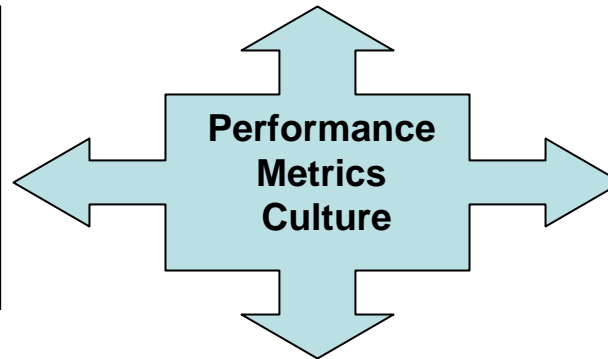
Standardized measures
Harmonized reports
Awareness of performance

Operations Management

Establish performance baselines
Define stretch targets
Measure progress against goals
Identify Best Practices
Drive process improvement

Decision Management

Timely decision making
Informed decisions
Get it RFT
Drive effective decisions



Strategy Management

Test the validity of strategy
Confirm change is delivering expected value
Manage strategy to deliver results
Drive Strategy evolution

Ultimate Performance Metric ROI is Improved Organizational Productivity!!

Value of Participating in Consortium Activities

Sponsor benefits from participating in the MCC:

- Influence over and full access to industry standards
- Industry shared learning and problem solving
- Increased productivity
- Simplified review and analysis of metrics data
- Ability to conduct “Apples to Apples” comparison of performance metrics:
 - among your service providers
 - between your organization and others in the industry
- More time focused on solving problems and celebrating successes in sponsor/service provider relationships

Value of Participating in Consortium Activities

Service provider benefits from participating in the MCC:

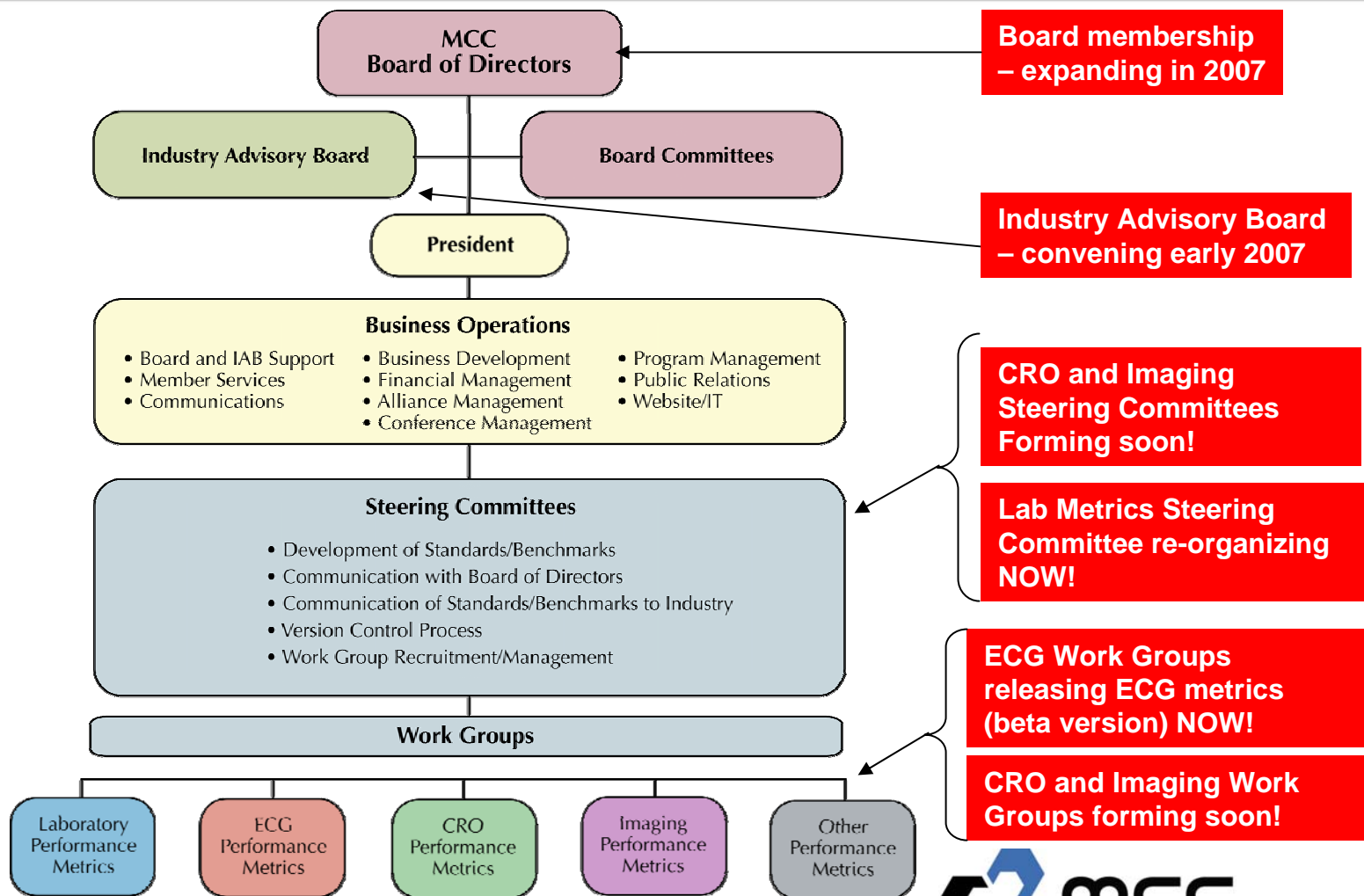
- Influence over and full access to industry standards
- Industry shared learning and problem solving
- Simplified review and analysis of metrics data
 - ability to invest in IT programming upgrades
 - increased productivity
 - ability to conduct “Apples to Apples” comparison of performance metrics among your sponsors
- Ability to focus on solving problems and celebrating successes in sponsor/service provider relationship
- Strengthened sponsor/service provider relationships

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

Opportunities for Engagement



- Continue your education
 - www.metricschampion.org
 - Contact MCC
 - Via web site – register to receive more info.
 - Guy Mascaro, President MCC – 317-848-2908
 - Brian Schrock, MCC Board Chairman – 317-433-3581
- Share with your organization
- Join & participate



The screenshot shows the MCC website homepage. At the top left is the MCC logo. To its right is a decorative banner with numbers and a blue background. Below the banner is a section titled "our mission" featuring a photo of four people in white lab coats. To the right of the photo is the text: "The mission of the Metrics Champion Consortium (MCC) is to develop and support service provider performance metrics within the biotechnology and pharmaceutical industry with the intent to jointly encourage performance improvement, effectiveness, efficiency, and appropriate levels of controls." Below this is a "login now" button. A "what's new?" section follows, with a sub-section for "membership information" that includes a link to "view membership benefits" and a note about a 15% discount for MCC members. Another sub-section for "work group information" includes links to "CLPM Metrics 1.0 summary.pdf" and "Service Provider Survey Sponsor Survey".

Questions?

