

# *Introduction to the Metrics Champion Consortium*

DIA

June 20, 2006

# Agenda

- Overview of Metrics Champion Consortium (MCC)
- Membership
- Introduction to Central Lab Performance Metrics Deliverable
- Panelist Comments
- Extracting Value from Consortium
- Q&A

# 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.

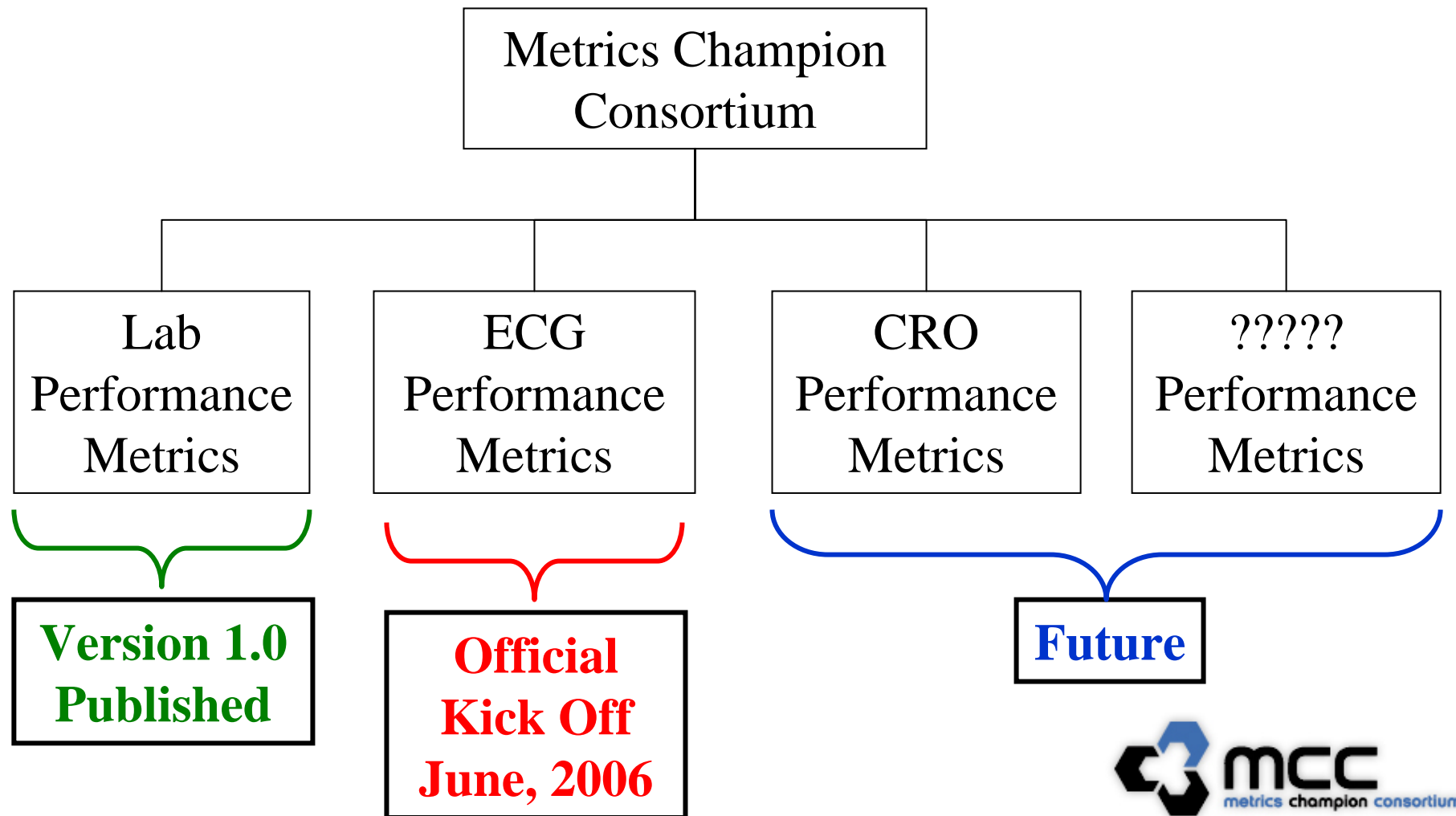
# Motivation for Consortium

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 Scope



# MCC Goals

- 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.

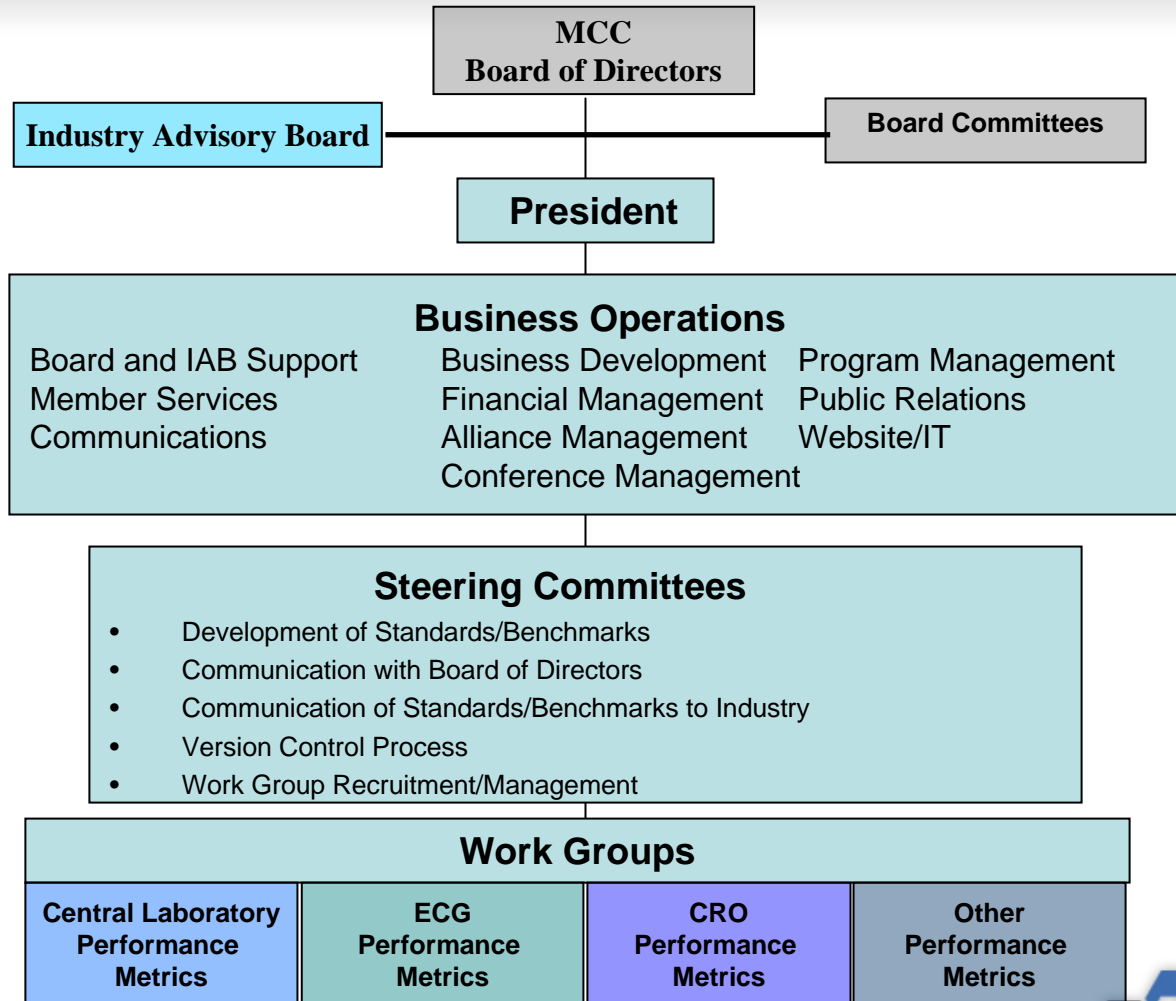
# MCC – Core Principles

- 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.

# MCC 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 Org Chart



# Participants

## Central Lab Performance Metrics

- Abbott
- Amgen
- Astra Zeneca
- Aventis
- Eli Lilly
- Gilead
- GSK
- J&J
- Merck
- Novartis
- Roche
- Schering Plough
- Vertex
- Valeant
- Wyeth

Early sponsor: Covance

## Consortium Members

- AstraZeneca
- Biomedical Systems
- Cardiocore
- Covance
- Daiichi Sankyo
- Eli Lilly
- eResearchTechnology
- Novartis
- ICON Laboratories, Inc.
- Mortara
- Quintiles
- Spacelabs
- Valeant
- Vertex

Implementation Partner: IIR



# 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
- MCC will publish service provider metrics
  - Not at this time, data remains between Sponsor and Service Providers
  - Industry Advisory Board will influence future direction
- Performance Metrics will reduce or eliminate creativity
  - Metrics change behaviors, help identify opportunities, increase learning, and monitor process performance – It's essential for sound business decisions & ops mgmt.
- 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. ”
- Service providers are not being included
  - Not true. Go to website and see all the new service providers joining!

# MCC Membership

# MCC Membership

- Not-for-profit Organization – Finalized March 2006
- Any company 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 separate MCC Board of Directors and Metrics Initiative Steering Committee areas of the website	*				
MCC Industry Advisory Board (IAB): Corporate Sponsors are entitled to have one representative on the IAB which provides advice to the MCC Board of Director 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 will MCC funds be 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
- All members will have access to annual financial reports accounting for all revenues and expenses via the MCC website.

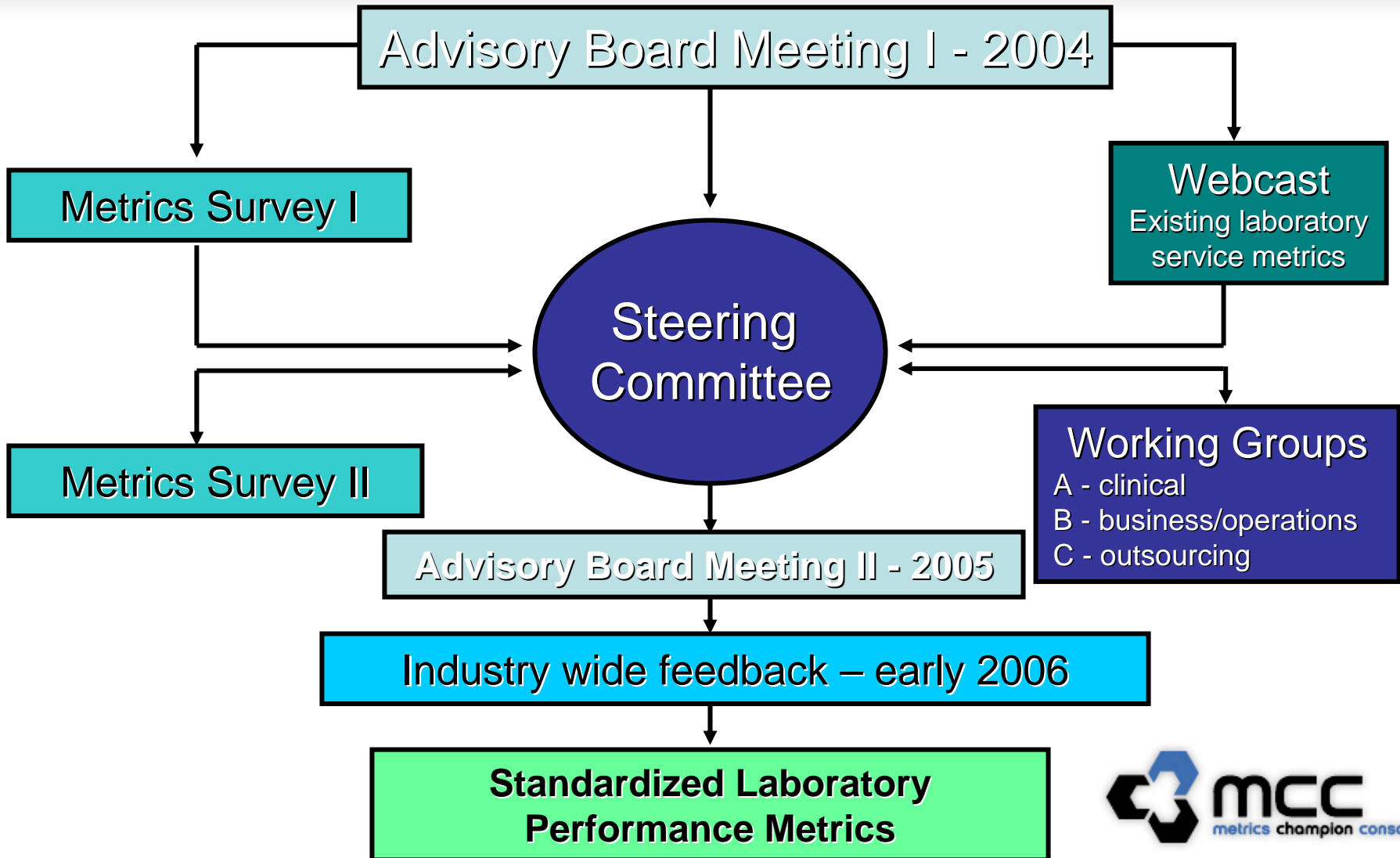
# Consortium funds will not be used for....

- IIR partnership covers\*: meeting planning, meeting conference space, some promotion
- Sponsor and service providers are expected to cover their own travel expenses\*\*
- Board members, Industry Advisory Board members, Steering Committee members, and working group members are volunteer positions and will not receive any monetary compensation

\*  
\*

# Central Lab Performance Metrics Deliverables

# Metrics Development Process



# Central Lab Performance Metrics

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 Details

## Metric #1: Project management turnover during protocol

Category	Definition*	Formula/Example	Unit of Measure	Reporting Frequency <sup>†</sup>	Target <sup>†</sup>
General Operations	<p><b>Minimum:</b> 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><b>Additional analysis on a "for cause" basis:</b> A list of project management turnover by name per protocol and/or by sponsor.</p>	<p><b>Formula:</b> (Total N project managers who have left the sponsor team / Total N project managers who are on the sponsor team) x 100</p> <p><b>Specific Example:</b> 1 Project Manager left a team of 5 persons supporting the sponsor Result: <math>(1/5) \times 100 = 20\%</math> 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.

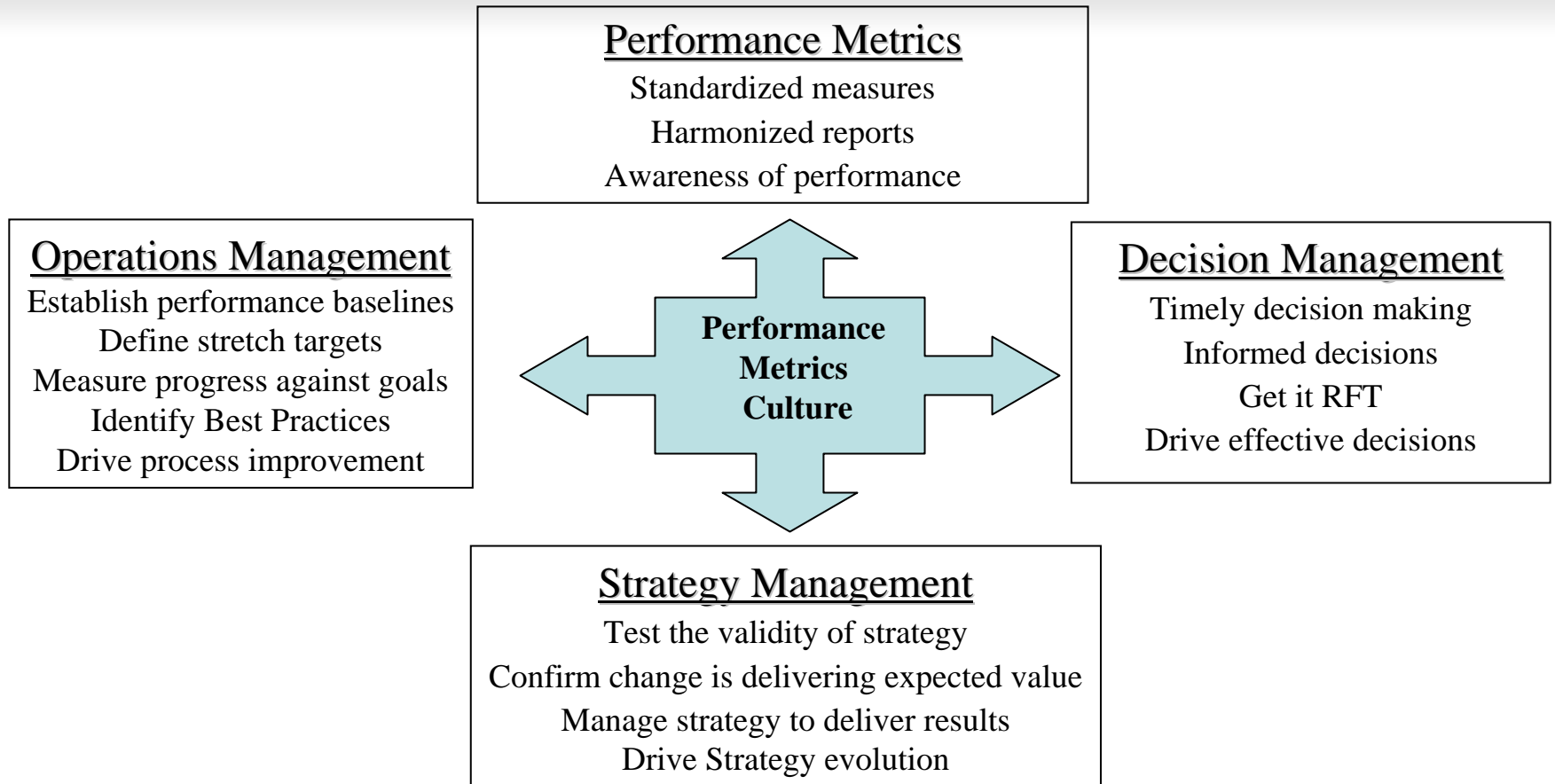
<sup>†</sup> The reporting frequency and target have been provided as working guidelines and the final definitions should be agreed upon between sponsor and service providers.

# Key Success Factors

- Pharma & Biotech 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



**Ultimate Performance Metric ROI is improved  
Organizational Productivity!!**

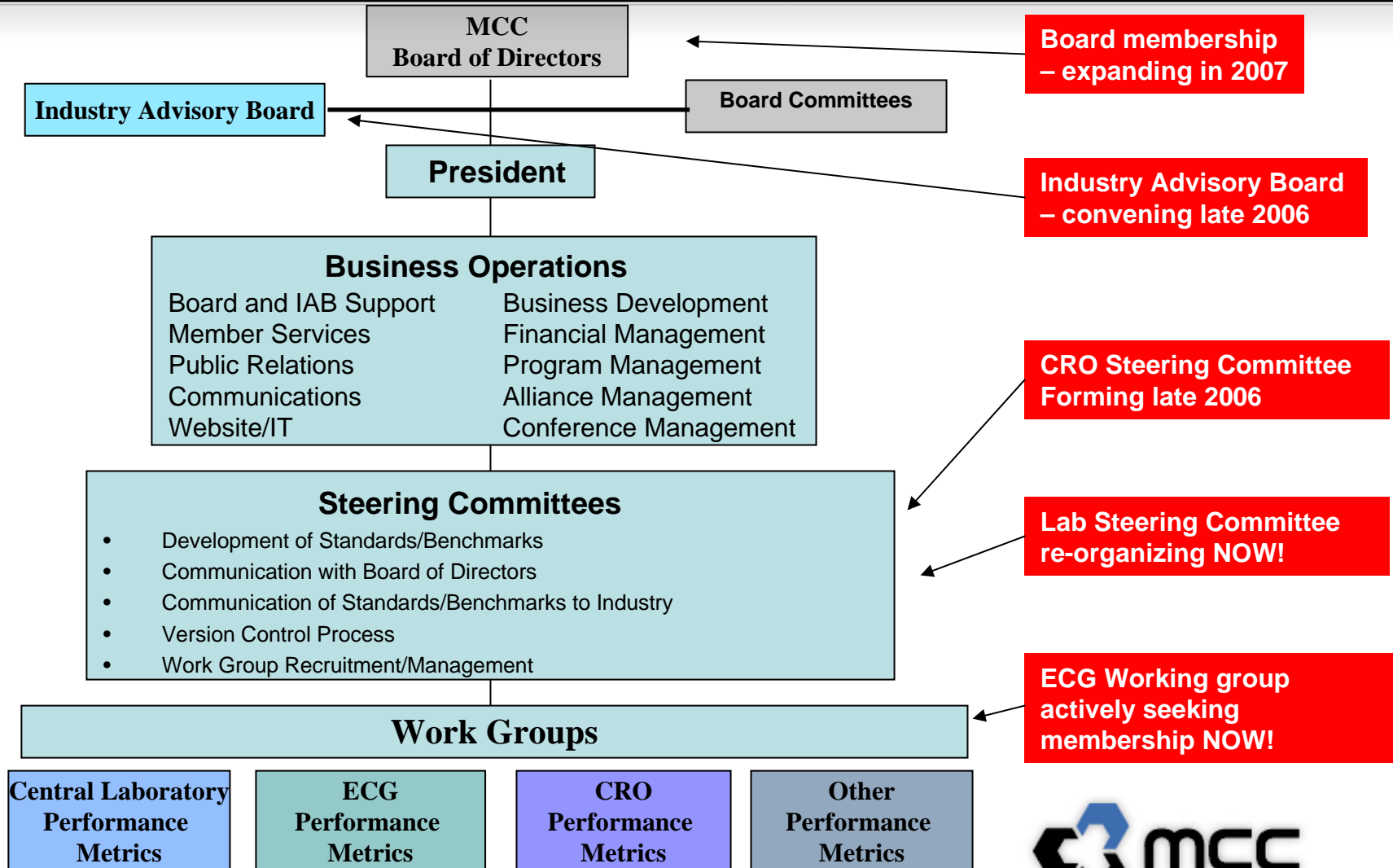
# Extracting Value

- Covance & QLABs starting to provide MCC Standard Metrics to Lilly
  - Seeing comparative data for first time (Lilly vs. Industry)
  - Sparking creative ideas to save money/improve process
  - Automation of metric production starting (tools to publish and review to follow)
- 6 sigma process improvement projects initiated driven by metrics\*
  - Sample storage (>\$300k annual)
  - Modification Reduction (>\$200k annual)
- Residual Value – Pharma, Biotech and Service Providers starting to use Metrics resulting in greater overall Service Provider efficiency
- Consortium Network helping to generate ideas across industry

\*Based on Lilly Standard Metrics which we have been collecting for 2 years



# Opportunities for Engagement



# Next Steps

- Continue your education
  - [www.metricschampion.org](http://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