

Workshop B1: Implementing Performance Metrics to Drive Time, Cost and Quality & Enhance Partnership Performance

April 10, 2007

Workshop Faculty:

Holly Hankins, Eli Lilly

Guy Mascaro, Metrics Champion Consortium

Brian Schrock, Eli Lilly

Badhri Srinivasan, Quintiles

David Zuckerman, Customized Improvement Strategies



Workshop Overview

9:00 – 9:30 am	<i>MCC Overview</i>
9:30 – 10:30 am	<i>CRO Performance Metrics History</i>
10:30 – 11:00 am	<i>Break</i>
11:00 – 12:00 pm	<i>Sponsor/Service Provider Model (Lilly & Quintiles)</i>
12:00 – 12:30 pm	<i>Breakout Session I</i>
12:30 – 1:30 pm	<i>Lunch</i>
1:30 – 3:00 pm	<i>Breakout Session I Debrief</i> <i>Breakout Session II</i>
3:00 – 3:15 pm	<i>Break</i>
3:15 – 4:30 pm	<i>Breakout Session II Debrief</i> <i>Panel Discussion</i>

Purpose of Today's Workshop

- To explore using performance metrics to drive process improvement and operational excellence for sponsors and service providers.
- To review how CRO performance metrics are being used by sponsors and service providers today.
- To discuss opportunities to work collaboratively to develop an industry wide set of CRO performance management metrics to improve quality and enhance partnership performance.

Metrics Champion Consortium Overview

MCC Overview

The Metrics Champion Consortium (MCC) is an open, multidisciplinary, non-profit organization comprised of biotechnology, pharmaceutical and service provider organizations.

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 alike.

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.”†

87% of service providers report a growing and/or a rapidly growing demand for performance metrics from sponsor organizations.‡

† Reengineering and Process Metrics, Dave Trimble - Senior Partner, ProSci – www.prosci.com

‡ MCC Metrics in Action Workshop Survey, 2007. n=15

MCC Goals

- Every key service area will have a defined set of performance metrics (e.g., Labs, ECG, CRO, Imaging).
- 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 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.

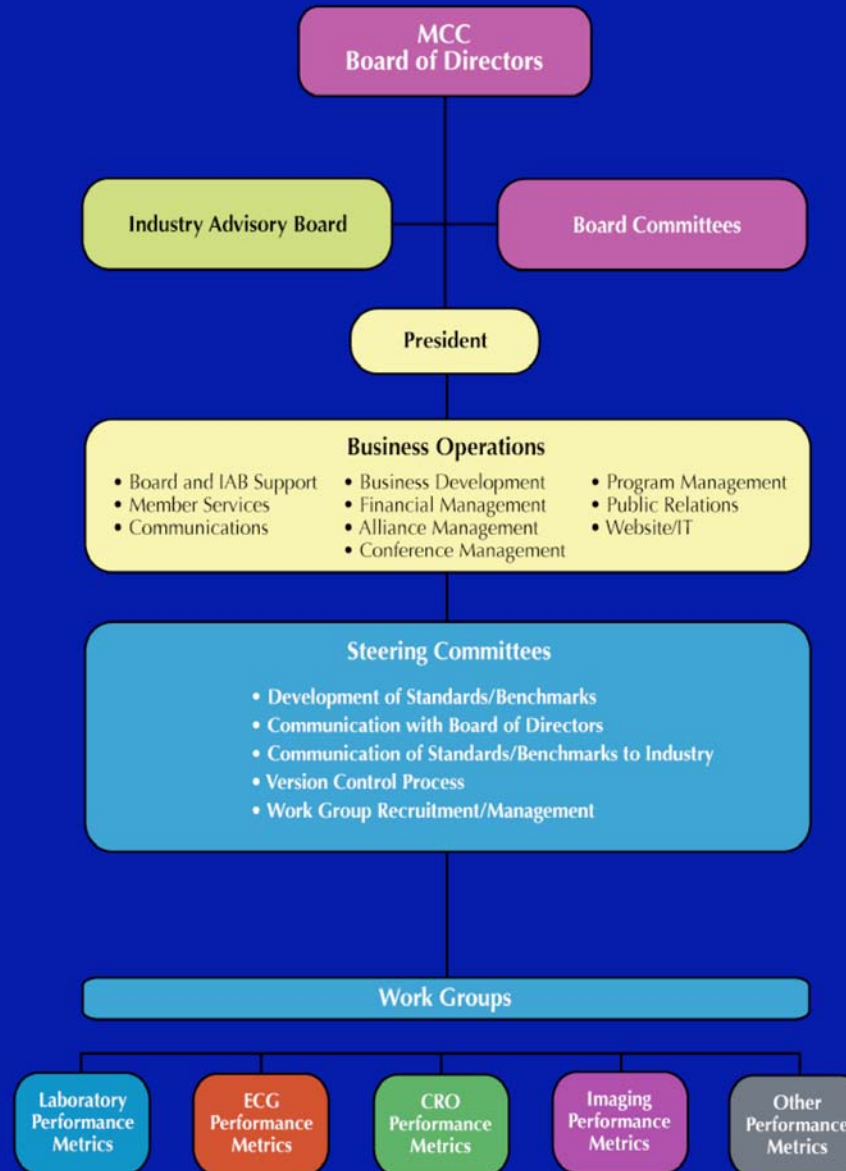
MCC Core Principles

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

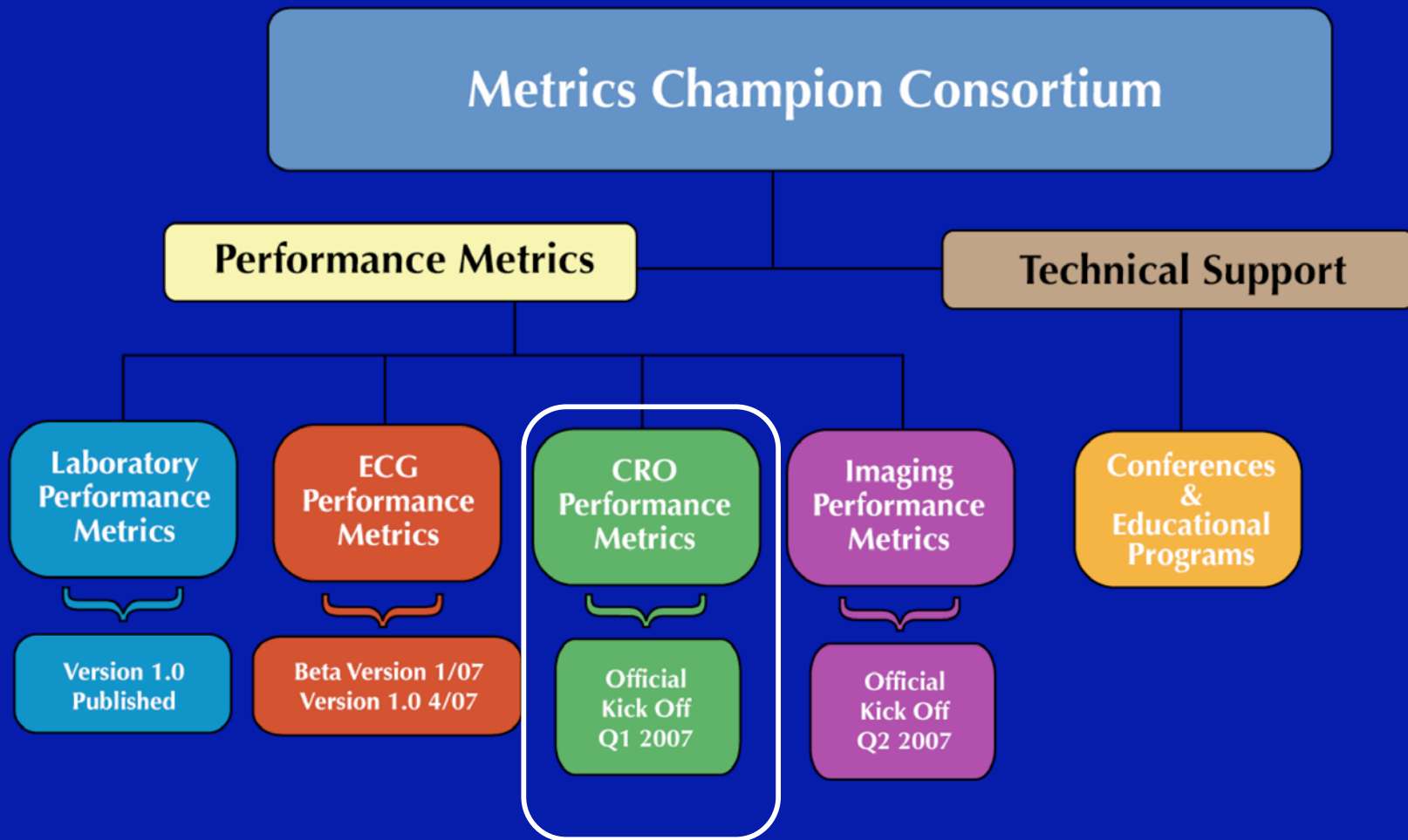
MCC Organization

- 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 Organization



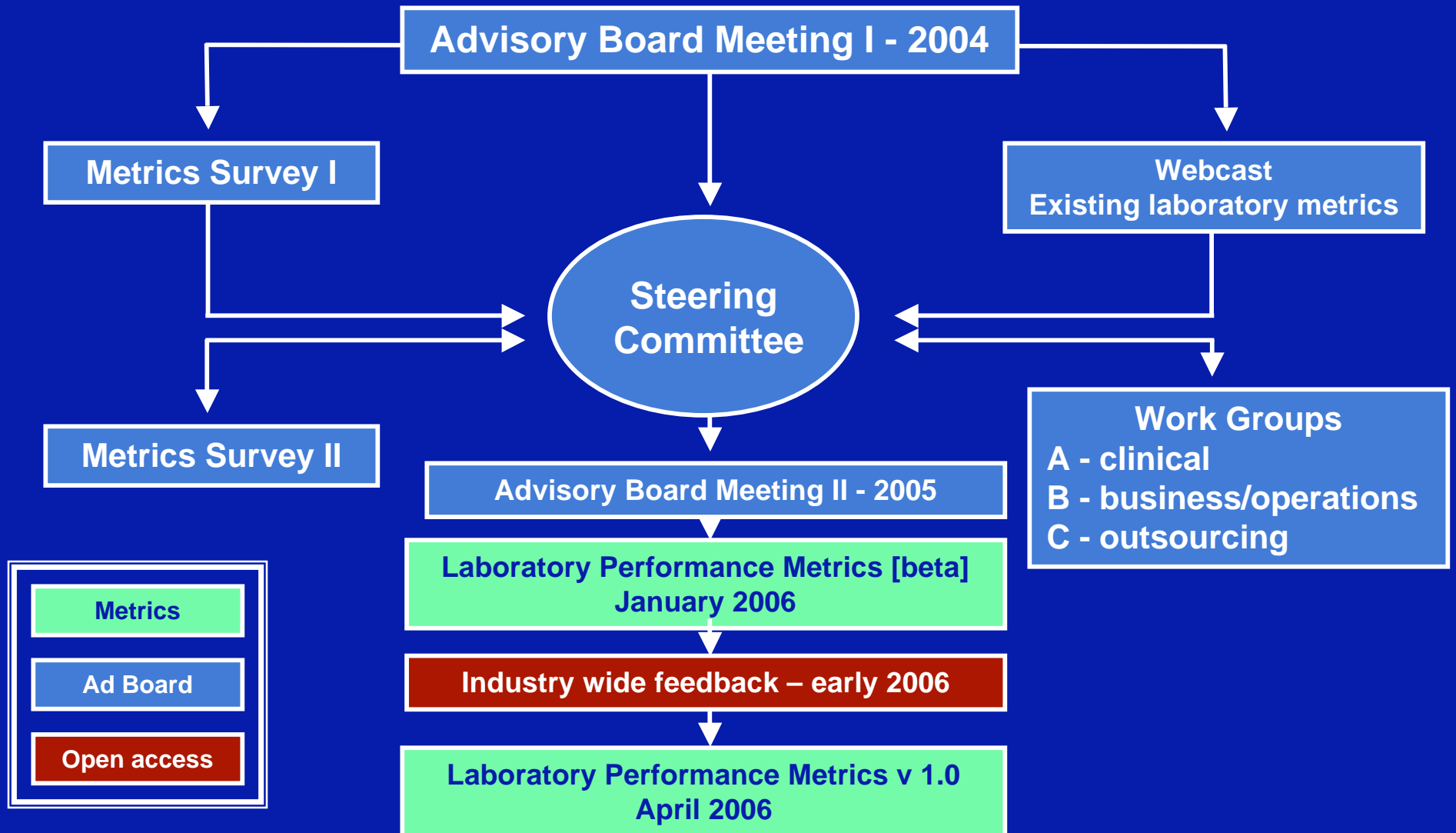
MCC Performance Metrics YTD



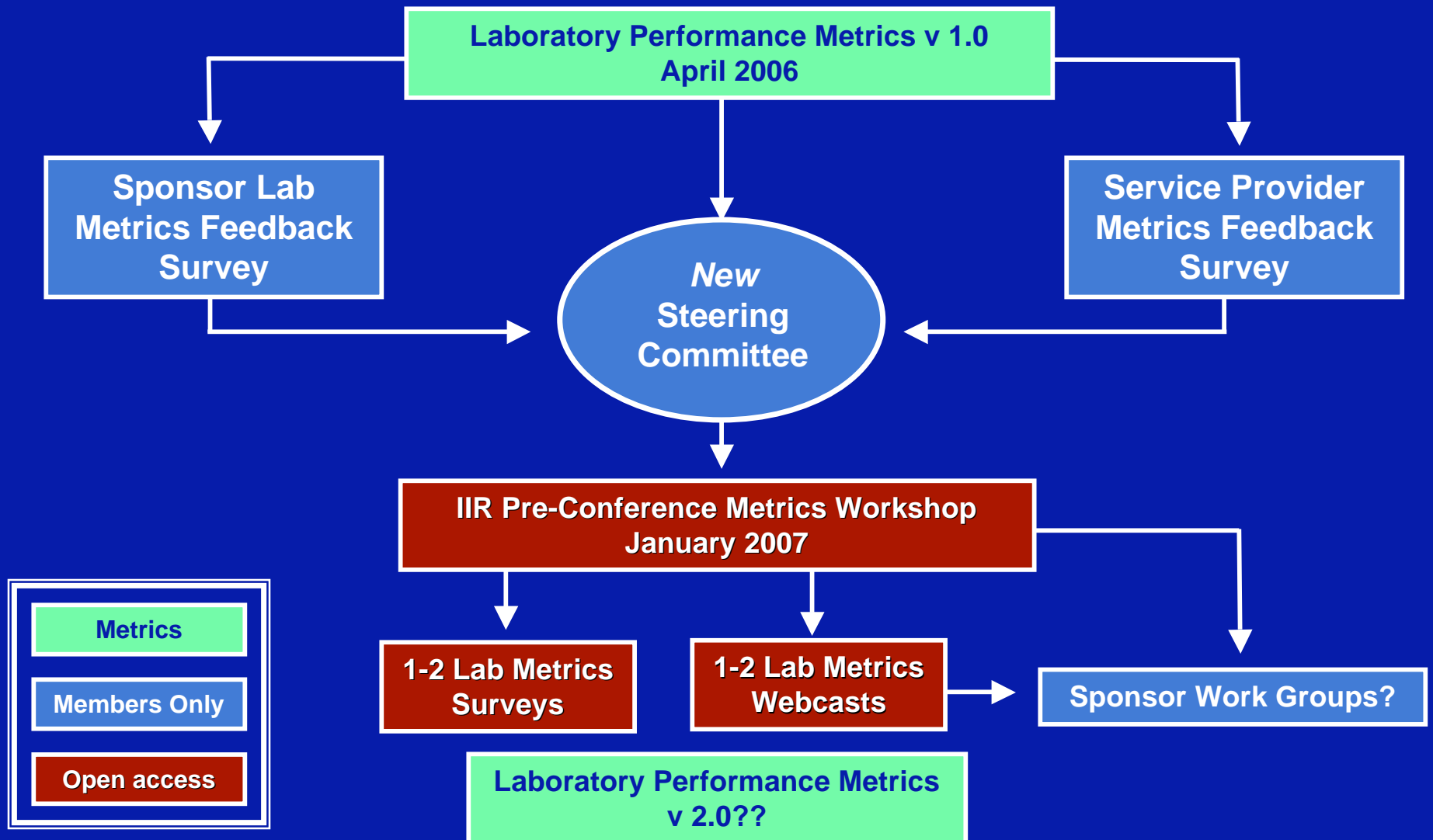
Performance Metrics Development Models

- Model I: Laboratory Performance Metrics
- Model II: ECG Performance Metrics

Lab Metrics Development Process



Lab Metrics Development Process



MCC Laboratory Performance Metrics v 1.0

Metric	Category	Metric Title	Metric	Category	Metric Title
1	General Operations	Project management turnover during protocol	9	Laboratory Operations	Percentage specific test(s) reported within expected turnaround time
2	Protocol Initiation	Average number of working days from statement of work signature to "database ready"	10	Laboratory Operations	Percentage tests not reportable
3	Site Initiation	Percentage first supplies shipped on time	11	Laboratory Operations	Percentage shipments / samples shipped from central laboratory on time to sponsor-directed third party
4	Data Cleaning	Percentage of queries from central laboratory to site based upon requisitions received	12	Data Management	Percentage on time accepted file transfers
5	Data Cleaning	Average turnaround for resolution of queries from central laboratory to site	13	Financial Management	Plan, Forecast and Actual Financial Report
6	Site Support Services	Percentage of queries from site to central laboratory based upon requisitions received	14	Financial Management	Comparison of budgeted and actual transportation costs by region and/or country
7	Site Support Services	Average turnaround time on queries from site to central laboratory	15	Quality Assurance	Percentage of audit findings closed within sponsor and central laboratory agreed upon timeframe
8	Safety	Percentage of panics successfully communicated to the sites within the defined turnaround time			

Laboratory Performance Metrics

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 analysis on a 'for cause' basis" metric(s) to provide additional insight into a general metric that 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.

Lab Metrics Development Process

Lessons Learned

**Covance Advisory Board
composed of 1 service
provider and 15
biotech/pharma organizations**



**Service providers concerned
they were not included in
metrics development process**

**Covance selected participants
with a variety of roles within
biotech/pharma but some did
not have performance
measurement interests**



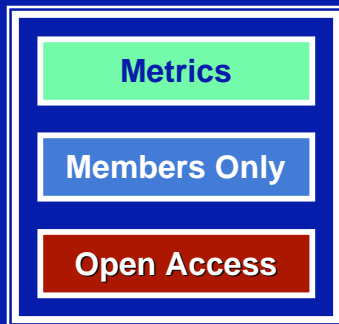
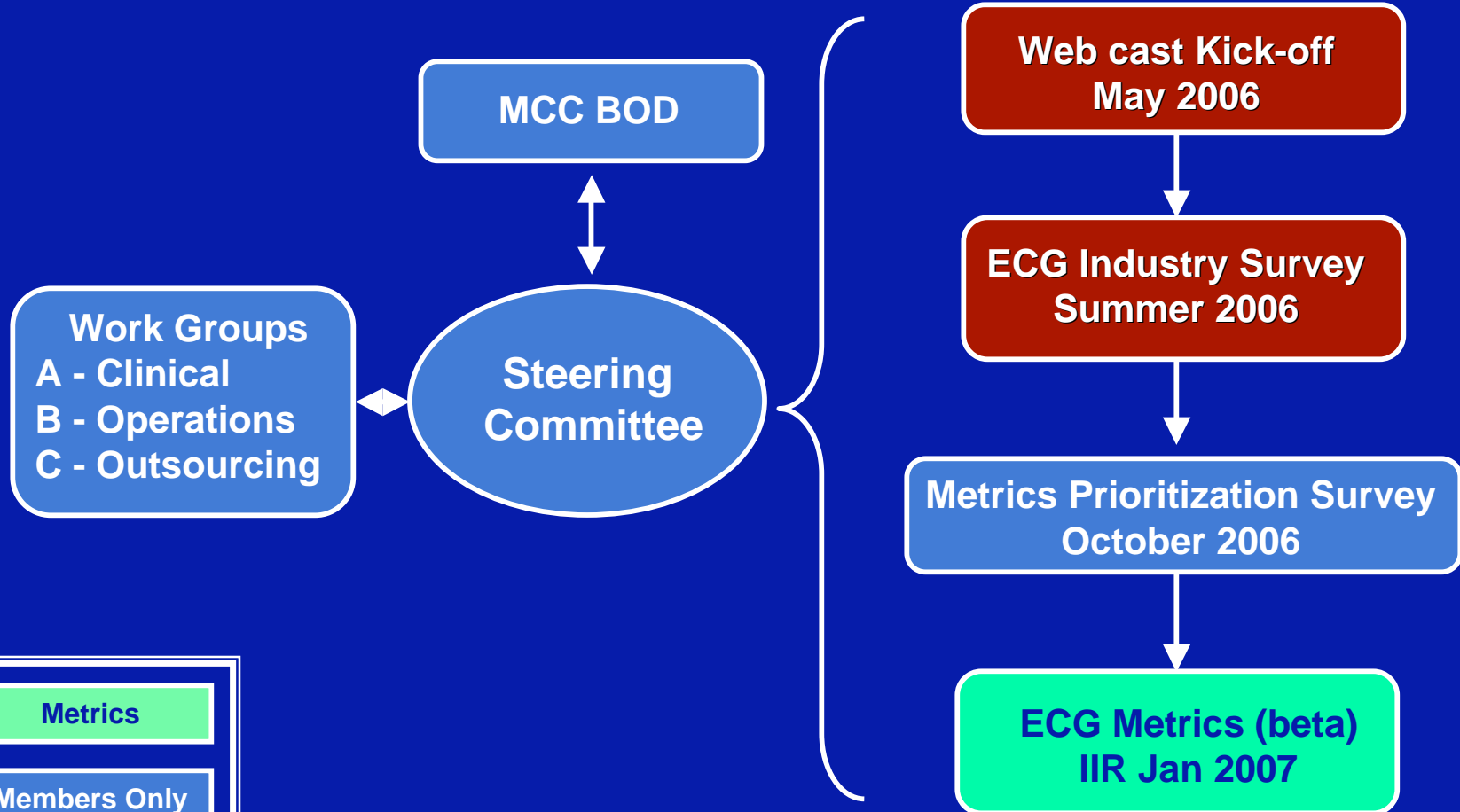
**Advisory Board participants
were not the right players to
drive implementation of
performance metrics within
their organizations**

ECG Metrics Development Process

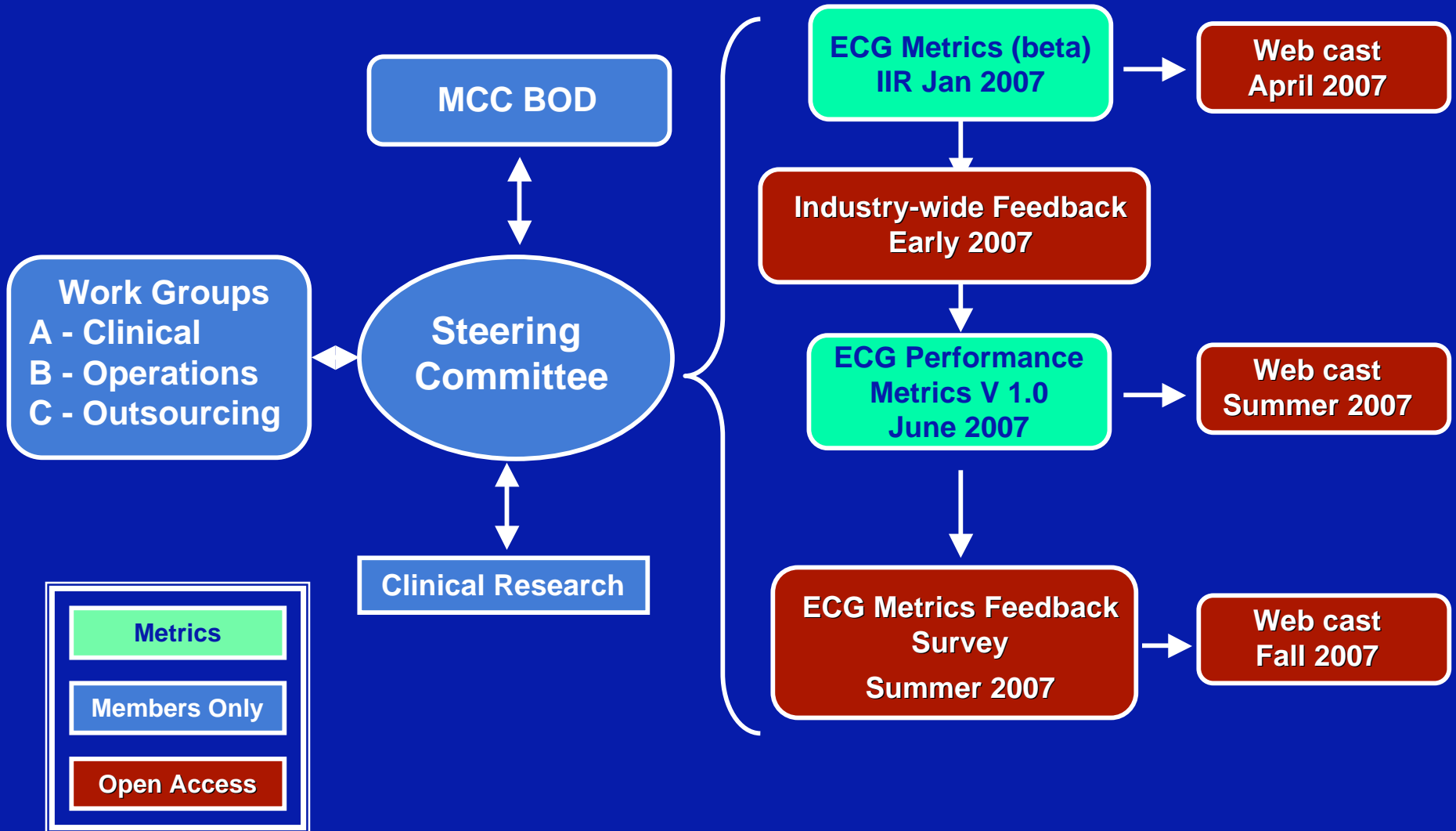
An Improved Approach

- Increased participation of service providers
 - ECG Steering Committee
 - Participated in all 3 Work Groups
- Recruited Work Group participants that felt strong ownership for metrics within their organizations.

ECG Metrics Development Process



ECG Metrics Development Process



MCC ECG Performance Metrics

Metric	Title
1	% ECGs reported within agreed turnaround time
2	% On-time equipment shipments to sites
3	% of queries from vendor to site
4	Turnaround time on resolution of site queries
5	% of on-time, accepted file transfers
6	Key personnel turnover during protocol
7	% of alerts successfully communicated to sites within turnaround time
8	Average days from specifications signature ready to receive ECGs
9	% Audit findings closed within timelines
10	% Sites who conduct test transmission prior to FPV
11	Average turnaround time on replacing faulty equipment
12	% of equipment failure
13	Average days from study award to contract signature

Metric	Title
14	Average % of variance maintained in budget
15	% ECGs interpretable from one study
16	% Manual adjustments of QT annotations from one study
Metrics 17-25: FDA ECG Warehouse	
17	Global low frequency noise content
18	Global high frequency noise content
19	Low frequency noise content around T-offset annotations
20	High frequency noise content around T-offset annotations
21	T-wave signal strength for beats with T-offset annotations
22	Signal-to-noise ratio of T-wave signal to high frequency noise content around T-offset annotations
23	% ECGs without annotations
24	% ECGs without annotations on expected number of QTs in primary lead
25	% ECGs with annotations in multiple leads

ECG Metrics Development Process

Lessons Learned

**ECG Steering Committee
comprised of 2 sponsors
and 1 service provider**



**All MCC Steering Committees
will have a minimum of 3
sponsors and 2 service
providers who will lead future
initiatives.**

**Work Groups comprised of
sponsor & service provider
representatives with strong
ownership for metrics
within their organizations**



**Significantly reduced metrics
development process timeline**

**Work Group members reported
great value in participating in
development process -- good
collaborative experience**

**Clinical Work Group requested
to conduct benchmarking
research in 2007**

Conclusion

- MCC Performance Metrics Development Model is evolving
- MCC members interested in developing CRO Performance Metrics