

Workshop B5

Metrics in Action: Lessons Learned from Implementation of MCC Metrics

IIR 5th Annual Partnering with Central Labs, ECG and
Imaging Labs
Pre-conference Workshop
January 17, 2007



1:30 – 1:50 pm

Introductions & MCC Overview

1:50 – 3:00 pm

Breakout Groups

1:50 – 2:40 Group Breakout Discussions

2:40 – 2:50 Group 1 presentation

2:50 – 3:00 Group 2 presentation

3:00 – 3:30 pm

Break

3:30 – 4:15 pm

Case Study Presentation

4:15 – 5:00 pm

Panel Discussion/Q&A

Purpose of Today's Workshop

- Provide you the opportunity to learn about the MCC Laboratory Performance Metrics and their implementation to date
- Compare how the metrics are being used by sponsors and service providers.
- Explore ways to address challenges to implementing the MCC Laboratory Performance Metrics

- **Brian Schrock**
Black Belt, Lilly Research Laboratories ELI LILLY AND COMPANY
Chairman, Board of Directors MCC
- **Sarah Martin-Munley, PhD**
Senior Director, Clinical Programs VERTEX PHARMACEUTICALS
Laboratory Metrics Steering Committee Chair MCC
- **Judy Klein**
Manager, CSS&P AMGEN
- **Cynthia Lindemann**
Central Laboratory Coordinator ELI LILLY AND COMPANY
- **Phyllis Haldimann**
Associate Director, Business Support Services QUINTILES
- **Guy Mascaro**
President MCC

Metrics Champion Consortium 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.

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.

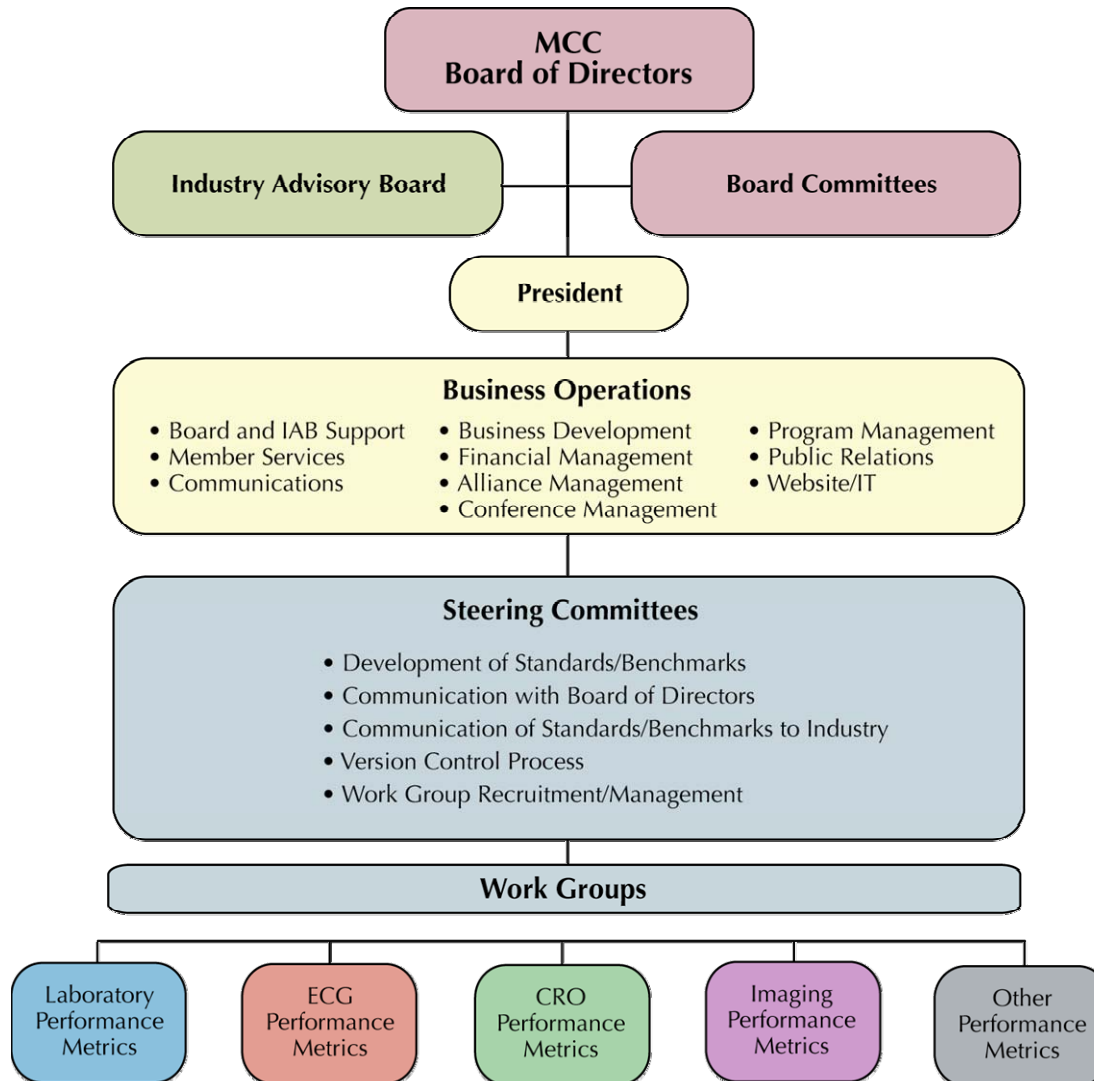
Motivation for Consortium

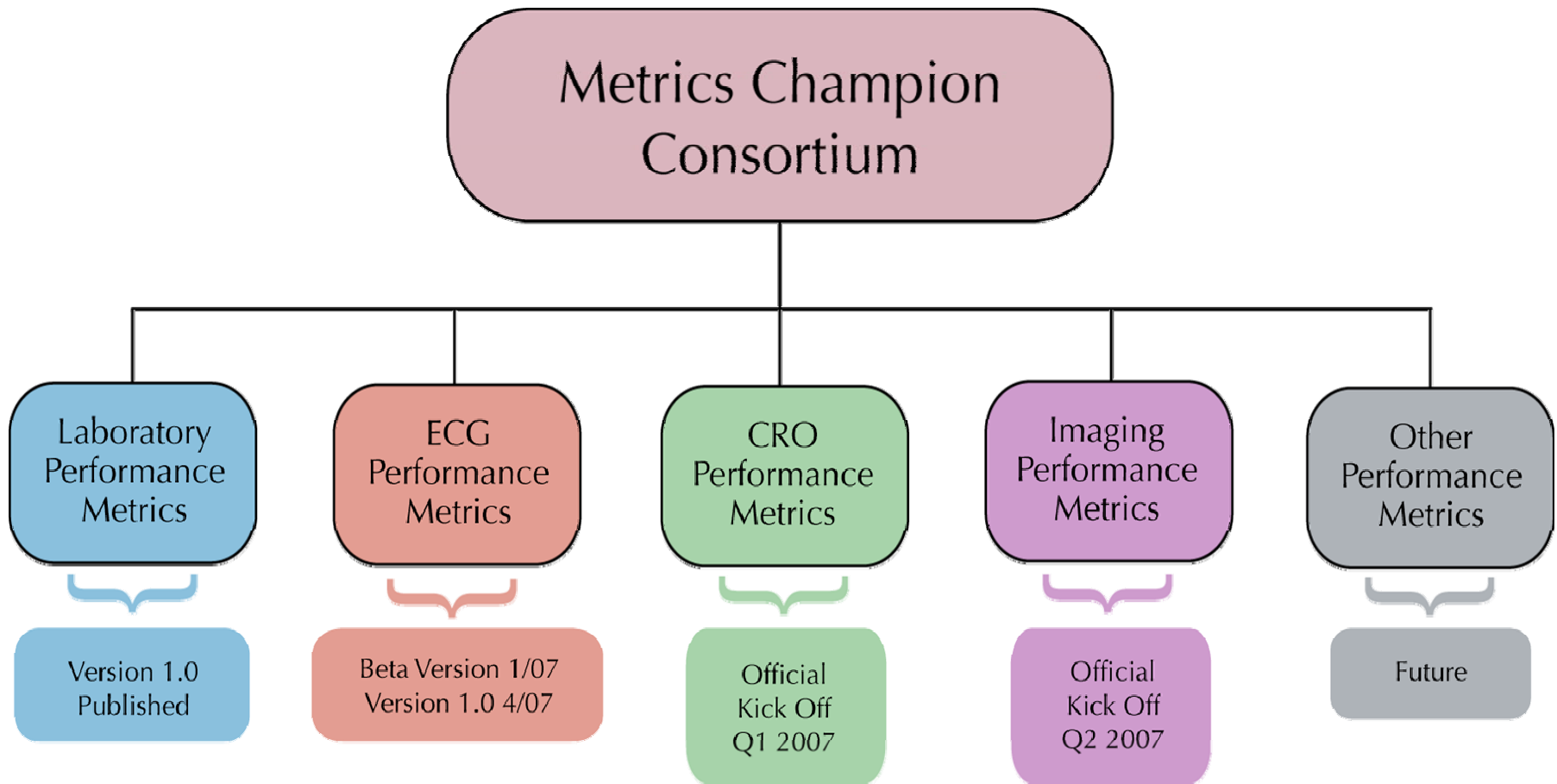
Industry must become more productive!

“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

- 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





- 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.

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.”*

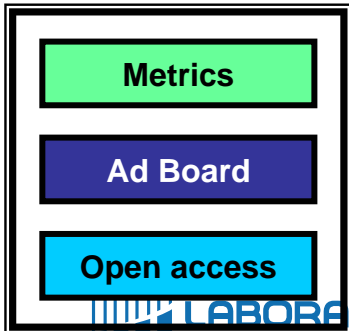
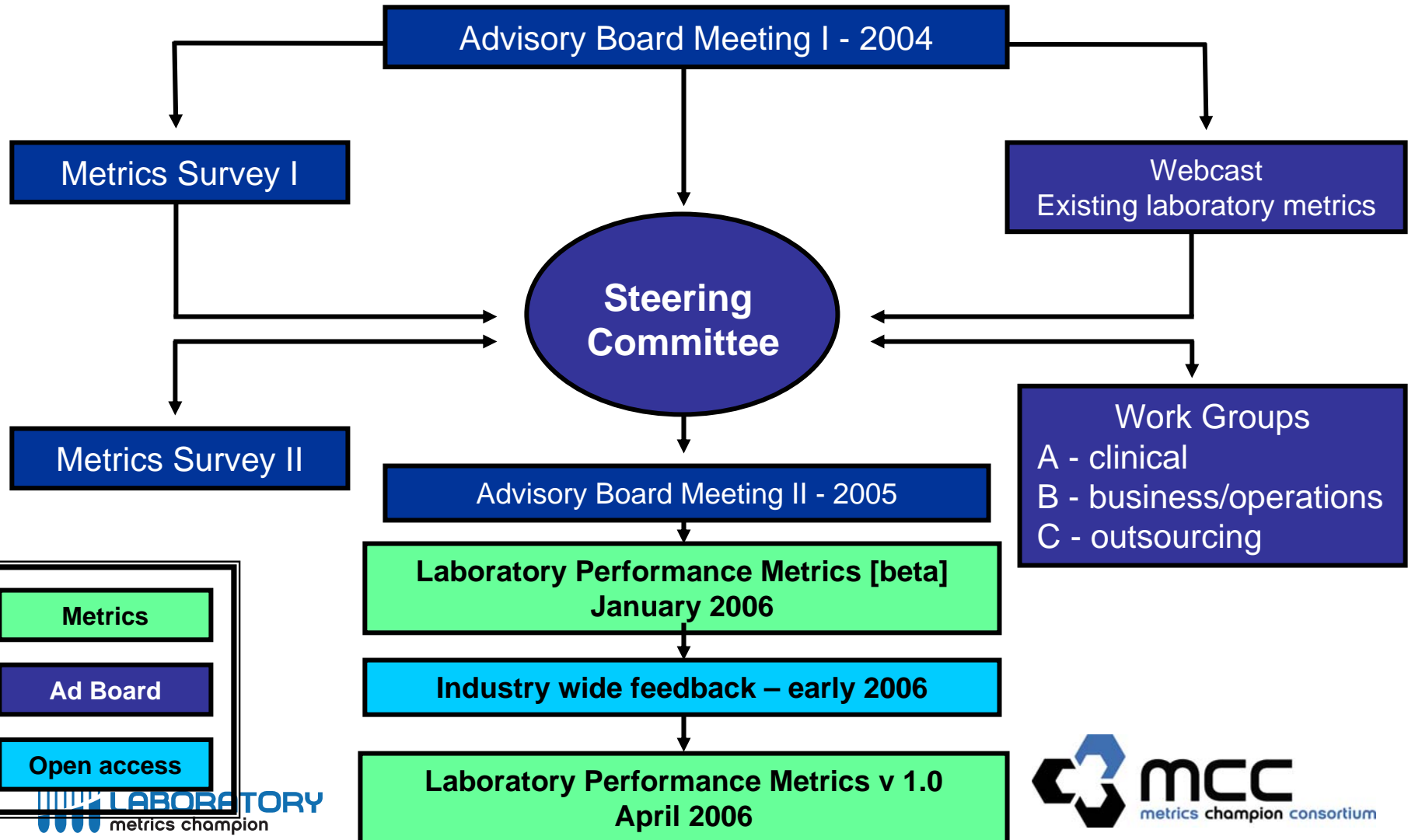
Common Questions/Concerns

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

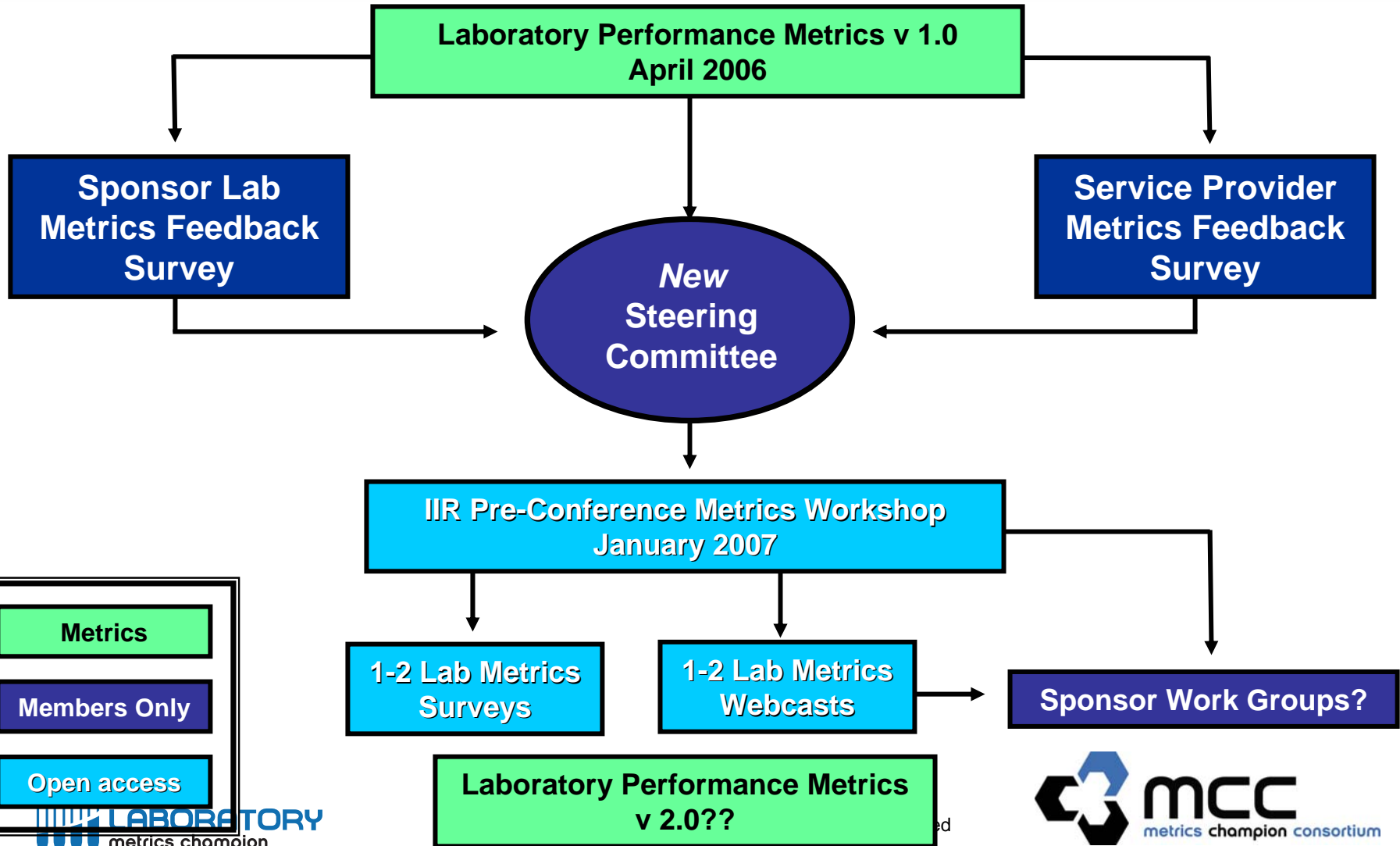
Laboratory Performance Metrics




Lab Metrics Development Process



Lab Metrics Development Process



Metrics
Members Only
Open access



Laboratory 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 #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.

Laboratory Performance Metrics

Metric	Category	Metric Title	General Benefit Statement
1	General Operations	Project management turnover during protocol	You will be informed of the service provider's project management staff turnover. This will allow evaluation of their ability to maintain consistent staff so that provider / sponsor continuity and associated lessons learned can be carried forward from protocol to protocol. This evaluation could help aid in discussions with the service provider should their services be negatively impacted by personnel not meeting expectations and / or not applying standard processes and / or lessons learned.
2	Protocol Initiation	Average number of working days from statement of work signature to "database ready"	You will be informed regarding the service provider's timely, effective development and completion of the database based on the contractual timelines. This will allow you to appropriately support the delivery of the first patient visit per the protocol timeline.
3	Site Initiation	Percentage first supplies shipped on time	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.
4	Data Cleaning	Percentage of queries from central laboratory to site based upon requisitions received	<p>You will be informed regarding the service provider's overall query levels and turnaround times. In addition, you will be informed as to the manner in which the site is able to effectively complete the required laboratory visits/requisitions. This information will allow you to identify those sites that may be struggling and address the challenges proactively via training, etc. as a reduction in queries helps to ensure that testing is completed / results provided in a timely fashion.</p> <p>Specifically, you can evaluate with the minimum report:</p> <ul style="list-style-type: none"> • Overall query rate per requisitions returned • Overall query resolution turnaround time per sponsor <p>Specifically, you can evaluate with the "for cause" report:</p> <ul style="list-style-type: none"> • Query rate per requisitions returned for a protocol • Query resolution turnaround time for a protocol • Reasons for the queries which are occurring • Site training opportunities • Protocol design considerations

Laboratory Performance Metrics

Metric	Category	Metric Title	General Benefit Statement
5	Data Cleaning	Average turnaround for resolution of queries from central laboratory to site	Refer to Benefits for Metric #4
6	Site Support Services	Percentage of queries from site to central laboratory based upon requisitions received	<p>You will be informed of the service provider's delivery with regards to central laboratory related site requests / needs. This information in conjunction with site feedback will allow you to proactively manage both the site and service provider expectations / services as the relationship between the two is critical to the success of the protocol.</p> <p>Specifically, you can evaluate with the minimum report:</p> <ul style="list-style-type: none"> • Query rate per requisitions returned • Query resolution turnaround time for the service provider <p>Specifically, you can evaluate with the "for cause" report:</p> <ul style="list-style-type: none"> • Query rate per requisitions returned for a protocol • Query resolution turnaround time for a protocol • Reasons for the queries which are occurring
7	Site Support Services	Average turnaround time on queries from site to central laboratory	Refer to Benefits for Metric #6
8	Safety	Percentage of panics successfully communicated to the sites within the defined turnaround time	<p>You will be informed regarding the service provider's delivery of panics to the sites so that you can evaluate and ensure that patient care is being maintained. In addition, timely, successful communication of alerts to the sites promotes site confidence in provider and sponsor.</p> <p>Specifically, you can evaluate:</p> <ul style="list-style-type: none"> • Panic turnaround delivery per protocol • Panic turnaround deliver per sponsor • Panic turnaround delivery per geography

Laboratory Performance Metrics

Metric	Category	Metric Title	General Benefit Statement
9	Laboratory Operations	Percentage specific test(s) reported within expected turnaround time	<p>You will be informed regarding the service provider's ability to meet the committed turnaround time for specific test(s) so that the sites receive timely laboratory reports in order to make informed decisions for patient care (safety) and protocol execution (inclusion / exclusion).</p> <p>Specifically, you can evaluate with the minimum report:</p> <ul style="list-style-type: none"> • General reporting meets contractual expectations • Essential test reporting meets protocol inclusion / exclusion requirements • Batch test reporting meets turnaround times • Referral testing reporting meets turnaround times <p>Specifically, you can evaluate with the "for cause" report:</p> <ul style="list-style-type: none"> • Sponsor-specific turnaround time requirements are met • Protocol-specific turnaround time requirements are met • Geographic turnaround (e.g. lab, sponsor, protocol)
10	Laboratory Operations	Percentage tests not reportable	<p>You will be informed of your test rate loss across your data sets thus allowing you to determine the impact of the data loss on the protocol and associated analyses. In addition, you can determine if there is a trend in these 'lost or unreportable' data in terms of clotting, hemolysis, mishandled and not received thus allowing you to retrain sites if appropriate to address those issues and increase the number of tests that are reportable / analyzable.</p> <p>Specifically, you can evaluate with the minimum report:</p> <ul style="list-style-type: none"> • General reasons and trends for the loss (e.g. clotting, mishandled, hemolysis, etc.) • Specific / primary markers to determine if lose rate may need to be reviewed in depth for a specific protocol • Geographic region trends <p>Specifically, you can evaluate with the "for cause" report:</p> <ul style="list-style-type: none"> • Protocol specific reasons and trends for the loss (e.g. clotting, mishandled, hemolysis, etc.) • Specific / primary markers lose rate and associated trends for a protocol • Geographic region impact and trends within a protocol

Laboratory Performance Metrics

Metric	Category	Metric Title	General Benefit Statement
11	Laboratory Operations	Percentage shipments/ samples shipped from central laboratory on time to sponsor-directed third party	<p>You will be informed regarding the service provider's delivery of the sample shipments to your third party providers per your defined expectations so that they can then in turn meet their timeline / expectations. This is often a critical step as the third party provider's testing is most commonly esoteric testing (more complex assays) that may require a longer turnaround time and may often be rate limiting for the protocol if the timeline is not met.</p> <p>Specifically, you can evaluate with the minimum report:</p> <ul style="list-style-type: none"> • Overview of shipments "on-time" • Overview of shipments not on time and the extent to which they are "late" <p>Specifically, you can derive with the "for cause" report:</p> <ul style="list-style-type: none"> • Samples shipped "on-time" (e.g. lab, sponsor, protocol) • Samples not shipped on time and the extent to which they are "late" (e.g. lab, sponsor, protocol)
12	Data Management	Percentage on time accepted file transfers	<p>You will be informed that the service provider is providing the data according to your defined expectations to support the final protocol report timeline. In addition, the "whys" behind performance challenges can be discussed and process improvements defined to assist current / future protocols.</p>

Laboratory Performance Metrics

Metric	Category	Metric Title	General Benefit Statement
13	Financial Management	Plan, Forecast and Actual Financial Report	<p>You will be informed via this budget reconciliation of the financial progress of your protocol (i.e. forecast compared to actual spend).</p> <p>Specifically, you can evaluate based on the information provided:</p> <ul style="list-style-type: none"> • Ability to request accurate forecasts • Ability to maintain budgets to "updated projected budget" • Comparison of final spend to budget • Identify areas where you may need to adjust your forecast in the future • Identify areas where you may need to adjust your actual spend rate • Identify areas that you can proactively evaluate during protocol development to assist in cost management
14	Financial Management	Comparison of budgeted and actual transportation costs by region and/or country	<p>You will be informed as to financial impact of the transportation costs on the your forecasted budget.</p> <p>Specifically, you can evaluate based on the information provided:</p> <ul style="list-style-type: none"> • Assess for trends in spending (i.e. mismanagement at various locations) • Ability to assess the accuracy of the original forecasts for transportation; apply learning to the next forecast • Ability to update budgets as reviewed to more accurately reflect costs which will be incurred over the course of the protocol's execution; allows proactive communication of these budget updates • Comparison of final spend to budget for transportation • Actions that can be shared with the sites to assist in cost management (e.g. number of shipments, etc.)
15	Quality Assurance	Percentage of audit findings closed within sponsor and central laboratory agreed upon timeframe	<p>You will be informed regarding the service provider's success in resolving audit findings. Thus, as a customer, you will be in a better position to understand service provider risk and proactively manage these risks.</p>

Purpose:

Provide participants the opportunity to share challenges, issues, concerns about implementing standardized performance metrics in an open forum with peers.