

Current and Future MCC Metrics Initiatives

Guy Mascaro, *President*

Sue Hwang, *Amgen*

Steve Asbury, *Eli Lilly*

David Rauh, *Eli Lilly*

**7th Annual Partnering with Central Labs,
ECG and Imaging Labs Conference**

January 27, 2009 Las Vegas, NV

Agenda

- MCC Overview
- MCC Metrics Initiative Updates & 2009 Plans
 - Central Lab Metrics: Sue Hwang
 - ECG Metrics: Steve Asbury
 - Imaging Metrics: David Rauh
 - CRO Metrics: Guy Mascaro
- Conclusion
- Q&A

Industry Under Pressure to Improve R&D Productivity

Today's drug development industry is under increased pressure to improve R&D development performance / strategies by reducing drug development times and costs, while at the same time increasing productivity and maintaining quality.

Overview

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

MCC Mission Statement

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 in support of the drug development process.

MCC Membership

- 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

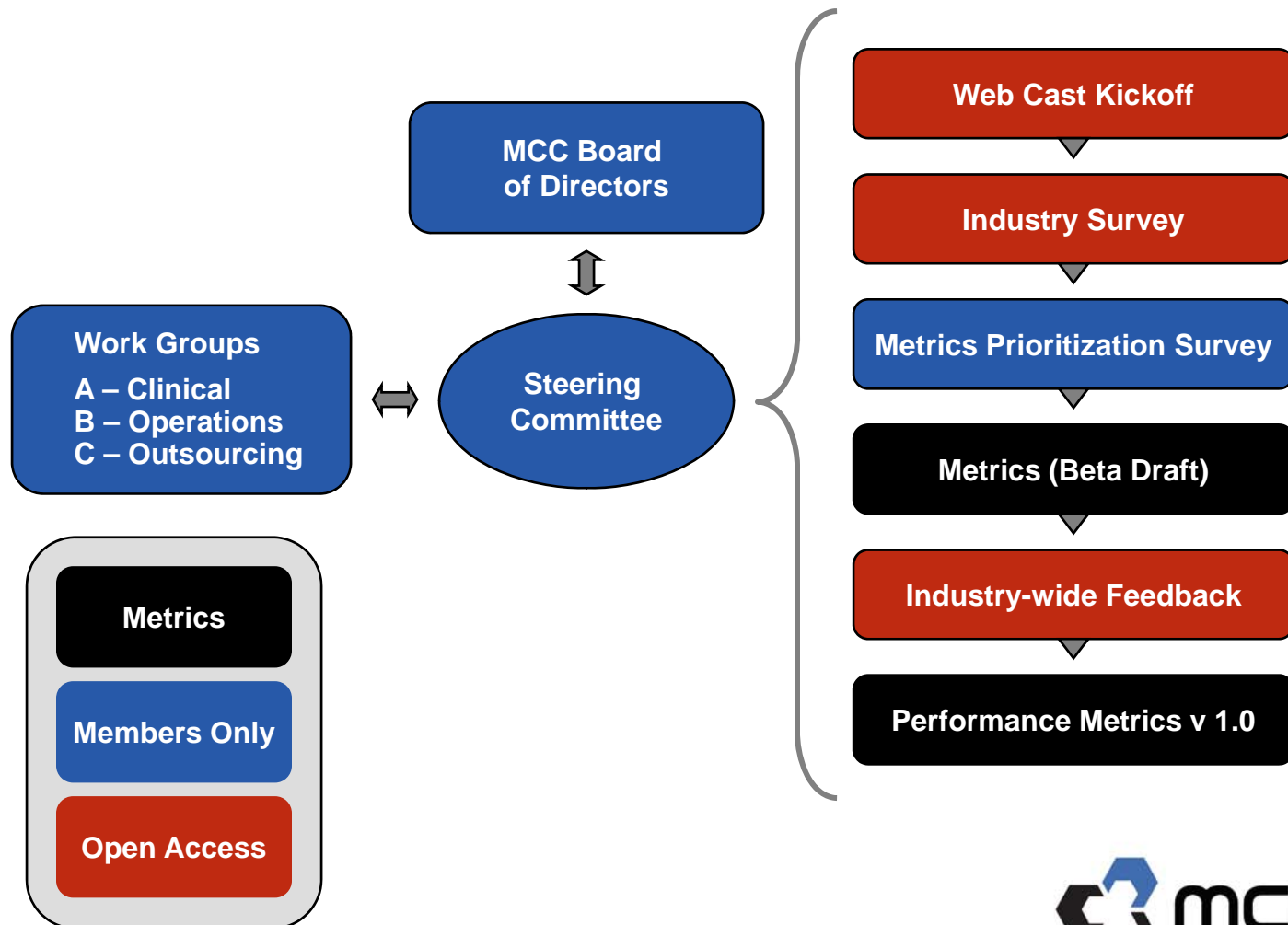
MCC Membership

Company Size	Corporate Sponsorship	Corporate Membership	Associate Membership
>1,000 employees	1 st Yr \$35K Annual \$10K	1 st Yr \$10K Annual \$10K	N/A
501-1000	1 st Yr \$15K Annual \$5K	1 st Yr \$5K Annual \$5K	N/A
100-500	1 st Yr \$10K Annual \$3K	1 st Yr \$3K Annual \$3K	N/A
<100	1 st Yr \$3K Annual \$1K	1 st Yr \$1K Annual \$1K	N/A
Academic Institutions			1 st Yr \$1K Annual \$1K

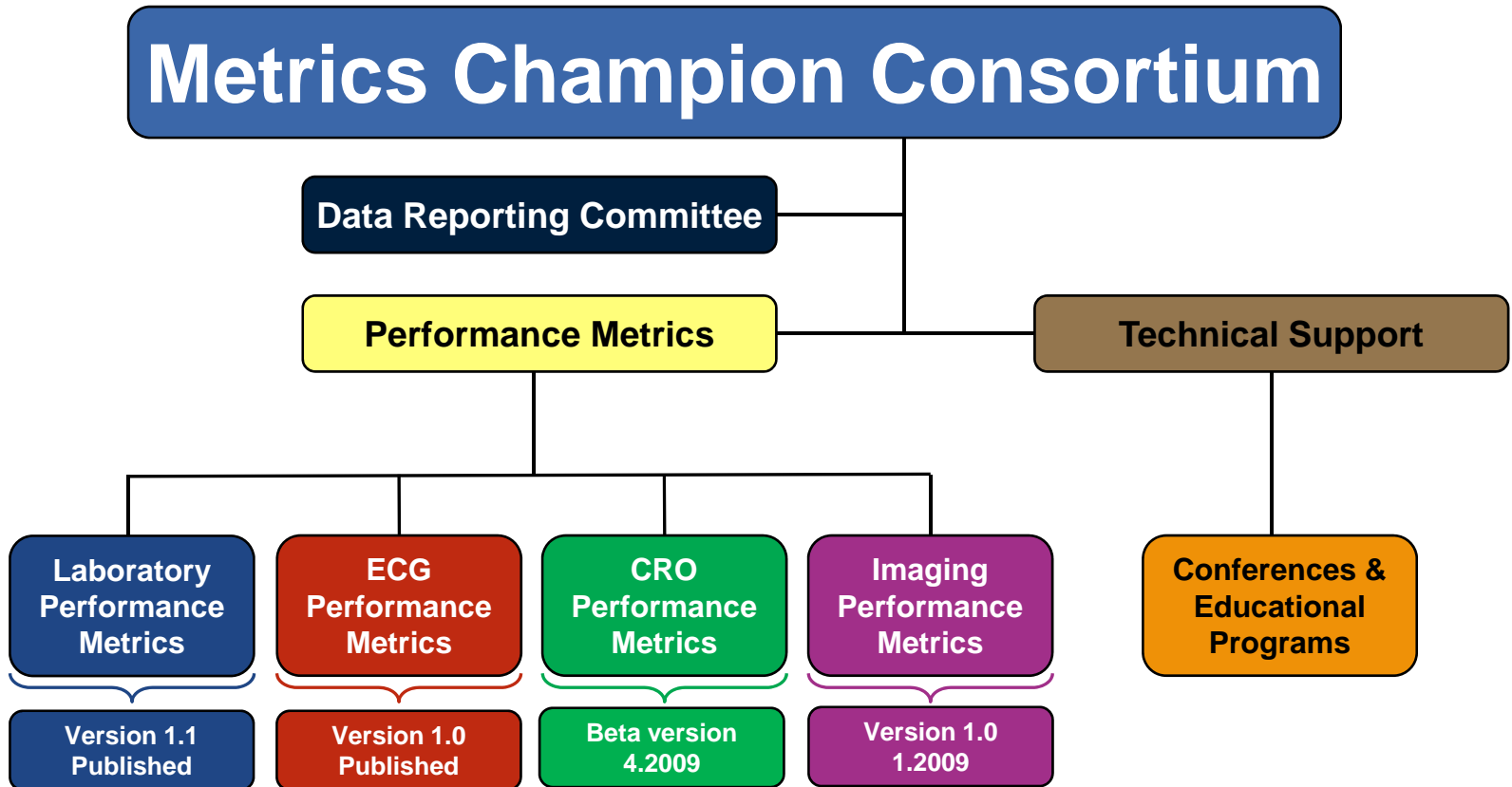
MCC Membership

Company Size	Corporate Sponsorship	Corporate Membership	Associate Membership
>1,000 employees	1 st Yr \$35K Annual \$10K	1 st Yr \$10K Annual \$10K	N/A
501-1000	1 st Yr \$15K Annual \$5K	1 st Yr \$5K Annual \$5K	N/A
100-500	1 st Yr \$10K Annual \$3K	1 st Yr \$3K Annual \$3K	N/A
<100	1st Yr \$3K Annual \$1K	1st Yr \$1K Annual \$1K	N/A
Academic Institutions			1st Yr \$1K Annual \$1K

Metrics Development Process



MCC Overview



2008 Highlights

- Added ACRO representation to the MCC Board of Directors
 - Sean Larkin, PharmaNet
 - Paul Colvin, PPD
- Expanded MCC membership
- Continued to build strong “learning community” through web-based work group meetings and online collaborative workspace



Sue Hwang

Senior Manager, R&D Global Strategic Sourcing
Amgen

Central Lab Metrics Initiative 2008 Update



- Engaged representatives from 5 Sponsor and 7 Central Lab organizations in Metrics Definition Refinement WG
- Released Central Lab Performance Metrics v 1.1
- Conducted Implementation WG meetings

Central Lab Metrics Initiative 2009 Activities



- Launch/relaunch MCC CL work groups:
 - Data collection tool
 - Create a standard data reporting template
 - Implementation / Shared Learning
 - Develop case studies
 - Develop “white paper” (How to use metrics to improve clinical trial performance)
 - Develop “Welcome Packet” and other training aids

Central Lab Metrics Initiative Conference Session



1.28.09 Track A: Central Lab Relationship Development

*1:30 pm Overview of Metrics: Definition
Refinement & Update from the
MCC Lab Metrics Initiative*

Sue Hwang, Senior Manager, R&D
Global Strategic Sourcing, **Amgen**

Cynthia Lindemann, Central Laboratory
Coordinator, **Eli Lilly & Company**

Alissa Kerry, Sr. Manager,
Business Process Measurements,
Covance Central Laboratory



Steve Asbury

Global ECG Coordinator
Eli Lilly & Company

ECG Metrics Initiative 2008 Update



- Developed ECG Case Studies
- Conducted web-based Implementation WG sessions
- Began development of Inter-, Intra-reader variability QA metrics
- MCC ECG Metrics initiative acknowledged as important player in ECG arena by Dr. Norman Stockbridge, FDA –CDER at an ECG industry meeting (October 2008)

ECG Metrics Initiative

2009 Activities



- Conduct Sponsor & ECG Core Lab surveys
- Update ECG Case Studies
- Reconvene Clinical WG to focus on QA metrics (variability metrics)
- Support Implementation through Implementation/Shared Learning Working Group
- Begin metrics review process in late 2009

1.27.09 Track C: Improving and Standardizing ECG and Cardiac Safety Studies –

4:15 pm Using the MCC ECG Metrics

Jeffrey Litwin, MD, Chief Medical Officer & EVP,
eResearchTechnology

Steve Asbury, Global ECG Coordinator,
Eli Lilly & Company



David Rauh

Clinical Diagnostic Services Imaging Management,
Eli Lilly & Company

Imaging Metrics Initiative 2008 Update



- 22 Sponsor & Imaging Core Labs participated in three metrics work groups:
 - Operations
 - Outsourcing
 - Clinical
- Featured speakers at PhRMA/FDA Imaging meeting October 2008
- Developed MCC Imaging Metrics (beta version)

Imaging Metrics Initiative 2009 Activities



- Launch Implementation WG to support implementation, including development of standard data reporting template
- Clinical WG to assess provisional variability metrics
- Continue to gather industry feedback to enhance metric implementation and use.

Imaging Metrics Initiative Conference Session



1.27.09 Track B: Standardization in Imaging Studies

*2:00 pm MCC Imaging Performance
Metrics Announcement*

David Rauh
Clinical Diagnostic Services Imaging Management
Eli Lilly & Company



Guy Mascaro

President

Metrics Champion Consortium



CRO Metrics Initiative 2008 Update



- Launched metrics development process at Partnerships with CROs Conference (4.08)
- Convened 5 work groups:
 - Biometrics (Biostatistics & Data Management)
 - Business Operations / Finance
 - Clinical Operations / PM/ Medical Writing
 - Drug Supply
 - QA / Regulatory Affairs / Safety
- Held MCC Metrics workshop (11.08)

CRO Metrics Initiative

2009 Activities



- Release CRO performance metrics [beta version] at full-day workshop at 2009 Partnerships with CROs meeting
- Workgroups will continue to meet throughout 2009
- Gather industry feedback and release CRO performance metrics [v1.0] by December 2009

Conclusions

- MCC metrics initiatives made significant progress in 2008
- 2009 will be an important year:
 - Release Imaging and CRO metrics
 - Develop additional case studies
 - Support metrics implementation among sponsor/service provider partnerships
- No current plans to launch new metrics initiatives in 2009

Questions?

Please visit www.metricschampion.org or contact Guy Mascaro and Linda Sullivan at 1.317.848.2908

