

MCC ECG Performance Metrics v 1.0 and Next Steps

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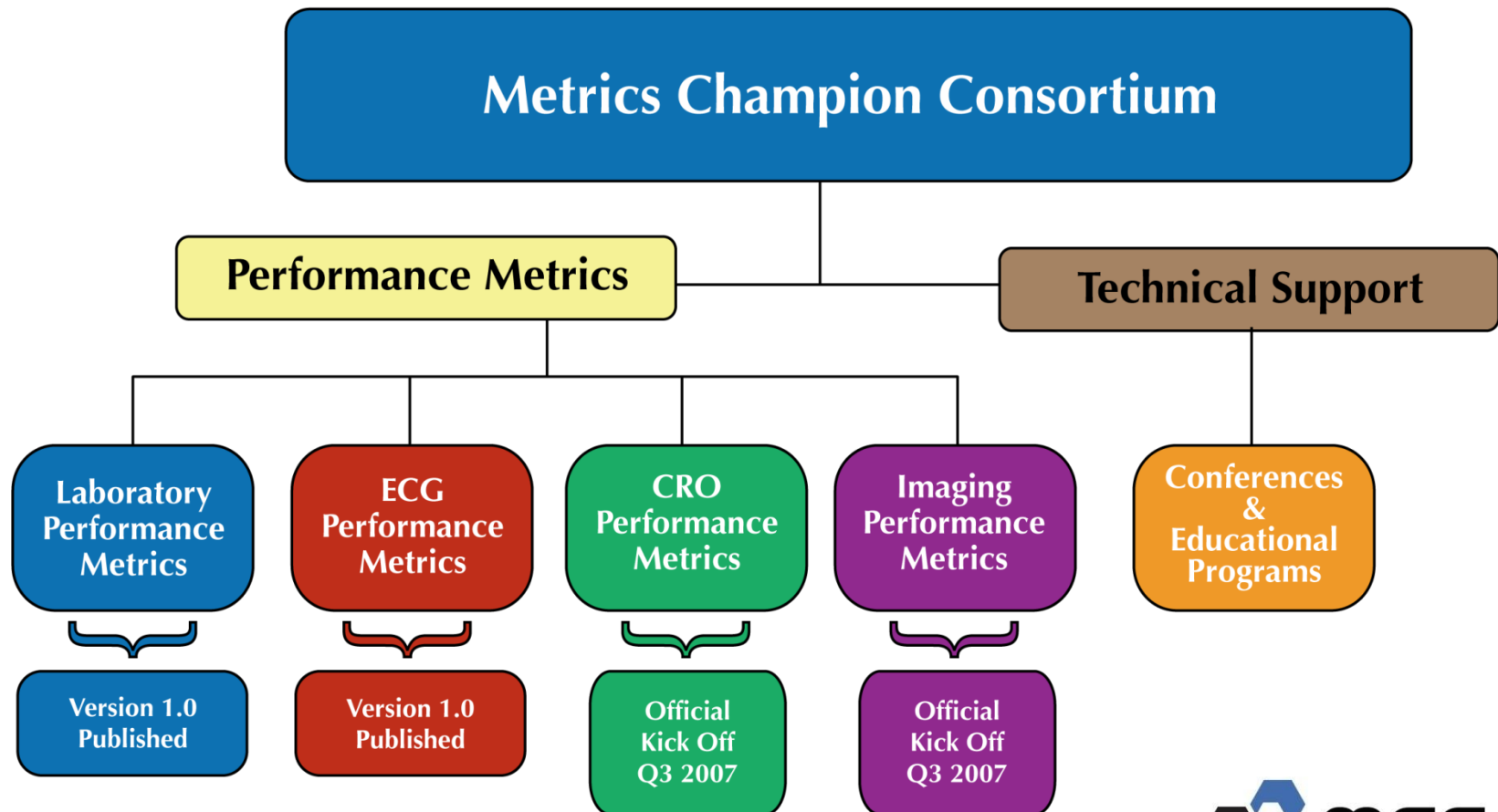
- Introductions from ECG Steering Committee
- Update on MCC activities
- MCC ECG Performance Metrics (v 1.0) & draft data collection tool
- MCC ECG Performance Metrics Initiative plans for 2008
 - New Working Group format for 2008
 - Upcoming MCC metrics events
- Q&A

New Pharma / Biotech Members

- Medarex
- Merck
- Pfizer
- Wyeth

New Service Providers Members

- Bio-Imaging Technology
- Mayo Clinical Trial Services
- MDS Pharma
- Perceptive Informatics
- PharmaNet
- PPD
- RadPharm



MCC ECG Performance Metrics v 1.0

Metric	Metric Title
1	Average number of days from ECG study award to contract signature Note: For stand-alone ECG projects
2	Average number of days from signed ECG technical specifications document (TSD) signature to vendor ready to receive ECGs
3	% of on-time ECG equipment shipments to sites
4	% of sites who conduct a successful test ECG transmission prior to 1st subject visit
5	% of ECGs reported to Investigator Sites within agreed turnaround time
6	% of ECG data queries from vendor to site
7	Turnaround time on resolution of ECG site queries from central vendor
8	% of ECG alerts successfully communicated to sites within defined turnaround time

Metric	Metric Title
9	% of ECGs received from one study that were interpretable by the core lab
10	% of manual adjustments of automated QT annotations from one study (semi-automatic "computer assisted" method with visual inspection and manual adjustment whenever necessary)
11	% of ECG equipment failure
12	Average turnaround time on replacing faulty ECG equipment
13	% of on-time, accepted ECG file transfers
14	Key ECG core lab personnel turnover during protocol
15	% of ECG core lab audit/assessment findings closed within agreed timelines
16	Average % of variance maintained in the ECG budget

MCC ECG Performance Metrics v 1.0

SPECIAL NOTE

Inter-/Intra-reader Variability Metrics: Due to the various ECG over read methodologies as well as the variety or manners of assessing inter-/intra-reader variability amongst the core labs, a defined and standardized set of variability metrics is not available at this time. However, since the ICH E14 (“The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs”) calls for these metrics (by stating “The degree of inter- and intra-reader variability should be established by having the assessors reread a subset of the data (both normal and abnormal) under blinded conditions”), it is very important that the core labs create these variability data and the sponsors should both review the data as well as understand how it was created. The data generated by each core lab should be a standard adhered to by that lab for all work performed as this can have an impact on the quality of data generated during the study.

ECG Performance Metrics Collection Tool

- Tool for Sponsor and Corelab to collate and analyze data
- Early Version available in the members area of MCC website. If you do not know your user/password contact Linda Sullivan at MCC.
- Central lab group is starting to develop a similar tool in effort to standardize approach.
- ECG Metrics Collection Tool is a “work in progress”

MCC ECG Metrics Initiative

Next Steps

MCC ECG Working Group

- Forming a single workgroup for 2008 (Integrated Sponsor – Core lab collaboration)
- Purpose is to discuss implementation issues, share best practices and identify areas for improvement
- Opportunities for Case study development that supports need for metrics both at supplier side and sponsor
- Collection of feedback on metrics for input on Version 2 to be revisited at the end of 2008 for potential refinement.
- Meetings to be held monthly and chaired by Steering Committee members with potential guest speakers.



Workshop B2: Lab Outsourcing 201
MCC Case Study-Implementation of MCC Central Lab Performance Metrics
Wednesday, January 23, 2008
2:15 – 3:30 p.m.

**Informal Session - Meet the MCC Central Lab, ECG and
Imaging Performance Metrics Steering Committees**
Thursday, January 24, 2008
7:30 – 8:30 a.m.
Grand Ballroom, Salon 6

Plenary Session
**Using Performance Metrics to Strengthen
Partnerships & Increase ROI**
Thursday, January 24, 2008
11:00 – 11:30 a.m.



Practical Approach to Implementation and Utilization of MCC ECG Metrics
Thursday, January 24, 2008
1:50 – 2:30 p.m.



**MCC Leader Update - Lilly, Amgen & Merck Detail Their Efforts to Standardize
Performance Metrics for Imaging Core Labs**
Friday, January 25, 2008
3:30 – 4:00 p.m.

Upcoming Events

17th Annual

Partnerships™
with **CROs**
and other Outsourcing Providers

April 14-16, 2008
Mandalay Bay, Las Vegas



Full-Day Workshop B1: Implementing Performance Metrics to Drive Time, Cost and Quality & Enhance Partnership Performance
Monday, April 14, 2008
9:00 – 4:30 p.m.

- New Members of MCC are welcome to join and participate in 2008 ECG Working Group
- MCC offers Sponsors and Suppliers an opportunity to improve what we do as an industry in a collaborative and innovative forum

Thank you for Participation today!

QUESTIONS?