

ECG Performance Metrics

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On behalf of the

Metrics Champion Consortium



Outline

- Metrics Champion Consortium Overview
- Process and Timeline
- Description of ECG Metrics and Benefits to the Industry

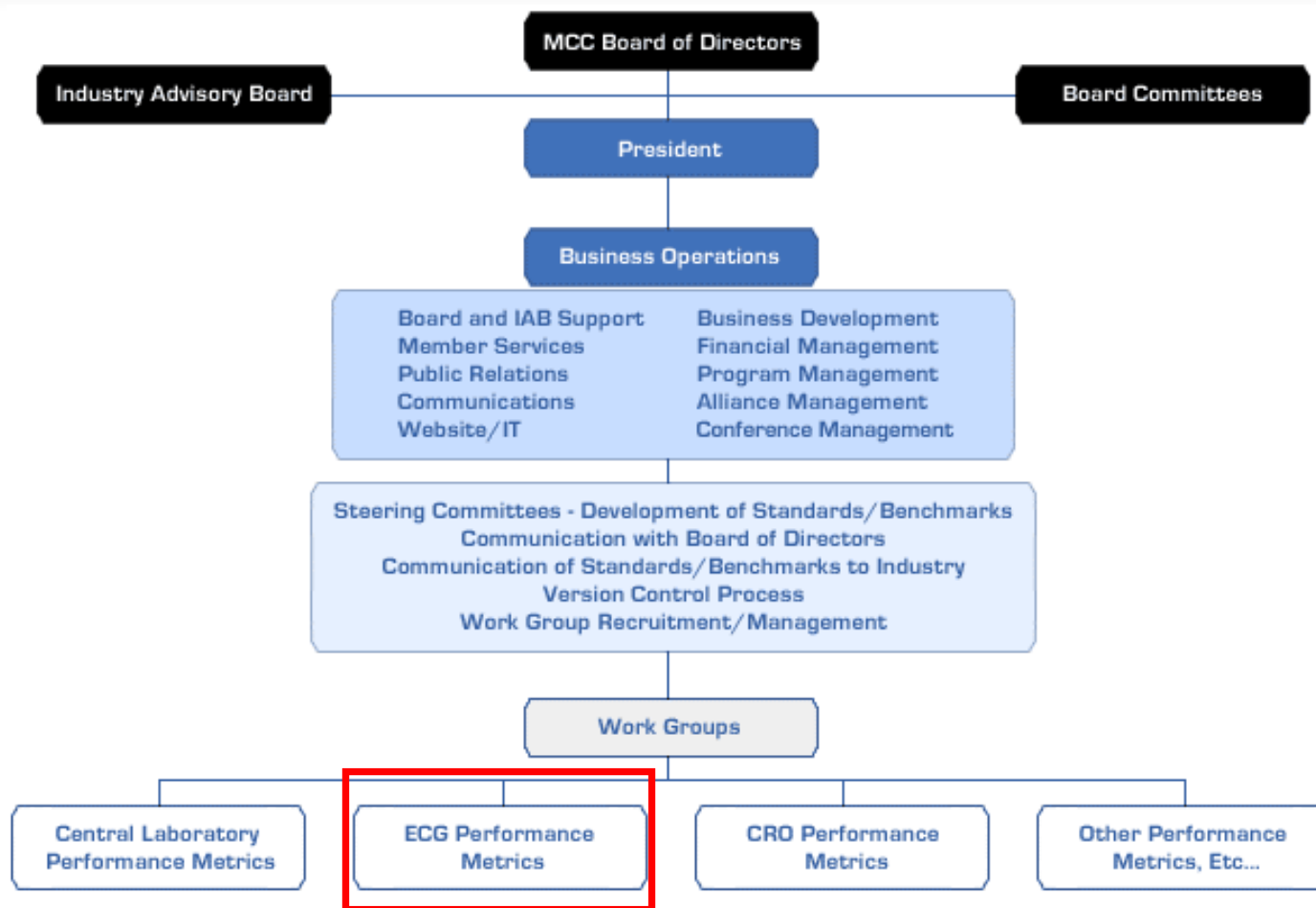
MCC Mission Statement

To 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.

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



ECG Performance Metrics Mission Statement

Develop and support a baseline set of ECG service provider performance metrics within the biotechnology and pharmaceutical industry with the intent to ***jointly*** encourage the sponsors, service providers and investigative sites in gaining performance improvement, effectiveness, efficiency, and appropriate levels of controls.

- Steering Committee formed in March 06
- Steering Committee members:
 - Nenad Sarapa MD, Executive Director, Translational Medicine, Daiichi Sankyo Pharma Development
 - Solomon Babani, Associate Director, CRO Management, Novartis Pharmaceuticals Corp.
 - Steve Asbury, ECG Coordinator, Senior Clinical Diagnostic Services Associate, Eli Lilly and Company

Current and Potential Participants

- **Biotech/Pharma**
 - AstraZeneca
 - Eli Lilly
 - Daiichi Sankyo
 - Novartis
 - Valeant

- **Service Providers**
 - Biomedical Systems
 - Quintiles
 - Covance
 - eRT
 - Spacelabs
 - Mortara
 - Cardiocore
 - St. Louis University

- **Special Consultants**
 - FDA – Norman Stockbridge
 - St Georges Medical School -- Marek Malik
 - ICH E14 Expert Working Group – Borje Darpo

ECG Performance Metrics Milestones

- November 2006 – ECG Steering Committee Finalizes ECG Performance Metrics [beta version]
- December 8 -15, 2006 – Board of Directors Reviews Metrics
- January 17-19, 2007 – 5th Annual IIR Partnering with Central Labs, ECGs and Imaging Labs Conference
 - Present ECG Performance Metrics (beta version)
- January – February 2007 – ECG Steering Committee reviews comments about ECG Performance Metrics
- April 2007 – ECG Performance Metrics v1.0 released

ECG Metrics Development

