

Overview of the Metrics Champion Consortium Imaging Metrics Initiative: History and Methodology

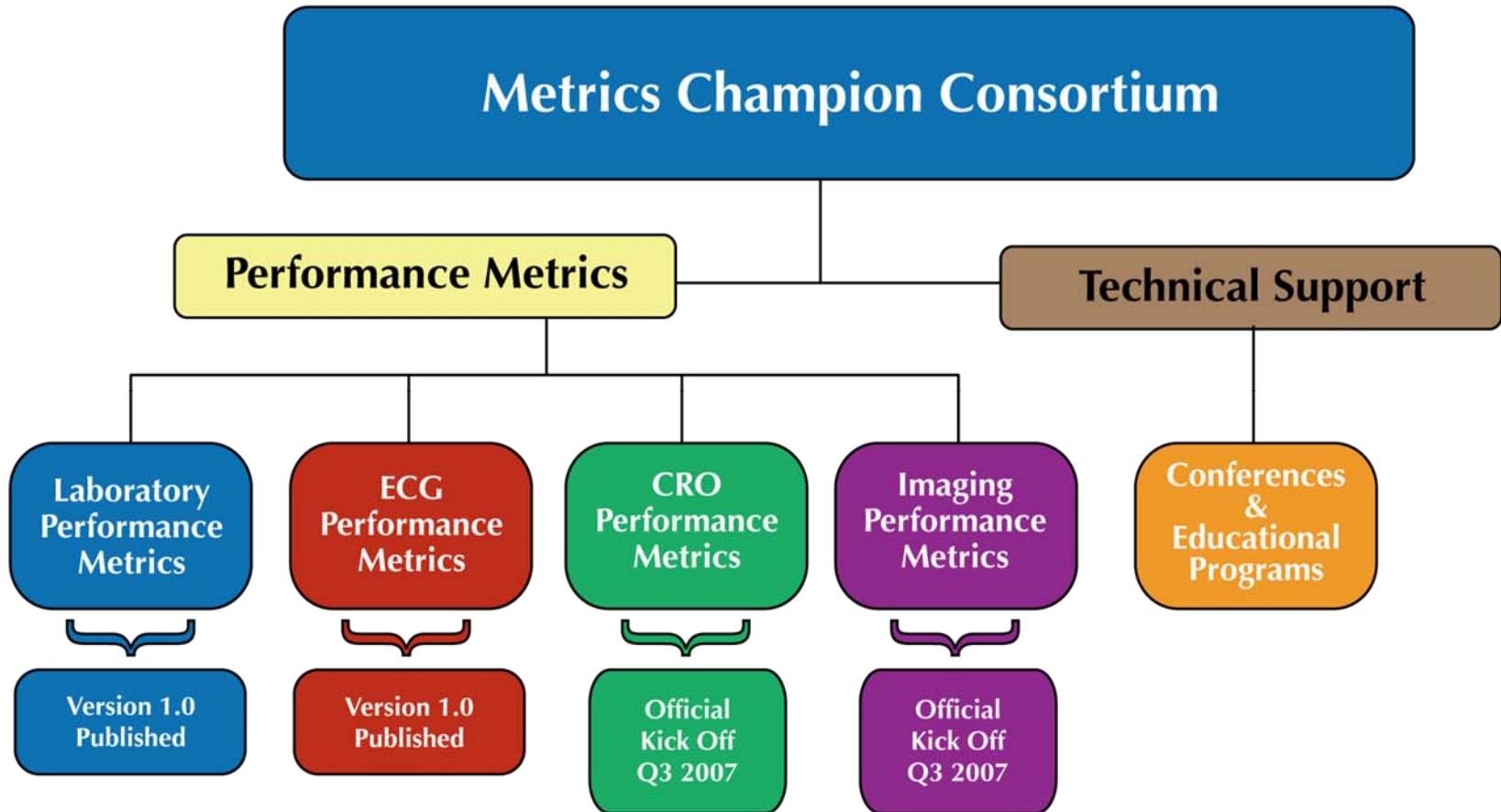
David Rauh, Eli Lilly and Company

DIA Conference: MEDICAL IMAGING CONTINUUM
Path Forward for Advancing the Uses of Medical Imaging in the
Development of New Biopharmaceutical Products, Bethesda, MD
October 2, 2008

- MCC Overview
- Imaging Metrics Mission
- Imaging Metrics Process
- Value of Participation
- Common Questions
- Open Discussion

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

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**.



- MCC organizations work collaboratively to develop standardized performance metrics which aim to improve the efficiency and effectiveness of clinical trial operations *for each* sponsor/supplier relationships.
- Organizations use the standardized performance metrics to identify opportunities to improve performance within their own sponsor/supplier relationship where results do not meet expectations within a study or across a group of studies.

- After identifying opportunities for improvement, sponsor/service provider partners work together to determine how best to enhance the process in order to ***improve performance and strengthen their partnership.***
- The MCC provides an environment for biotechnology, pharmaceutical and service provider organizations to share “best practices” and learn from each other through participation in MCC learning forums and collaborative work groups.

To develop metrics to provide consistent and **standardized performance measurement** for central image review covering clinical, operational, outsourcing/financial aspects of the **sponsor, core lab and site** delivery partnership. Consistent industry standard metrics will provide critical information for **decision making and drive change**. Specifically, the identification of areas for process improvement and issue escalation for all of the stakeholders in terms of **what works and what needs improvement**.

Immediate impact: Internal Sponsor & Core Lab Use:

Design, create and implement imaging metrics to allow for timely and accurate assessment of performance:

-- Site, study, compound, sponsor/core lab level

Expectation: Identify and jointly address areas for process performance. This may be site or study specific; it may be a sponsor or core lab process.

Long Term impact: Industry Use

Obtain baseline data which accurately reflects imaging performance in clinical trials.

Utilize baseline data to identify specific areas for industry process improvement.

The Process: Imaging Metrics Development

Imaging Metrics Steering Committee

- Formed in Dec 2007
- Composed of sponsor and core lab personnel
- Charge: Facilitate Imaging Metrics working groups

Working Groups

- Clinical, operations and outsourcing working groups were created to achieve metrics development goals
- Open to all sponsor and core lab personnel that join the MCC

Participation from sponsors and core labs provides objectivity and ensure a well balanced approach for metric development

The Process: Imaging Metrics Development

Working Groups

- Open discussion meetings focused on metrics development
- Utilize the MCC format for creating metrics
 - Metric title
 - Metric definition
 - Formula for deriving metric
 - Unit of measure
 - Recommended reporting frequency
 - Target threshold
 - Benefit statement

MCC Imaging Metrics Steering Committee

Clinical Working Group Leaders	Outsourcing Working Group Leaders	Operations Working Group Leaders
Helen Young, AstraZeneca Lewis Cohen, Medarex Bob Ford, RadPharm Ciaran Cooper, M2S Jim Conklin, ICON Medical Imaging	Craig Lipset, Pfizer Dawn Flitcraft, Bio-Imaging	Annette Chan, Amgen Kevin Jaynes, Perceptive
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Kristine Szabo, Schering-Plough
David Herron, Synarc
Joyce Suhy, Synarc
Mark Tengowski, Virtual Scopics
Christina Mastandrea, WorldCare Clinical
Patrick Chokron, WorldCare Clinical

Value of Participating in Consortium Activities

Industry benefits from participating in the MCC:

- Influence over development process
- Industry shared learning and problem solving
- Simplified review and analysis of metrics data
- Ability to conduct “Apples to Apples” comparison of performance metrics
- More time focused on solving problems
“Less debate about what you have and more time focused on solving problems”

Value of Participating in Consortium Activities

Standardized Metrics...Harmonized Reports... Performance Awareness...Increased Productivity

Sponsor:

- Metrics calculated the same for all your studies
- Access to timely and consistent data
- Ability to interpret data across the various spectrums (site, study, etc...)

Core Lab

- Provide the same standardized metrics in the same report format for all sponsors
- Ability to interpret data across the various spectrums (therapeutic, modality, etc...)
- Ability to track Sponsor metrics

A Common Question is: Will MCC publish metrics?

- Not at this time, data remains between Sponsor and Core Labs
- Industry Advisory Board will influence future direction

Additional Comment

Primary goal will be to create metrics that can be utilized by sponsors and core labs to identify opportunities to improve performance where results do not meet expectations; Drive change as appropriate.

Our long term goal will be to identify key areas in the industry that would benefit from a collaborative process improvement initiative

A Common Question is: Will data will be used against service providers or sponsors?

- 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. ”*

Additional Comment

Although the expectation is that the imaging core labs will program, collect and report the metrics; some metrics may correlate with core lab performance while others may correlate with sponsor and site performance.

- Standardized performance measures
- Harmonized reporting
- Benefits sponsors, core labs, sites, patients
- Improve decision making
- Drive change as appropriate
- “Come to the table” – participate in MCC initiative

Oct 2008: Present draft metrics at DIA Medical Imaging Continuum

Purpose: gather feedback to facilitate completion of version 1.0

Dec 2008: Finalize MCC Imaging Metrics version 1.0

Jan 2009: Present MCC Imaging Metrics version 1.0 at IIR Partnerships

Feb 2009 – May 2009: Develop tools to assist with the implementation and reporting of metrics version 1.0.

Note of Appreciation

On behalf of the MCC Imaging Steering Committee, we would like thank and acknowledge the significant contributions of

Linda Sullivan

Vice President of Operations
Metrics Champion Consortium