

Overview of the Metrics Champion Consortium Imaging Metrics Initiative

David Rauh, Eli Lilly and Company

7th Annual Partnering with Central Labs, ECG, & Imaging Labs
January 26-28, 2009

Agenda

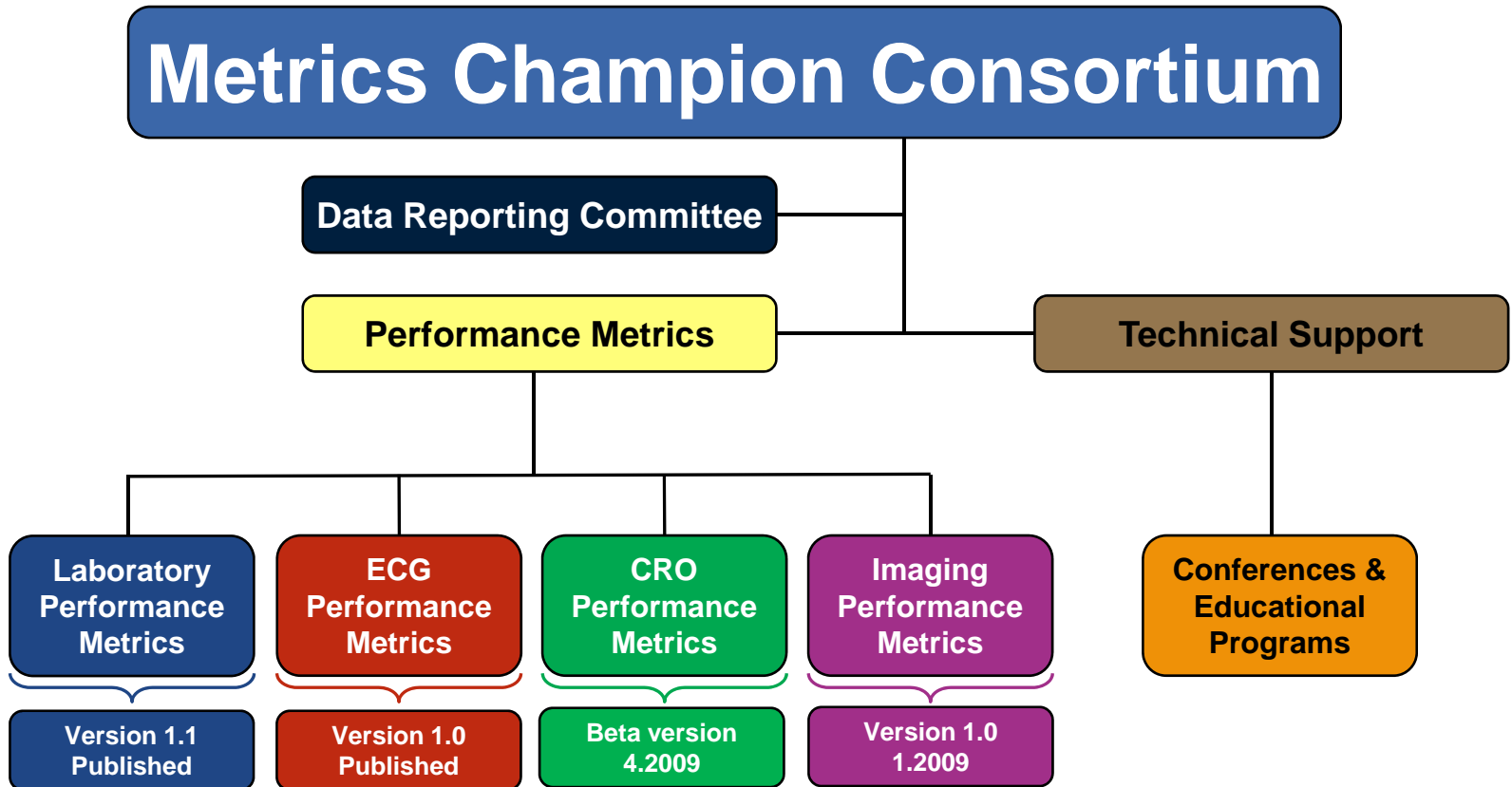
- MCC Overview
- Imaging Metrics Mission
- Imaging Metrics Process
- Imaging Metrics v1.0
- Path Forward
- Open Discussion

MCC Mission

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** in support of the drug development process.

Overview of MCC Activities



MCC Environment

- MCC organizations work collaboratively to develop standardized performance metrics
- Organizations use the standardized performance metrics to identify opportunities to improve performance
- Sponsor/service provider partners work together to determine how best to enhance the process
- A forum for biotechnology, pharmaceutical and service provider organizations to share “best practices”

Imaging Metrics Mission

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.

The Structure: 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 discussion meetings focused on metrics development
- Open to all sponsor & core lab personnel that join the MCC

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



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
David Mozley, Merck		
David Rauh, Eli Lilly MCC Imaging Metrics Chairperson		

In 2009: David Polakovs, Genentech and Brian Garfield, M2S will join Steering Committee

MCC Imaging Operations WG

Brenda Young , ACR Image Metrix
Mike Morales, ACR Image Metrix
Annette Chan, Amgen
DeJane Hussey, Amgen
Ria Lopez, Amgen
Helen Young, AstraZeneca
Kevin Murray, AstraZeneca
Brenda Noel, Bio Imaging Technologies
Lenore Noonan, Bio Imaging Technologies
Chris Schaefer, Biomedical Systems
Don Cooper, Biomedical Systems
Sam Dranoff, Biomedical Systems
Kees Groenhout, Cardialysis
Peter-Paul Kint, Cardialysis
David Rauh, Eli Lilly
Kim Scanlan, ICON Medical Imaging
Ciaran Cooper, M2S
Gregory Lange, M2S
Lewis Cohen, Medarex
David Mozley, Merck

Debbie Walton, Merck
Diane Stinson, Merck
John Griffin, Novartis
Scott Sawicki, Novartis
Amber Fotinos-Hoyer, Perceptive Informatics
Elizabeth Owens, Perceptive Informatics
Kate Stumpo, Perceptive Informatics
Kevin Jaynes, Perceptive Informatics
Michael Flatley, Perceptive Informatics
David Raunig, Pfizer
Jim Golando, RadPharm
Ron Berg, RadPharm
Kristine Szabo, Schering-Plough
Nick Donovan, Synarc
Toni Handzel, Virtual Scopics
Christina Mastandrea, WorldCare Clinical
Kelly Mizer, WorldCare Clinical
Patrick Chokron, WorldCare Clinical
Vanessa Conde, WorldCare Clinical

MCC Imaging Outsourcing WG

Mike Morales, ACR Image Metrix

Annette Chan, Amgen

Robert Vaccaro, Amgen

Helen Young, AstraZeneca

Matthew Bardsley, AstraZeneca

Dawn Flitcraft, Bio Imaging Technologies

Mark Endres, Bio Imaging Technologies

Nicole Risnychok, Bio Imaging Technologies

Sam Dranoff, Biomedical Systems

Kees Groenhout, Cardialysis

David Rauh, Eli Lilly

Blaise Hall, ICON Medical Imaging

Sandra Arrieta, Genentech

David Polakovs, Genentech

Zhenhai Shen, Genentech

Ciaran Cooper, M2S

David Mozley, Merck

Debbie Walton, Merck

John Griffin, Novartis

Scott Sawicki, Novartis

Bryan Wayne, Perceptive Informatics

Karen Connor, Perceptive Informatics

Kevin Jaynes, Perceptive Informatics

Veronica Ludensky, Perceptive Informatics

Craig Lipset, Pfizer

David Raunig, Pfizer

Michael Clark, Synarc

Erik Jensen, Virtual Scopics

Rosemary Shull, Virtual Scopics

Toni Handzel, Virtual Scopics

Kelly Mizer, WorldCare Clinical

Vanessa Conde, WorldCare Clinical

Michael Sullivan, Wyeth

MCC Imaging Clinical WG

Bruce Hillman, ACR Image Metrix
Mike Morales, ACR Image Metrix
Annette Chan, Amgen
DeJane Hussey, Amgen
Ria Lopez, Amgen
Robert Vaccaro, Amgen
Helen Young, AstraZeneca
Barbara Costantini, Bio Imaging Technologies
Colin Miller, Bio Imaging Technologies
Dawn Flitcraft, Bio Imaging Technologies
Jennifer Minko, Bio Imaging Technologies
Don Cooper, Biomedical Systems
Sam Dranoff, Biomedical Systems
Kees Groenhout, Cardialysis
David Rauh, Eli Lilly
Jim Conklin, ICON Medical Imaging
Ted Gastineau, ICON Medical Imaging
Ciaran Cooper, M2S
Josh Longacre, M2S
Gregory Lange, M2S
Lewis Cohen, Medarex
David Mozley, Merck

John Griffin, Novartis
Scott Sawicki, Novartis
Alaaddin Akkaya, Perceptive Informatics
Barbara Chandler, Perceptive Informatics
Joanna Hicks, Perceptive Informatics
Kate Stumpo, Perceptive Informatics
Kevin Jaynes, Perceptive Informatics
Sandra Chica, Perceptive Informatics
Subashini Chandrasekaran, Perceptive Informatics
Craig Lipset, Pfizer
David Raunig, Pfizer
K Shamsi, Rad-MD
Rick Patt, Rad-MD
Bob Ford, RadPharm
Kristin Borradaile, RadPharm
Kristine Szabo, Schering-Plough
David Herron, Synarc
Joyce Suhy, Synarc
Mark Tengowski, Virtual Scopics
Christina Mastandrea, WorldCare Clinical
Patrick Chokron, WorldCare Clinical

Expected Outcomes

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.

Expected Outcomes

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.

Expected Value

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

Recent Activity

- MCC Imaging working groups created a “final draft” of metrics in Sep 2008
- Clinical working group worked closely with David Raunig, Pfizer to develop process/language for “experimental” reader variability metrics
- “Final draft” metrics were presented at the Oct 2008 DIA PhRMA Imaging Working Group Conference
- Version 1.0 of Imaging Metrics being presented at IIR Partnership meeting, Jan 2009

Imaging Metrics v1.0

Metric	Category	Metric Title
1	Financial	Average percentage of variance in the imaging budget
2	Contract Signature	Average number of calendar days from imaging study award to contract signature
3	Site Start-Up	Percentage of sites qualified vs. actual
4	Site Start-Up	Average number of calendar days from site designated ready to first date of image receipt
5	Image Acquisition	Average number of calendar days from image acquisition to image receipt
6	Image Acquisition	Average number of calendar days from image receipt to initial feedback to site
7	Image Processing	Average number of calendar days from image QC complete to reporting of eligibility results
8	Image Processing	Average number of calendar days from image receipt to ready for independent review
9	Image Processing	Average number of calendar days from when the image is designated for review to completion of the review

Imaging Metrics v1.0

10	Image Quality	Percentage of suboptimal (but evaluable) images
11	Image Quality	Percentage of non-evaluable images versus total received
12	Image Quality	Percentage of non-evaluable baseline images
13	Missing Imaging	Percentages of missing imaging visits
14	Image Queries	Percentage of site queries
15	Image Queries	Average number of calendar days an imaging query is outstanding
16	Export Submission	Average number of calendar days from last patient reviewed to delivery of dataset
17	Export Submission	Average number calendar days from original estimate to actual for export submission
18	Independent Review Charter	Number of weeks to develop and write independent review charter
19	Acquisition Protocol Robustness	Number of image acquisition technique-related amendments per modality per protocol

Imaging Metrics v1.0

The following metrics are “Exploratory” Metrics (see MCC website for additional information)

E1	Reader Variability	Intra-reader variability (categorical endpoint) – Kappa
E2	Reader Variability	Inter-reader variability (categorical endpoint)—Kappa
E3	Reader Variability	Intra-reader variability (continuous end point) - Concordance Correlation Coefficient
E4	Reader Variability	Inter-reader variability (continuous end point) - Concordance Correlation Coefficient

Implement the MCC Imaging Metrics

This require time, effort, and cooperation from all...
MCC Imaging groups, Sponsors, and Core Labs

Path Forward – Collective Responsibilities

MCC Imaging Groups

- Form an Implementation team to develop tools to assist core labs & sponsors with providing/receiving metrics
 - Develop a report template – offers a visual of the primary and secondary metrics

Core Labs

- Begin process of developing/programming metrics for internal and sponsor use.

Sponsors

- Begin requesting core labs to develop and implement MCC metrics

Path Forward – Collaboration

Although metrics may be requested, it will take time for most of the core labs to program and implement

Implementation template(s) may lag slightly behind requests

Metrics will likely need to be fine tuned/clarified as we move through the implementation process, resulting in minor revisions to the standard metrics

Sponsors and core labs need to inform MCC Imaging Steering Committee of any issues, comments, recommendations based on their experience with utilizing the metrics.

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

Questions?

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

