MCC CRO Initiative
Working Group Kick-off Session

Cory Gutterman, Steering Committee Chairperson

May 19, 2008

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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.

Industry Under Pressure to Improve R&D Productivity

Biotech & pharma organizations that are currently achieving efficient clinical trial cycle times attribute their success to the following "best practices"†:

- focusing on core competencies
- prioritizing utilization of resources
- outsourcing services

† Kaitin KI. "Pushing the Innovation Envelope: Drug Development Metrics and the Changing Dynamics of Pharmaceutical R&D." Presented at the 6th Annual Pharmaceutical Metrics Event: Driving Quality, Cost, & Time; October 16-18, 2007; Cambridge, Massachusetts.

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Building Partnerships Around Standardized Performance Metrics

- The Metrics Champion Consortium, (MCC) is an open, multidisciplinary, non-profit organization comprised of biotechnology, pharmaceutical and service provider organizations.
- Within the MCC, member organizations work collaboratively to develop and implement standardized performance metrics aimed at improving the efficiency and effectiveness of managing and tracking resources needed to successfully run clinical trials.

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MCC Mission

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.

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Participating Organizations

- Abbott
- Amgen
- AstraZeneca
- Bio-Imaging Technology
- Biomedical Systems
- Bristol Myers Squibb
- Cardiocore
- Cordium Links
- Covance
- CRL.Medinet
- Eli Lilly
- eResearch Technology
- Esoterix
- Eurofins Medinet
- Genzyme
- ICON Central Labs
- ICON Medical Imaging
- Incyte
- M2S
- Mayo Clinical Trial Services
- MDS Pharma
- Medarex
- Merck
- Perceptive Informatics
- Pfizer
- PharmaNet
- Quintiles
- Rad-MD
- RadPharm
- Schering-Plough
- Spacelabs
- Synarc
- Valeant
- Vertex
- Viasys Clinical Services
- Virtual Scopics
- Wyeth

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MCC Value Proposition

MCC organizations work collaboratively to develop standardized performance metrics which aim to improve the efficiency and effectiveness of clinical trial operations and sponsor/supplier relationships. Organizations (sponsors and service provider partners) use standardized performance metrics to identify opportunities to improve performance where results do not meet expectations within a study; across a group of studies; or comparatively across a group of sponsors or service providers. 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 the partnership.

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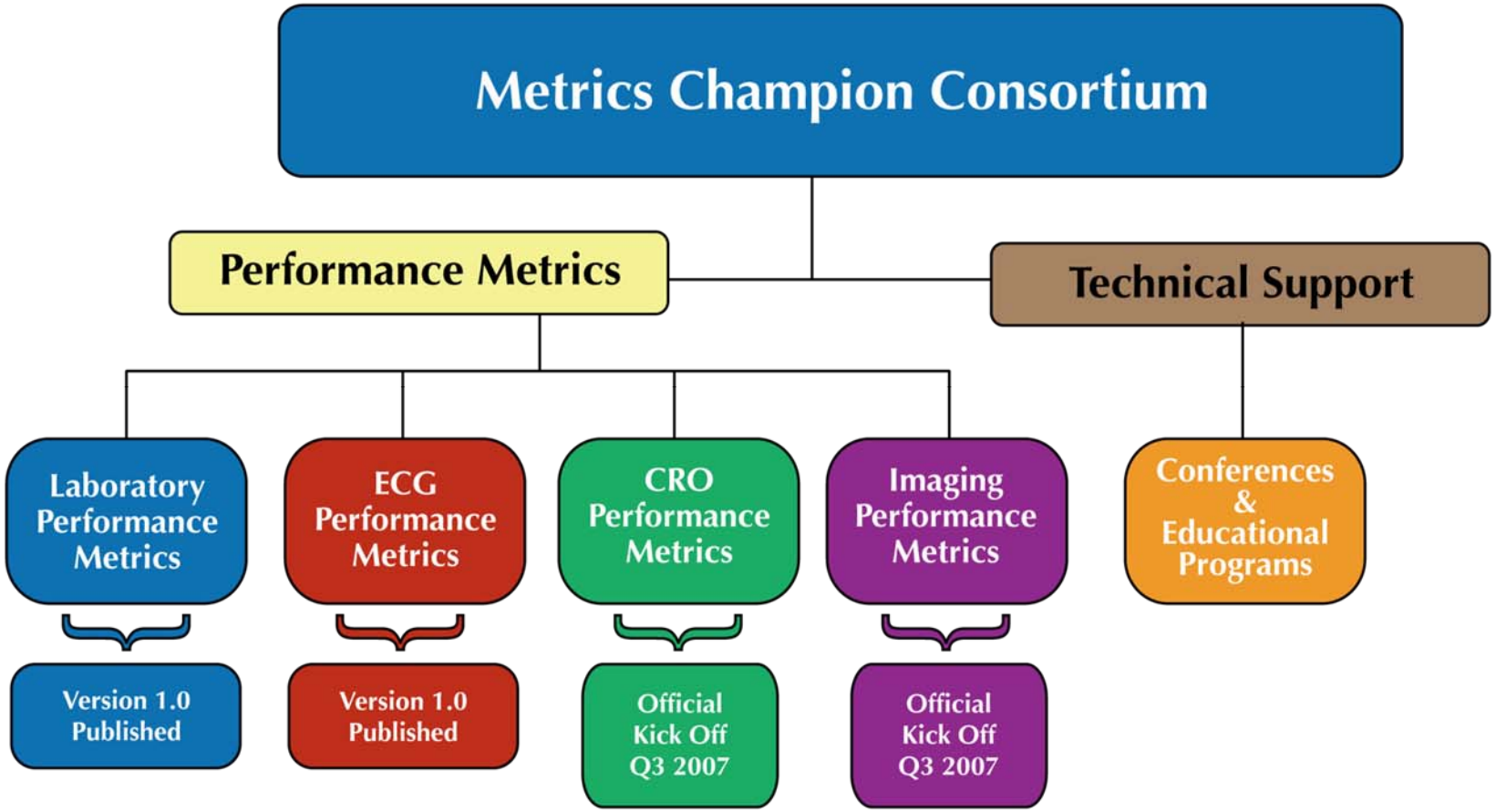
Overview of MCC Activities



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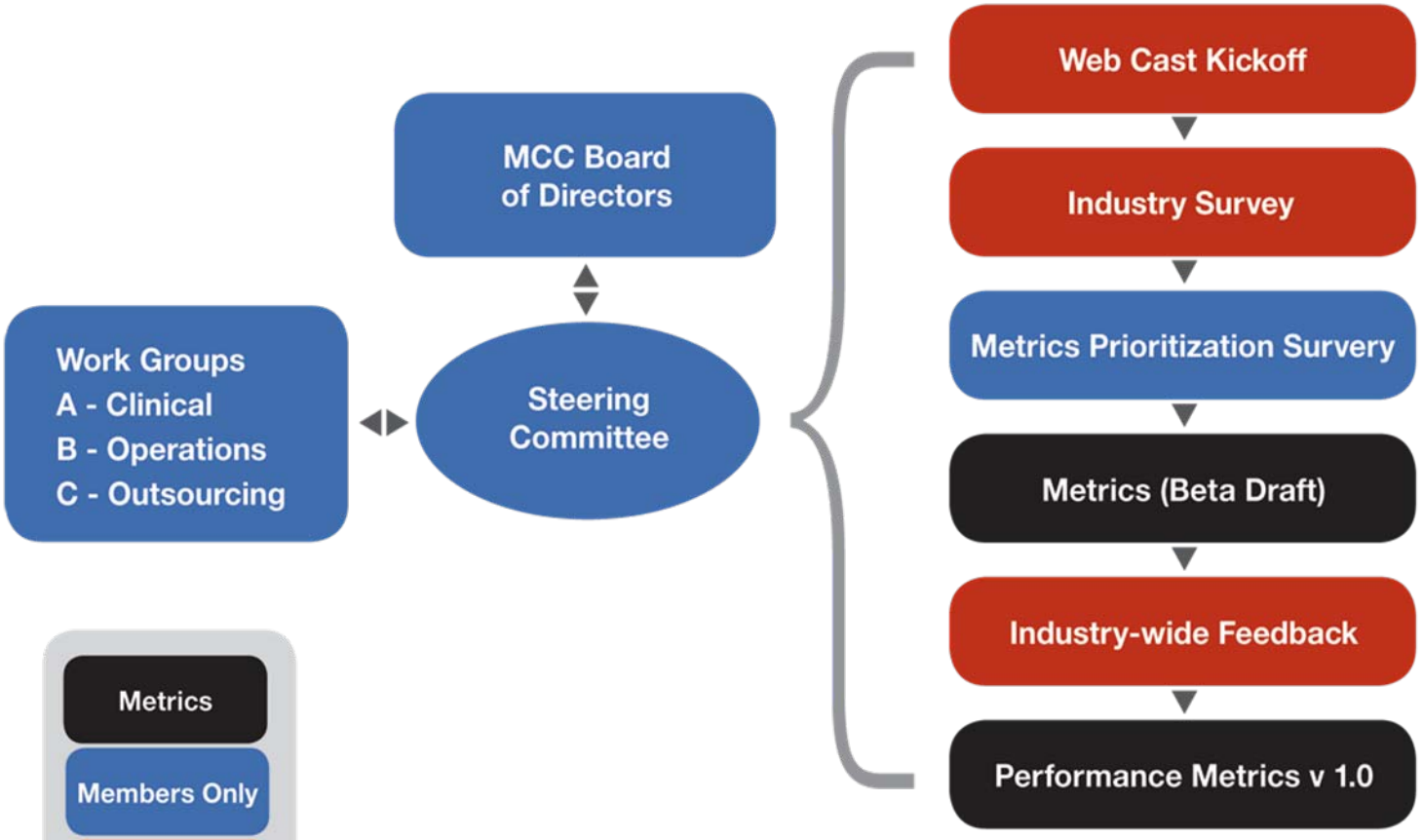
Metrics Development Process



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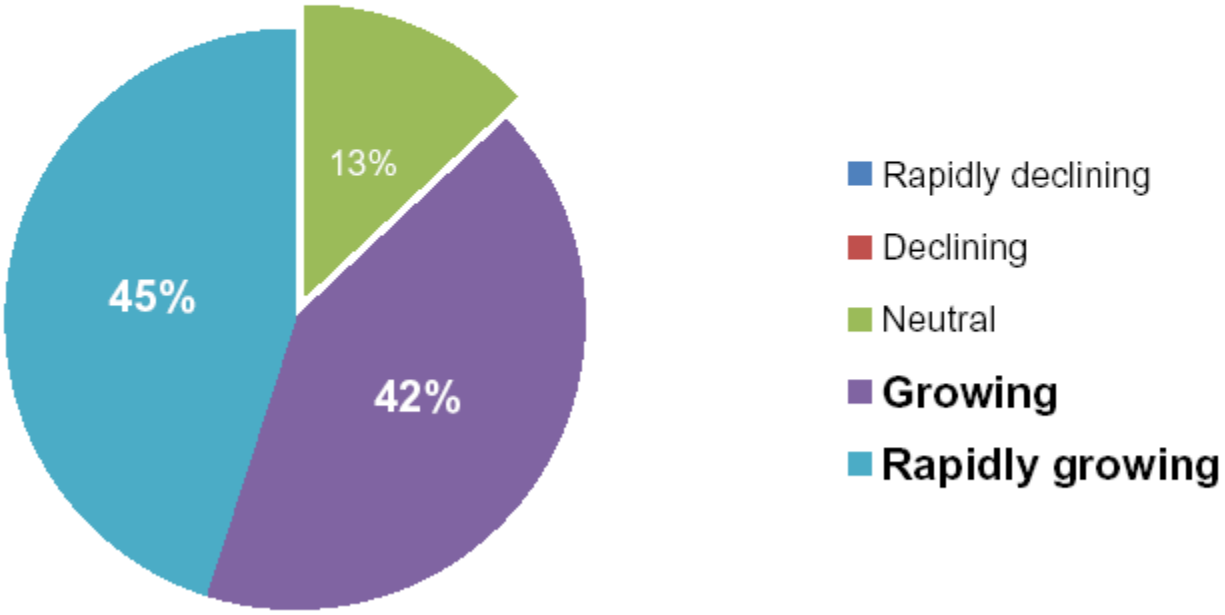
Metrics Industry Survey

Responses of note from Sponsor companies (n=32) included:

87% reported that the demand for performance metrics in the industry was either growing (42%) or rapidly growing (45%) (Exhibit 1)

The demand from our organization for performance metrics is:



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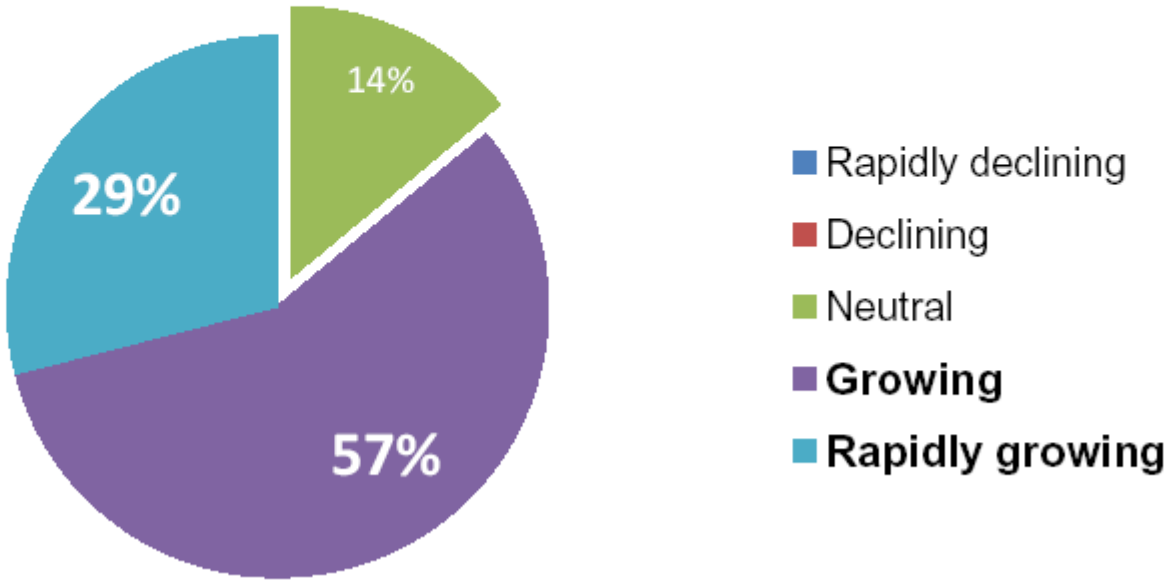
Metrics Industry Survey

Responses of note from CROs (n=14) included:

86%
reported that the demand for performance metrics was growing (57%) or rapidly growing (29%) among sponsor companies (Exhibit 6)

The demand from our sponsor organizations for performance metrics is:



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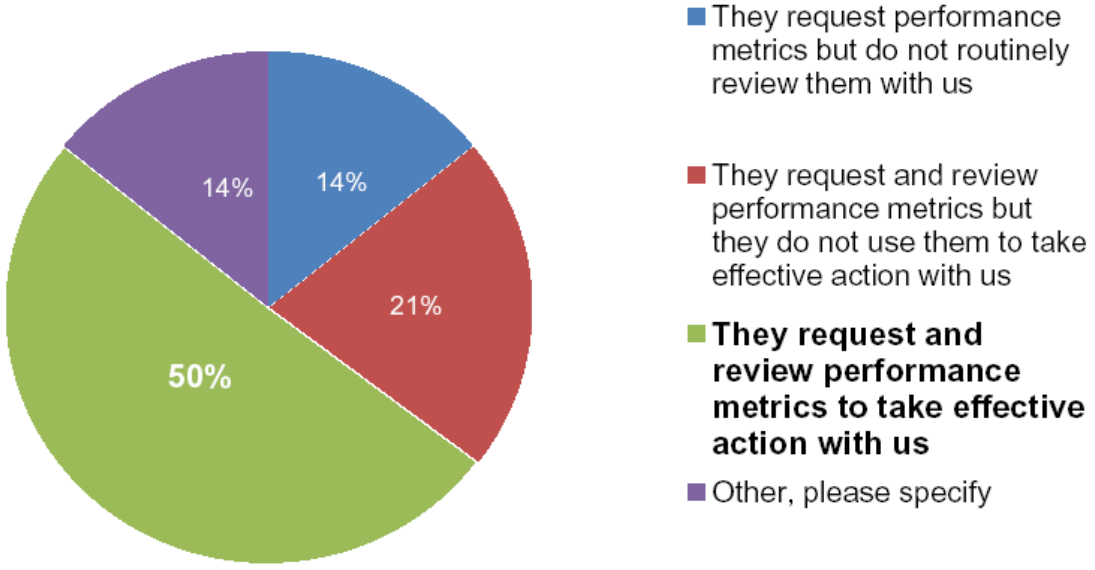
Metrics Industry Survey

50%
reported that sponsor companies requested and reviewed performance to take effective action with them (Exhibit 7)

Which category best describes your perception of how "average" sponsor organizations use performance metrics to help manage their relationship with your organization:



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CRO Metrics Mission

To develop metrics to provide consistent and standardized performance measurement for clinical research activities covering clinical, operational, outsourcing/financial aspects of the sponsor, CRO and site 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.

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Expected Outcomes

Immediate impact: Internal Sponsor & CRO Use:

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

-- Site, study, compound, sponsor, CRO level

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

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Expected Outcomes

Long Term impact: Industry Use

Obtain baseline data which accurately reflects CRO and sponsor performance in clinical trials.

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

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CRO Metrics Development

CRO Metrics Steering Committee

- Formed in Fall 2007
- Composed of sponsor and CRO personnel
- Charge: Facilitate CRO Metrics working groups

Working Groups

- Clinical, operations and outsourcing working groups are being created to achieve metrics development goals
- Open to all sponsor and CRO personnel that join the MCC

Participation from sponsors and CROs will provide objectivity and ensure a well balanced approach for metric development

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MCC CRO Metrics Steering Committee

- Cory Gutterman / Abbott
- Ed Cannon / AstraZeneca
- Beenu Kapoor / Covance
- Holly Hankins / Eli Lilly
- Kathe Balinski / Medarex
- Magaly Woolard / Merck
- April Davis/ Perceptive Informatics
- Scott Treiber / PharmaNet
- Kristy Morgan / Quintiles
- Paul Shin / Valeant

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MCC CRO Metrics Development Process

CRO Work Groups

1. Business Operations
2. Finance
3. Clinical Operations
4. Drug Supply
5. Project Management
6. Data Management
7. Biostatistics
8. Medical Writing
9. Quality Assurance
10. Safety
11. Regulatory Affairs

- Work groups will be chaired by CRO Steering Committee members
- All MCC organizations are entitled to have multiple representatives on the CRO work groups

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CRO Metrics Steering Committee

Business Operations Working Group Leaders	Clinical Operations Working Group Leaders	Project Management Working Group Leaders
Kathe Balinski, Medarex Holly Hankins, Eli Lilly Scott Treiber, PharmaNet Magaly Woolard, Merck	**Scott Treiber, PharmaNet** Kathe Balinski, Medarex Holly Hankins, Eli Lilly Magaly Woolard, Merck Paul Shin, Valeant	**Beenu Kapoor, Covance** Holly Hankins, Eli Lilly Scott Treiber, PharmaNet April Davis, Perceptive
Cory Gutterman, Abbott Laboratories, CRO Metrics Chairperson		

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The Process: CRO Metrics Development

Working Groups

- Open discussion meetings focused on metrics development
  - Our goal is to define and implement industry metrics
  - The “industry” is not 4 or 5 individuals or a few sponsors and service providers
  - Need everyone’s participation/ideas

- Working Group leaders (Steering Committee members)
  - Facilitate discussions
  - Capture discussion notes/minutes
  - Update Steering Committee

- Base set of potential metrics ideas are available
  - This is a starting point

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The Process: CRO Metrics Development

Example – Business Operations

- Time
  - Actual vs. budgeted vs. work completed
- Money
  - Actual vs. budget vs. work completed
  - Number of change orders driven by protocol changes
  - Number of change orders not driven by protocol changes
- Relationship
  - Percent change of key staff over the duration of a trial

The Process: CRO Metrics Development

Example – Clinical Operations

- Time
  - Investigator contract to FPI at a site
- Performance
  - Queries per CRF
  - Projected vs. actual recruitment
- Leading indicators
  - Percent of sites with no subjects entered

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The Process: CRO Metrics Development

Example – Project Management

- Time
  - Approved protocol to FPI
  - Last subject out to database lock
- Performance
  - Regulatory timelines per country

The Process: CRO Metrics Development

Working Groups

- Expand on base set of potential metrics
  - Start with the question: What do we want to measure?
  - Develop the metrics based on the answers to this question
  - Address the following questions:
    - What metrics is your organization currently utilizing (Sponsor & CRO)
    - What metrics are being requested by your sponsors (CRO)
    - What metrics would you like to see implemented (Sponsor & CRO)

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The Process: CRO Metrics Development

Working Groups

- Utilize the MCC format for creating metrics
  - Metric title
  - Metric definition
  - Formula for deriving metric
  - Unit of measure
  - Recommended reporting frequency
  - Target threshold
  - Business Driver / Benefit statement

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Central Laboratory Performance Metric #3

Metric	Category	Metric Title	Definition*	Formula/Example	Unit of Measure	Reporting Frequency	Target
3	Site Initiation	Percentage first supplies shipped on time	**Minimum:** The percentage of protocols that have the first supplies shipped date met based on the defined expectations between sponsor and central laboratory. **Additional analysis on a "for cause" basis:** A listing of protocols that did not meet the first supply ship date based upon the defined expectations between sponsor and central laboratory per business unit and per protocol.	**Formula:** (Total N of protocols with first supplies shipped date / Total N of protocols with first supplies required) x 100 **Specific Example:** 10 protocols initiated; 9 received first supplies as expected (1 did not) Result: (9/10) x 100 = 90% received first supplies within expectations	Total N and %	Quarterly	>95%
			Business Driver / General Benefit Statement	You will be informed regarding a service provider's ability to finalize the predefined database, prepare and/or ship kits and deliver what is required for the site to achieve first patient visit from a central laboratory requirement perspective per your contractual agreement. In addition, you can extrapolate that if the service provider can provide the required start-up supplies per the timeline; resupply will occur in the same timely manner thus a resupply metric was not defined at this time.			

Central Laboratory Performance Metrics v1.0

Metric	Category	Metric Title
1	General Operations	Project management turnover during protocol
2	Protocol Initiation	Average number of working days from statement of work signature to "database ready"
3	Site Initiation	Percentage first supplies shipped on time
4	Data Cleaning	Percentage of queries from central laboratory to site based upon requisitions received
5	Data Cleaning	Average turnaround for resolution of queries from central laboratory to site
6	Site Support Services	Percentage of queries from site to central laboratory based upon requisitions received
7	Site Support Services	Average turnaround time on queries from site to central laboratory
8	Safety	Percentage of panics successfully communicated to the sites within the defined turnaround time

Metric	Category	Metric Title
9	Laboratory Operations	Percentage specific test(s) reported within expected turnaround time
10	Laboratory Operations	Percentage tests not reportable
11	Laboratory Operations	Percentage shipments / samples shipped from central laboratory on time to sponsor-directed third party
12	Data Management	Percentage on time accepted file transfers
13	Financial Management	Plan, Forecast and Actual Financial Report
14	Financial Management	Comparison of budgeted and actual transportation costs by region and/or country
15	Quality Assurance	Percentage of audit findings closed within sponsor and central laboratory agreed upon timeframe

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The Process: CRO Metrics Development

Working Groups

- Question every potential metric; every step of the way
  - Why are we recommending this potential metric?
  - Who will use it and how will it be used?
  - Will this metric provide an accurate indication of what is trying to be measured?
  - Can we drive change/process improvement with this metric?

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The Process: CRO Metrics Development

Working Groups

What we are not doing…….

- We are not creating metrics for sake of saying we have industry metrics.

What we are doing……

- Our purpose is to identify “what works” and “what needs improvement”.
- Utilize information obtained from metrics to drive appropriate change.

If a potential metric does not address these key points, it should not be one of our metrics.

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Value of Participating in MCC 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…)

CRO

- 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

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Common Questions/ Concerns

A Common Question is: Will MCC publish metrics?

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

Additional Comment

Primary goal will be to create metrics that can be utilized by sponsors and CROs 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

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Common Questions/ Concerns

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 CROs will program, collect and report the metrics, some metrics may correlate with CRO performance while others may correlate with sponsor and site performance.

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Key Points

- Standardized performance measures
- Harmonized reporting
- Benefits sponsors, CROs, sites, patients
- Improve decision making
- Drive change as appropriate

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Next Steps

- *MCC CRO Metrics - Business Operations WG*
  Date: Wednesday, June 11, 2008
  Time: 12:00 pm, Eastern Daylight Time
- *MCC CRO Metrics - Clinical Operations WG*
  Date: Tuesday, June 10, 2008
  Time: 12:00 pm, Eastern Daylight Time
- *MCC CRO Metrics – Project Management WG*
  Date: Thursday, June 12, 2008
  Time: 12:00 pm, Eastern Daylight Time

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Next Steps

- *MCC CRO Metrics – Other workgroups*
  Date: Launch throughout 2008 -TBD
  Time: TBD
- *Workgroups meet throughout 2008*
  Frequency: Every 2 weeks
  Time: 1 hour
- *MCC CRO Metrics – Beta Release*
  Date: April 2009
  Location: Partnerships with CRO's Meeting

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Questions?

Thank you for participating in the MCC CRO Metrics Initiative.

Please contact Cory Gutterman (Cory.Gutterman@Abbott.com) or Linda Sullivan (lsullivan@metricschampion.org) regarding any questions or concerns.