

# How the Industry-Wide Effort to Develop and Implement Standardized Clinical Trial Performance Metrics Helps BD's Relationship with their Clients

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ExL Pharma Effective Business Development for Clinical Trial Service Providers  
Conference ♦ July 15, 2009 ♦ Washington DC



# Overview of the Metrics Champion Consortium (MCC): A Collaborative Effort to Jointly Improve Performance

Guy Mascaro, MCC President

ExL Pharma Effective Business Development for Clinical Trial Service Providers Conference ♦ July 15, 2009 ♦ Washington DC



- Industry Overview
- MCC Mission & Goals
- Value Proposition
- Current MCC Performance Metrics  
Initiatives
- Conclusion

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.

Biotech & pharma organizations that are currently achieving efficient clinical trial cycle times attribute their success to the following “best practices”<sup>†</sup>:

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

<sup>†</sup> Kaitin Kl. “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.



# Building Partnerships Around Standardized Performance Metrics

A group of biotechnology, pharmaceutical and service provider organizations helped form a not-for-profit organization, the Metrics Champion Consortium (MCC), where 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.

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.

# Participating Organizations

- Abbott
- ACRMetrix
- Amgen
- AstraZeneca
- Biogen Idec
- Bio-Imaging Technology
- Biomedical Systems
- Cardialysis
- Cardioanalytics
- Cardiocore
- Cerexa
- CHDI Foundations
- ClearTrial
- Cordium Links
- Covance
- CRL Medinet
- Duke Clinical Research Institute
- Eli Lilly
- eResearch Technology
- Esoterix
- Eurofins Medinet
- Facet Biotech
- Genzyme
- Genentech
- i3
- ICON
- Inc Research
- Incyte
- M2S
- Macrogenics
- MDS Pharma
- Medarex
- Merck
- NERI
- Novartis
- Paragon Biomedical
- Perceptive Informatics
- Pfizer
- PharmaNet
- Quest Diagnostics
- Quintiles
- Rad-MD
- RadPharm
- Regeneron
- Social & Scientific Systems, Inc.
- Spacelabs
- Synarc
- Valeant
- Vertex
- Viasys Clinical Services
- Virtual Scopics
- WorldCareClinical

# Collaboration with Other Industry Groups

- ACRO representation to the MCC Board of Directors
  - Sean Larkin, PharmaNet
  - Paul Colvin, PPD
- CDISC
- FDA
- PhRMA
- Research Initiatives Foundation for the NIH
- eClinical Forum
- SCDM

- Key service areas (e.g. Labs, ECG, CRO, Imaging) will have defined sets of performance metrics that are utilized by sponsor/service provider partnerships to manage clinical trial performance
- Entire industry actively participates in metrics creation and change management processes
- Constructive conversations are generated between all parties because of metrics
- Sponsors and service providers grow more productive as a direct result of MCC initiatives

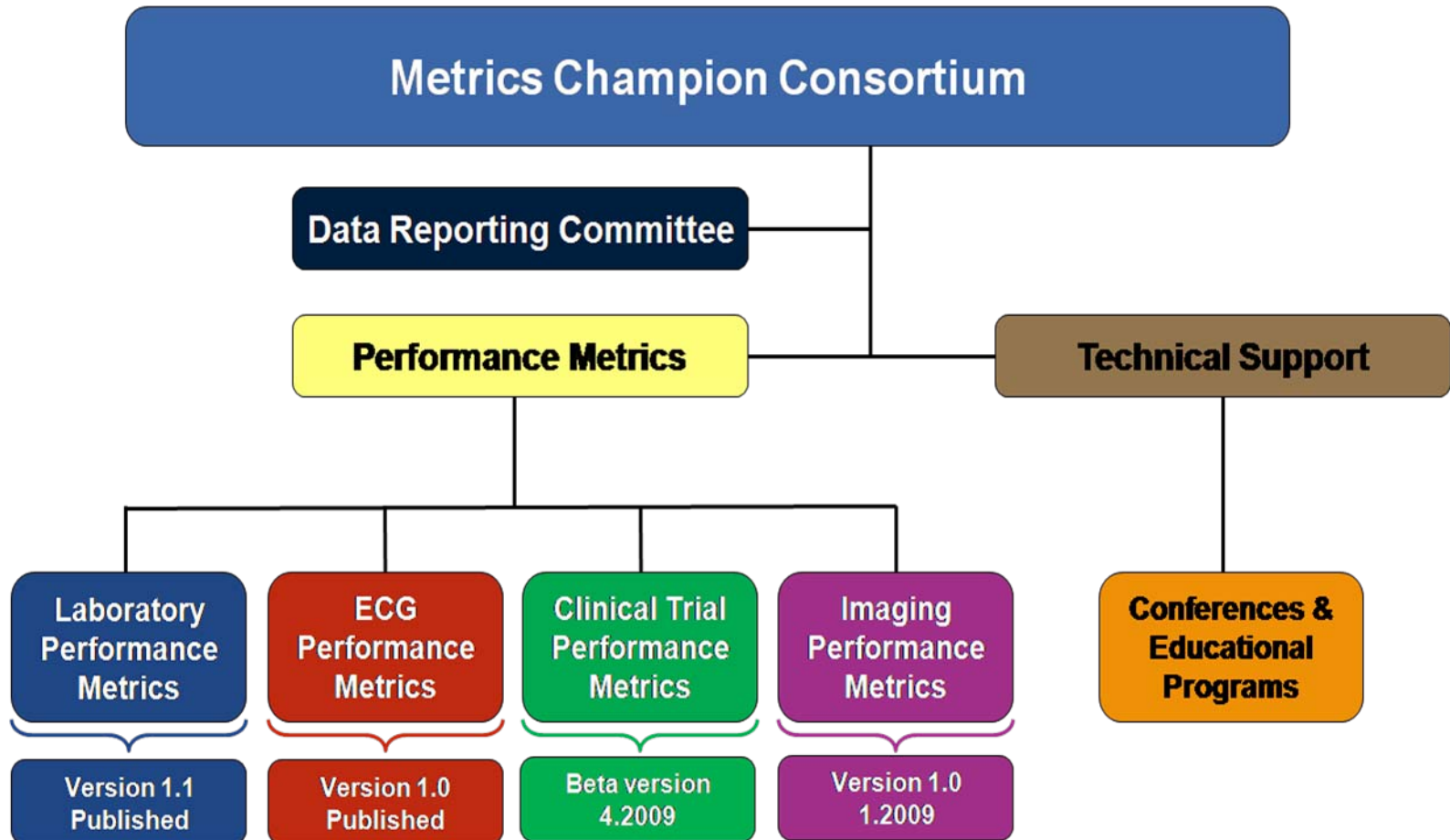
- MCC organizations work collaboratively to develop standardized performance metrics which aim to improve the efficiency and effectiveness of clinical trial operations *for each* sponsor/supplier relationship.
- Organizations use the standardized performance metrics to identify opportunities to improve 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.

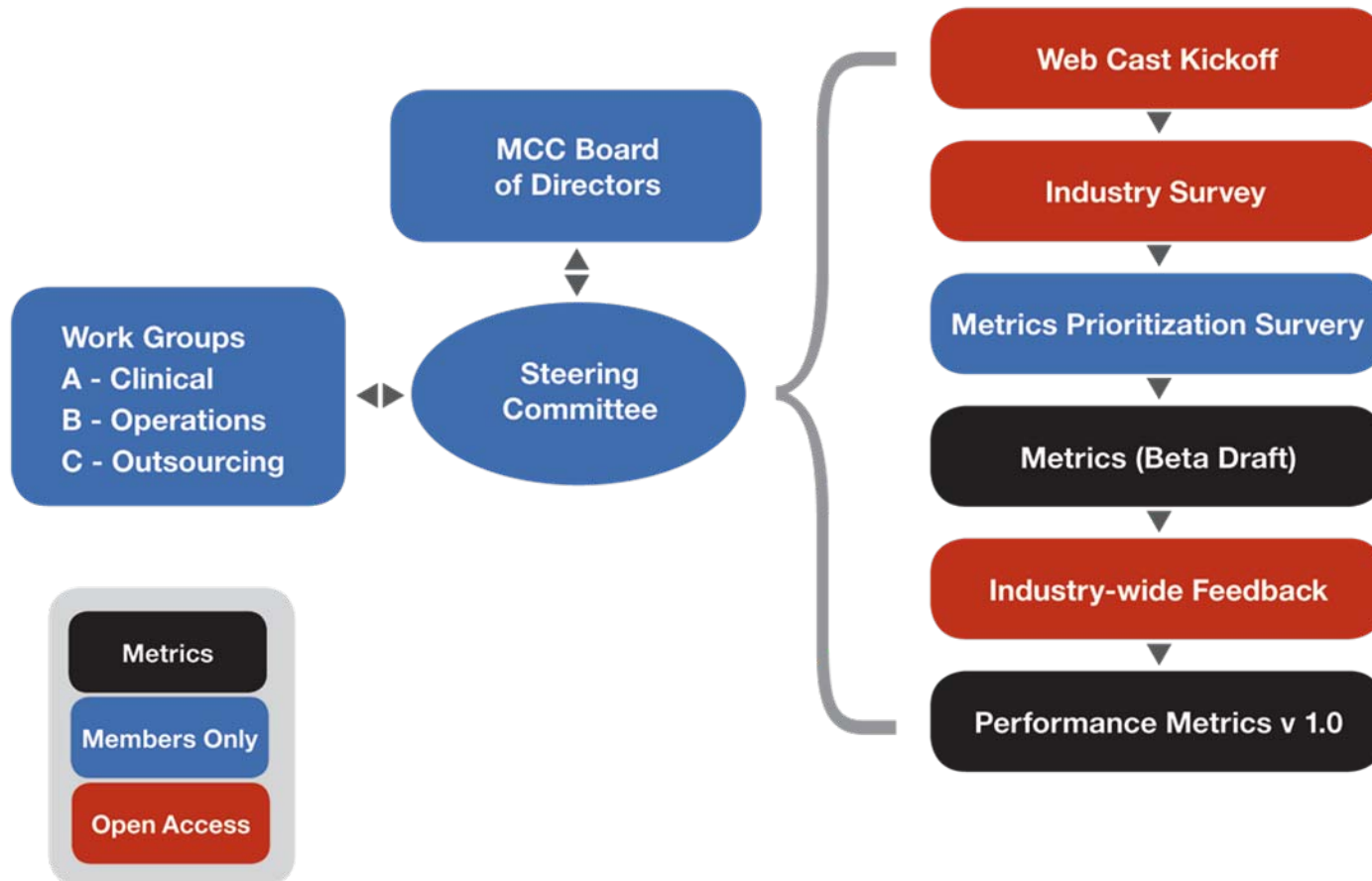
# Value of Participating in Consortium Activities

## Industry benefits from participating in the MCC:

- Industry shared learning and problem solving
- Increased productivity
- Richer dialogue between sponsor and service providers - less debate about what you have and more time focused on solving problems and celebrating successes in relationship
- Simplified review and analysis of metrics data
- Strengthened sponsor/service provider relationships



# Metrics Development Process





# MCC Central Laboratory Performance Metrics v1.1

Metric	Category	Metric Title
1	General Operations	Project management turnover
2	Protocol Initiation	Percentage first supplies shipped on time to the first site for first patient
3	Site Initiation	Percentage first supplies shipped on time for all sites (all regions)
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

Metric	Category	Metric Title
8	Safety	Percentage of panics that had both 1st attempt made and were successfully communicated to the sites within the defined turn around times
9	Laboratory Operations	Percentage specific test(s) reported within expected turnaround time
10	Laboratory Operations	Percentage tests not reportable
11	Data Management	Percentage on time accepted file transfers
12	Financial Management	Plan, Forecast and Actual Financial Report
13	Financial Management	Comparison of budgeted and actual transportation costs by region and/or country
14	Quality Assurance	Percentage of audit findings closed within sponsor and central laboratory agreed upon timeframe

# MCC 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	<p><b>Minimum:</b> The percentage of protocols that have the first supplies shipped date met based on the defined expectations between sponsor and central laboratory.</p> <p><b>Additional analysis on a “for cause” basis:</b> 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.</p>	<p><b>Formula:</b> (Total N of protocols with first supplies shipped date / Total N of protocols with first supplies required) x 100</p> <p><b>Specific Example:</b> 10 protocols initiated; 9 received first supplies as expected (1 did not) Result: (9/10) x 100 = 90% received first supplies within expectations</p>	Total N and Percentage	Quarterly	>95%
			<p><b>General Benefit Statement</b></p> <p>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.</p>				

# MCC ECG Performance Metrics v1.0

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	Percentage of on-time ECG equipment shipments to sites
4	Percentage of sites who conduct a successful test ECG transmission prior to 1st subject visit
5	Percentage of ECGs reported to Investigator Sites within agreed turnaround time
6	Percentage of ECG data queries from vendor to site
7	Turnaround time on resolution of ECG site queries from central vendor
8	Percentage of ECG alerts successfully communicated to sites within defined turnaround time

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



# MCC Imaging Performance 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

Metric	Category	Metric Title
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

## Conducting monthly Implementation/Shared Learning Work Group meetings:

- Sponsors & service providers
- Lessons learned
- Sharing ideas
- Case studies
- Data collection tools / templates

- 2009 will be an important year:
  - Release Clinical Trial metrics
  - Develop additional case studies
  - Support metrics implementation among sponsor/service provider partnerships
  - Explore developing data reporting templates across MCC metrics initiatives
- No plans to launch new metrics initiatives in 2009
- Future metrics initiatives may include biomarkers





# How the Industry-Wide Effort to Develop and Implement Standardized Clinical Trial Performance Metrics Helps BD's Relationship with their Clients

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Cory Gutterman  
Associate Director, GPRD Outsourcing  
Abbott Laboratories

Chair, Clinical Trial Performance Metrics Steering Committee  
Metrics Champion Consortium

July 15, 2009

# Metrics (a short but evolving story)

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- The need to measure
- How to utilize and manage the information
- What to measure / The role of the MCC

# The need to measure

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## Objective:

- We want to increase productivity, work smarter, make better decisions

## Management believes:

- \_\_\_\_\_ takes too long
- \_\_\_\_\_ costs too much
- I remember when \_\_\_\_\_

## Validation / invalidation of beliefs

- Impossible to find consolidated data to provide a response one way or the other

# The need to measure

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## Pros:

- If you don't measure anything you are left with “institutional memory”
- There is a natural tendency to improve what is measured
- If you measure the right things.... You have the opportunity to improve
- By repeated measurement, you can discover trends
- By the use of metrics and the identification of areas that are of concern, you create an opportunity to improve processes

# The need to measure

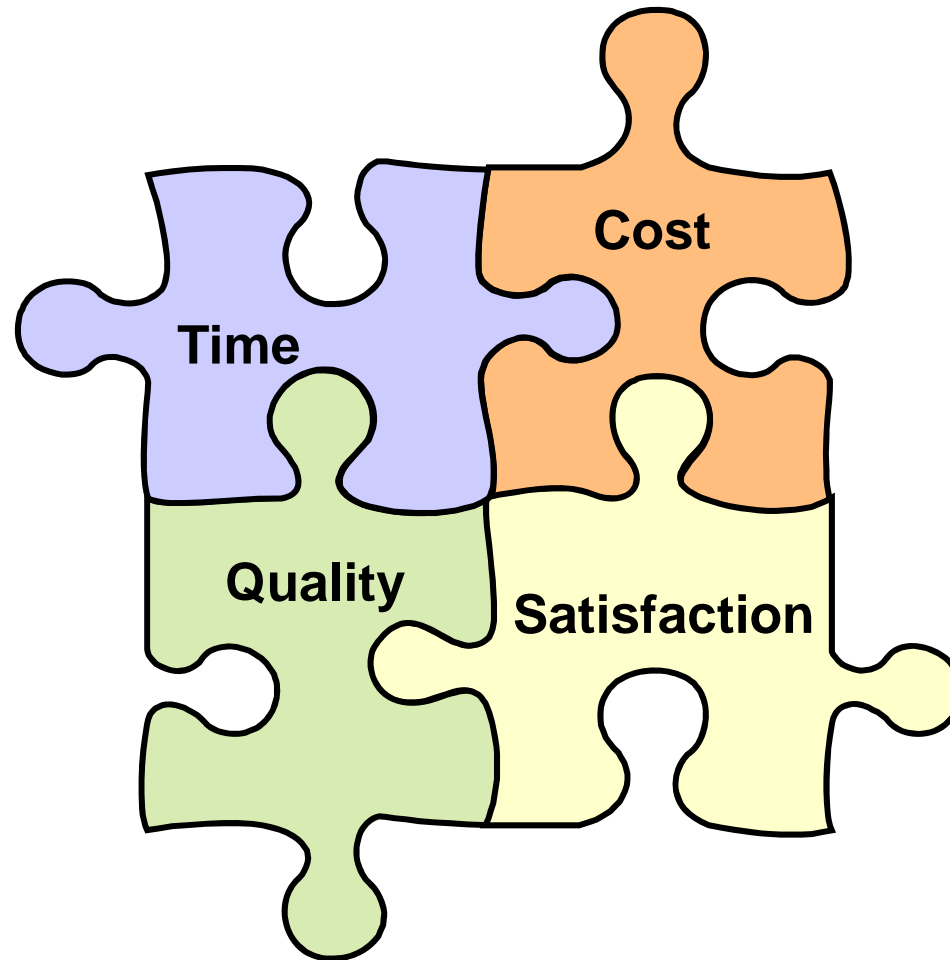
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## Cons:

- Metrics take time to collect
- If you collect them, you have to analyze them
- If you analyze them, you have to take action
- If you take action, you have to continue to collect metrics to see if the action taken affected the metrics
- You can become obsessed with metrics and lose sight of the “big picture”

# What to Measure

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# What to Measure

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## Time

- Begin Activities
- Protocol Approved (CMR)
- First EC Approval
- First Lab Kit shipped
- First Subject Enrolled (CMR)
- First Dose to Subject (CMR)
- Last Subject Enrolled (CMR)
- Last Subject Last Visit (CMR)
- Database Lock (CMR)
- CSR sign off
- Final CRF approved
- Database ready
- First lab data load
- Time from funding to protocol
- Time to enter CRFs
- Time to execute contract

# What to Measure

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## Cost

- Scope Changes
  - Sponsor initiated
  - Supplier initiated
- Invoice Payment Timeliness
  - Meeting payment obligations
- Costs Incurred Relative to Study Progress
  - Cash flow
  - Performance
  - Number of accessions relative to budget

# What to Measure

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## Quality

- Data Management Metrics
  - Query rates, time queries are outstanding
  - Data loads
- Staffing Metrics
  - CRA turnover
  - Project Manager turnover
- Audit Findings
- Clinical Monitoring Metrics
  - Timeliness (trip reporting / visits according to monitoring plan)
  - Quality (queries)

# What to Measure

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## Satisfaction

- Sponsor Satisfaction
  - Qualitative measurement
  - All quantitative measures can be “green” but team could be very dissatisfied
- Supplier Satisfaction
  - Qualitative measurement discussed at semi-annual meetings
- Voice of the Customer
  - Who is the customer

# How does Business Development Fit In

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## Use of Metrics to Manage and Build Relationship(s)

- Provide feedback to suppliers on performance and Sponsor impressions
- Provide feedback to internal staff on performance and Supplier impressions
- Spot trends
- Work to enhance performance
- Identify areas for mutual improvement

# Supplier Management Program

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**CRO Provides Performance Metrics**

**Suppliers provide feedback to Sponsor**



**Outsourcing Shares Feedback/ Metrics with Clinical Teams (CPT)**

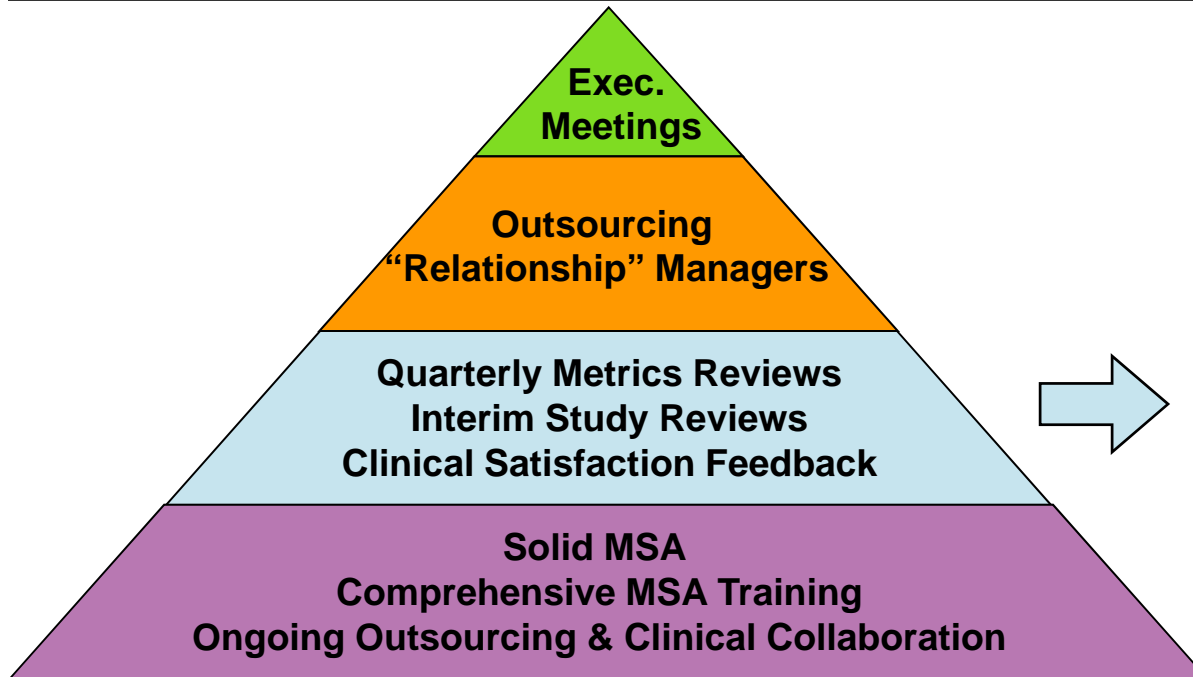
**Quarterly/Annual Supplier Meetings**

**CPT Provide Feedback to Outsourcing**

# Metrics in Relationships

## ***Supplier Management Objectives***

- Global oversight of CRO's
- Enforce contract terms
- Review supplier performance
- One point of contact for high level issue resolution
- Detect issues before they escalate to crisis level



## **Metrics Report Key Content**

- Project milestones tracking
- Enrollment
- Trip Report timeliness
- Data Clarification Field metrics
- CRO turnover
- Contract change orders
- Finance

**Also blinded data shared across suppliers.**

# What and how to measure

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- Metrics are available, but they are measured differently for each study and for each supplier
- Metrics are not stored in a central database
- Participation in CMR / KMR benchmarking studies are one-off activities
- We do not capture year over year learnings
- Variety of different data sources
- No one can agree on what to measure

# What's next

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- Selecting the right metrics
- Defining your metrics by setting a target
- Who is the gatekeeper of metrics? Who is ultimately responsible for gathering the information
- How to use metrics correctly according to their purpose
- Avoiding overambitious timelines and unrealistic expectations
- Gaining alignment around metric definitions to achieve a streamlined system
- ... Along comes the Metrics Champion Consortium ....

# MCC Clinical Trial Performance Metrics Development Process

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## Clinical Trial Metrics Steering Committee

- Cory Gutterman / Abbott
- Ed Cannon / AstraZeneca
- Holly Hankins / Lilly
- Colleen McCoy / Genentech
- Keith Dorricot / i3 (new)
- Pam Howard / ICON (new)
- Kathe Balinski / Medarex
- Maga Woolard / Merck
- April Davis / Perceptive Informatics
- Lorraine Waring / Pfizer
- Julie Szabo / PharmaNet
- Monika Frey / Quintiles

# MCC Clinical Trial Performance Work Group

## Participants

Abie Ekangaki	David Rodin	Joan Farrington	Lee Davis	Ned Connell
Allison Houghteling	Dawn East	Joanne Bailey	Li Ding	Nicolle Keally
Andrew Marvuglio	Dawn Porthouse	Joanne Machalaba	Linda Donahoe	Nobuhide Shimizu
Andy Bakker	Deidre Bevard	John Griffin	Linda Dunford	Olga Crowther
April Davis	Diane Mizerak	John Humphreys	Linda Gala	Pam Howard
Beth Cabage	Dianne Laumann	Joseph Giuliano	Linda Stevens	Patric Donaghue
Bonnie Beaver	Elise Kayson	Judith Chiostri	Lisa Chen	Patty Godfrey
Brenda Muldrow	Dorothy Hartley	Judith Goud	Lorene Bottom	Piper Laird
Brett Bishop	Ed Cannon	Julia Amo	Lori Carman	Randy Krauss
Brian Schrock	Eileen Ryan	Julie Engel	Lorraine Waring	Renee Lafaive
Carol Zhao	Elizabeth Shewell	Julie Szabo	Louis Grue	Richard Brotherton
Cassandra Kelley	Elizabeth Stankevich	Julie Tscharland	Louise Rochon	Richard Musselman
Catherine Elliott	Eric Hildebeitel	Kate Haratonik	Lynn Watson	Robert Holman
Charles Chesson	Eric Strait	Kathe Balinski	Magaly G. Woolard	Ronald Knickerbocker
Chili Li	Eva Kantanas	Karl Kiebertz	Marc Hamm	Rose Braxton
Christine Fitzpatrick	Gary Urban	Karl Meyer	Mary Baldovsky	Ryan Shortreed
Christopher Oligny	Gene Trimble	Karolyn Jackson	Mathew Bryant	Scott Sawicki
Cindy Casaceli	Gina Petrizio	Kathy M Haag	Matthew Stephens	Stacy Gletzakos
Colleen McCoy	Goran Kecman	Kati Gutierrez	Michael Malicsi	Stephanie Chan
Connie Seckel	Gordana Vucinic	Keith Dorricott	Michael Neidl	Stephen Kay
Connor Blakeney	Greg Pendell	Kelly Mizer	Michael Sobczyk	Sunshine Watkins
Cornelia Kamp	Guy Mascaro	Kelly Ong	Melika Davis	Tara Coughlan
Cory Gutterman	Hannah Legesse	Kelly Vaillant	Michael Bruns	Teleen Norman
Courtney Bryant	Hartmann Ammann	Krista Peters	Michael Friedman	Tess Pangan
Cynthia Hooper	Heidi Shea	Kristen Tomita	Michelle Stevens-Brogan	Thomas Purcell
Danie Montinard	Holly Hankins	Kristin Lucas	Mike Lange	Tiffany Crowell
Daniel Christen	Jean Pan	Kristy Morgan	Mike Soenen	Tracy Mayer
Daniela Popa	Jeff Marquis	Kristyn Karas	Monica Reddy	Vickie Crocker
Darren Hart	Jennifer Sugarman	Lakshmi Mahadevan	Monika Frey	Yvonne Baran
David Chambers	Jeremy Hemiup	Larry Blankstein	Morgan Shethah	Yvonne Ulrich
David Polakovs	Jim Wyatt	Lauren Freese	Nancy Yeates	

# MCC Clinical Trial Performance Metrics Development Process

## Clinical Trial Metrics Work Groups

1. Business Operations
2. Finance
3. Clinical Operations
4. Project Management
5. Drug Supply

6. Data Management
7. Biostatistics
8. Medical Writing
9. Quality Assurance
10. Safety
11. Regulatory Affairs

- Work groups are chaired by Clinical Trial Metrics Steering Committee members
- All MCC organizations are entitled to have multiple representatives on the Clinical Trial metrics work groups
- Work groups launched April 2008

# MCC Clinical Trial Performance Metrics Development Process

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## Proposed Metric - Qualities

Timeliness (T)

Cycle Time (CT)

Efficiency / Cost (E)

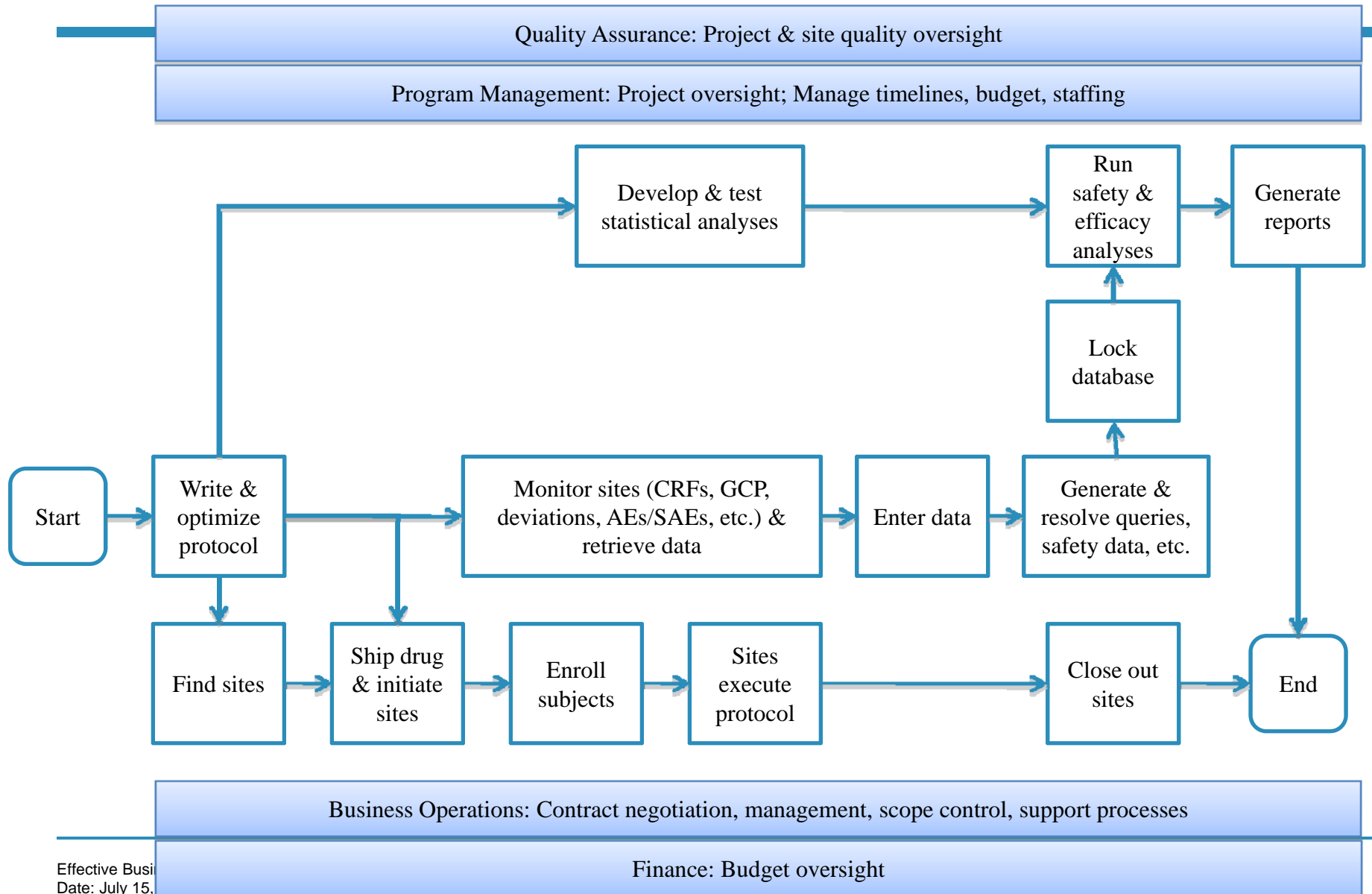
Quality (Q)

Relationship

Provide a benefit to Sponsor and  
Service Provider

Add Value

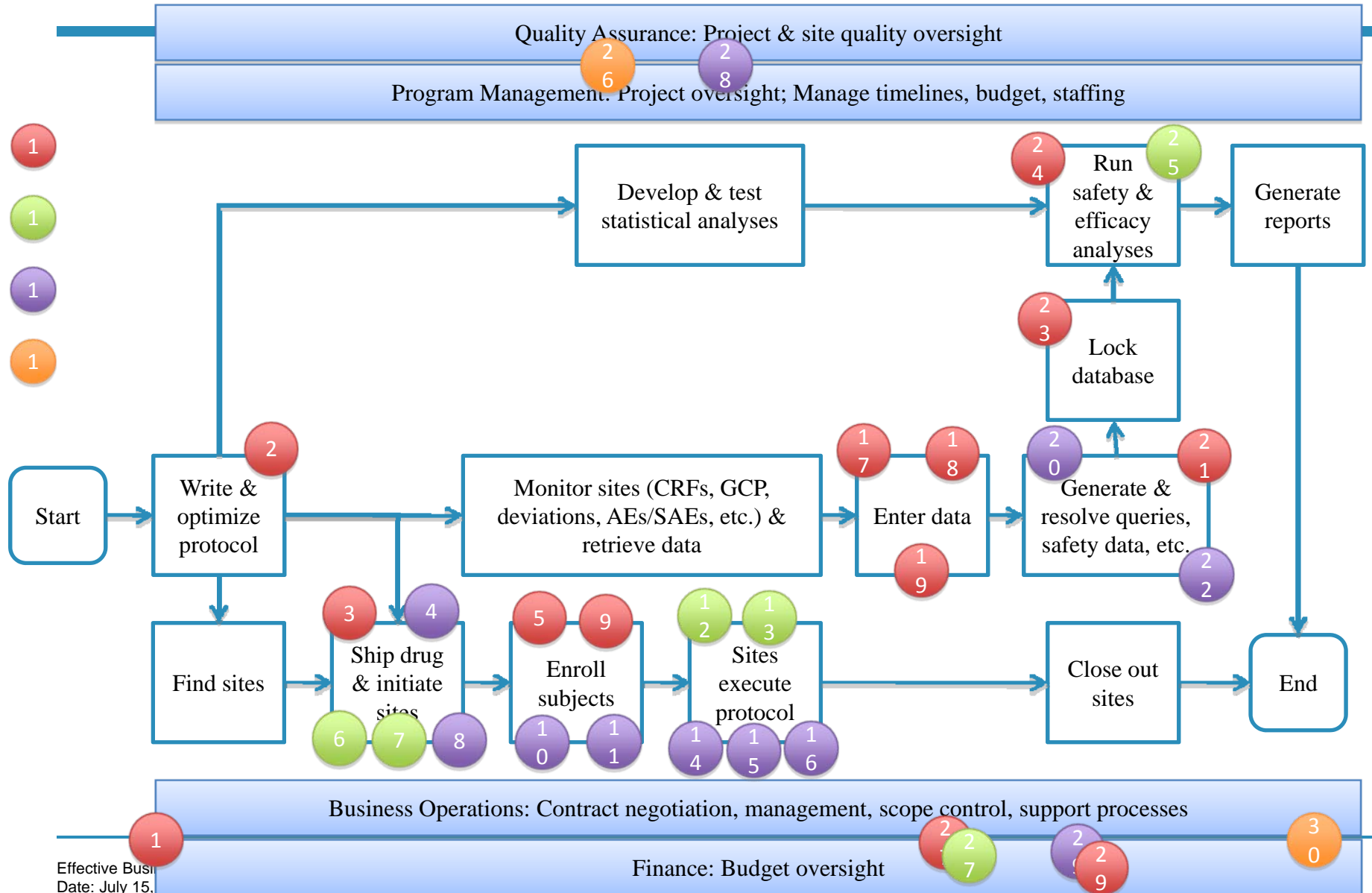
# Typical Trial-Level Process



# MCC Clinical Trial Performance Metrics Development Process

Metric #	Metric Type	Metric Title	Category	Metric Indicator
3	CT	Cycle Time protocol approval to first site activated	Site Selection and Activation	LEADING Indicator
		<b>Definition</b>	<b>Formula / Example</b>	<b>Reporting Detail</b>
		The total number of calendar days from the date the final approved protocol is released to the CRO to the date of first site activated (trial level, country level) where site activation is defined as site has been approved to begin screening patients.	Formula: X - Y, where X is Date of First Site Activated; and Y is Date of Protocol Approval  Specific Example: Protocol Approved April 13 and First Site Activated August 1; [Aug 1 -- Apr 13] = 109 calendar days	By trial level By country  <b>Unit of Measure</b> Days/Weeks
		<b>Business Driver(s) / Benefit Statement</b>	<b>Additional Analysis on a "for cause" basis</b>	<b>Reporting Frequency</b>  <b>Target</b>
		Leading indicator for protocol issues, site performance, CRO performance, regulatory approvals, etc. Increased understanding of geographical differences in site activation. The adherence to plan for site activation is a leading indicator for patient enrollment performance. Key project management indicator of adherence to project plan.	Analysis of reasons for delay include timelines for ethics approvals/ signed site agreement and regulatory approval. Monitoring resource availability. Protocol amendments.	Bi monthly during site selection phase  Plus or Minus 2 weeks per contract, by geography (G); within 2-4 weeks per contract by geography (Y); >4 weeks per contract by geography ( R)

# Metrics Distribution



# MCC Clinical Trial Performance Metrics (Beta version)

Metric	Metric Title	Metric Indicator
1	Contract finalization and execution timeliness	LAGGING Indicator
2	Final Approved Protocol to Final Approved CRF	LAGGING Indicator
3	Cycle Time protocol approval to first site activated	LEADING Indicator
4	Investigator Site Reg pack approval rate	LEADING Indicator
5	Cycle time from final Protocol Approval to First Patient-First Visit (all sites)	LEADING Indicator
6	% Planned Sites Activated	LEADING Indicator
7	Drug Onsite at Initiation	LEADING Indicator
8	Drug Supply Planning	LEADING Indicator

Metric	Metric Title	Metric Indicator
9	Cycle time from Site Activation to First Patient First Visit	LAGGING Indicator
10	Site Productivity	LEADING Indicator
11	Screen Failure Rate	LEADING Indicator
12	Correct Drug Inventory & Resupply	LEADING Indicator
13	% Patients randomized	LEADING Indicator
14	Patent Retention rate	LEADING Indicator
15	% Sites Prematurely Terminated	LAGGING Indicator
16	Audit Findings	LAGGING Indicator

LAGGING INDICATOR = End user will use metric to identify opportunities to affect change in the future study trials.

LEADING INDICATOR = End user will use metric to identify opportunities to affect change in the current trial.

# MCC Clinical Trial Performance Metrics (Beta version)

Metric	Metric Title	Metric Indicator
17	Final CRF/eCFR to Database "Go Live"	LAGGING Indicator
18	CRFs Received to Data Entry Complete - Paper	LEADING Indicator
19	Patient Visit Complete to eCRF data entered - EDC	LEADING Indicator
20	Data discrepancies generated by automated edit checks	LAGGING Indicator * *Could be LEADING Indicator if reported on a monthly basis
21	Receipt of Query Response to Database Update Time	LEADING Indicator
22	QC Rounds Required to Meet Target Error Rate	LAGGING Indicator
23	LPLV (last patient, last visit) to Database Lock	LAGGING Indicator

Metric	Metric Title	Metric Indicator
24	SAP Finalization to Final Pre-lock Blinded TLGs	LAGGING Indicator
25	TLGs delivered within target date	LAGGING Indicator
26	Determination of project progress versus planned	LEADING Indicator
27	Invoice and payment timeliness	LEADING Indicator
28	Issue identification, management and criticality	LAGGING Indicator
29	Measure of true change orders and timeliness of execution	LAGGING Indicator
30	Budget and pricing accuracy	LAGGING Indicator

LAGGING INDICATOR = End user will use metric to identify opportunities to affect change in the future study trials.

LEADING INDICATOR = End user will use metric to identify opportunities to affect change in the current trial.



# Thank You

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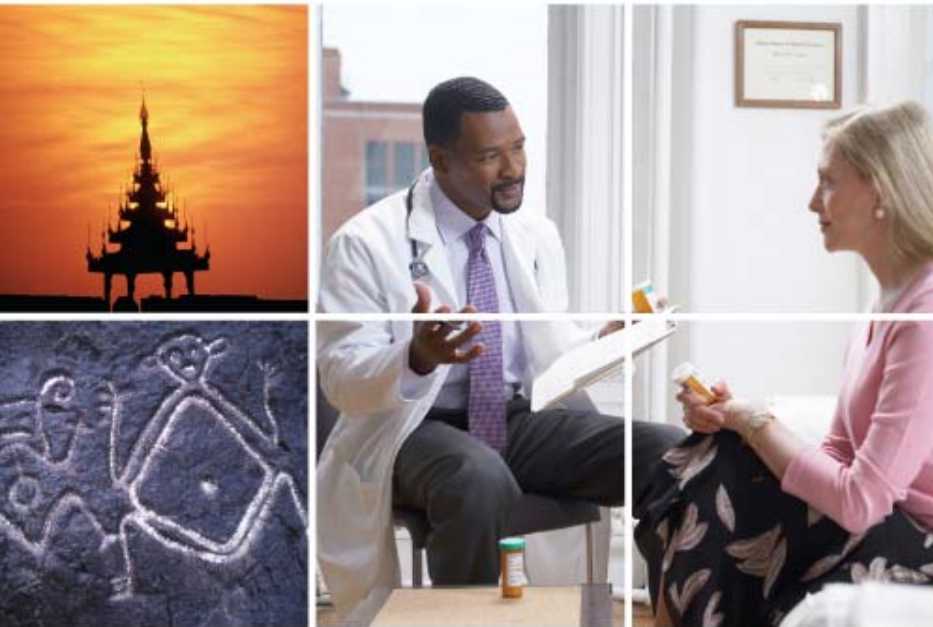
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# Performance Metrics as a BD Tool

## ICON Clinical Research

### Incorporating Performance Metrics into Proposals and Contracting

Mike Minor

15 July 2009

- **Historical perspective**
  - Metrics: Frequently requested, seldom consistent, often confusing, mostly misunderstood
- **MCC Standardization approach**
  - Facilitates collection and reporting
  - Well defined
  - Interpretable across participants
  - Relevant to work and performance

- Included in MSA (defined once)
- Discussed in governance (regular discussion promotes better understanding)
- Adopted in working practices (process improvements)
- Adjunct to internal KPIs (more focused)
- Assists with alignment of resources and goals
  - Timelines, quality gates, costs

# Metrics in the BD Continuum

**RFI ⇒ Proposal ⇒ Contract**

- Distinguish operations based on industry standards for timeliness and quality
  - Present tangible benefits to working with your CRO
- Set expectations for future engagements based on benchmarks
  - Reinforces marketing messaging with objective measures

- **Target Metrics add definition to scope**
  - Cycles and turnaround times
  - Quality gates and rejection rates
- **Better comprehension of deliverables expectations**
  - Yields more accurate costs
  - Fewer out of scopes and over budget situations

- Commit to **essential** metrics
- Reduce ambiguity in contracting objectives and incentives
- Promote relationship management through metrics maintenance in governance
  - Standardization of reporting and performance appraisal leads to open dialog and process improvement

- Documented solid performance encourages repeat performances
- Governance promotes awareness
- Benchmarking helps client do better
- Risks may be identified early
- Industry-wide definitions make reporting simpler and more efficient

- Requirements for achieving strong performance are well defined
- Should include both parties to evaluate process improvement opportunities
- Benchmark metrics can be used to score clients
  - Turn around or response times
  - DSOs
  - Helps identify potentially unrealistic expectations in evaluation of contracting risks

## **Use industry-wide metrics to answer RFIs or drive behavior change:**

- “Based upon your expertise, comment on what works well with/for other clients, but has not worked/been implemented with us. Where do you feel we can improve / realize efficiencies?”

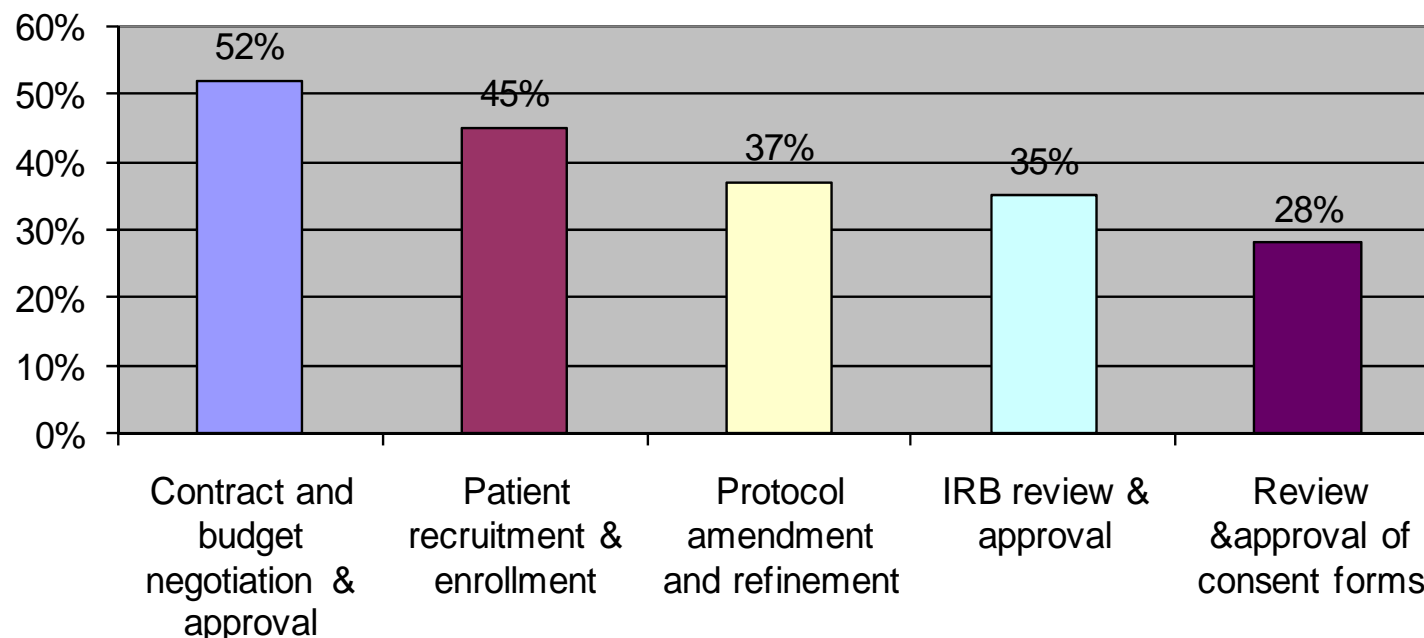
- Serves as foundation for operations-level win-win reviews
- Used as driver for expanded technical reference manuals
  - Mutually agreed practices or revised and updated SOPs
- Promotes constructive dialog leading to performance improvement
  - Partner vs. provider
- Consideration of targets leads to better risk management strategies

# Case Study

## Contracted Metrics Driven Process Improvement

# Identify Relevant Processes

## Factor Most Often Causing Study Delays United States

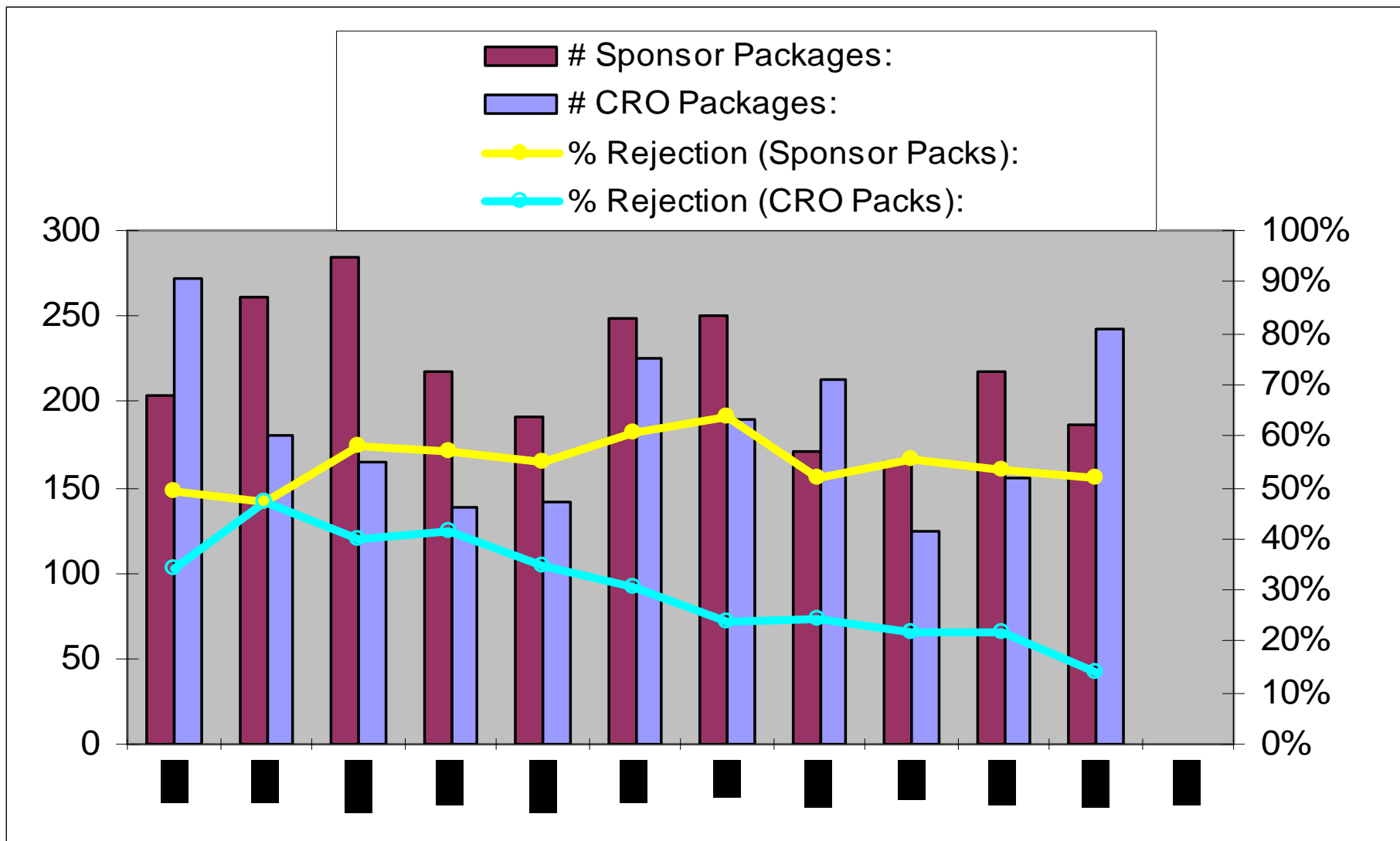


Source: Thomson CenterWatch 2005 Survey of 612 Investigative Sites in the U.S.

- **Observation**
  - Regulatory packages approval rate limiting to start-up
- **Contracted Essential Metrics**
  - Cycle time for approval
  - Rejection rate

- Functional Services
- Approval rate target
- Turnaround target
- Continuous improvement incentive
- Monthly metrics reporting
- Governance Board
  - Monthly functional review
  - Quarterly management review

# Metrics Data



- Internal and external benchmarking identified process improvement opportunities
- Significant improvement in cycle times and lowered rejection rates resulted
  - For Sponsor – faster start-up
- Sustained quality improvement achieved by CRO
  - Reduced oversight (and headcount) required by Sponsor
  - Incentives achieved by CRO
- Expanded assignment of work to CRO

# Questions?