

Overview of Metrics: Definition Refinement & Update from the MCC Central Lab Initiative

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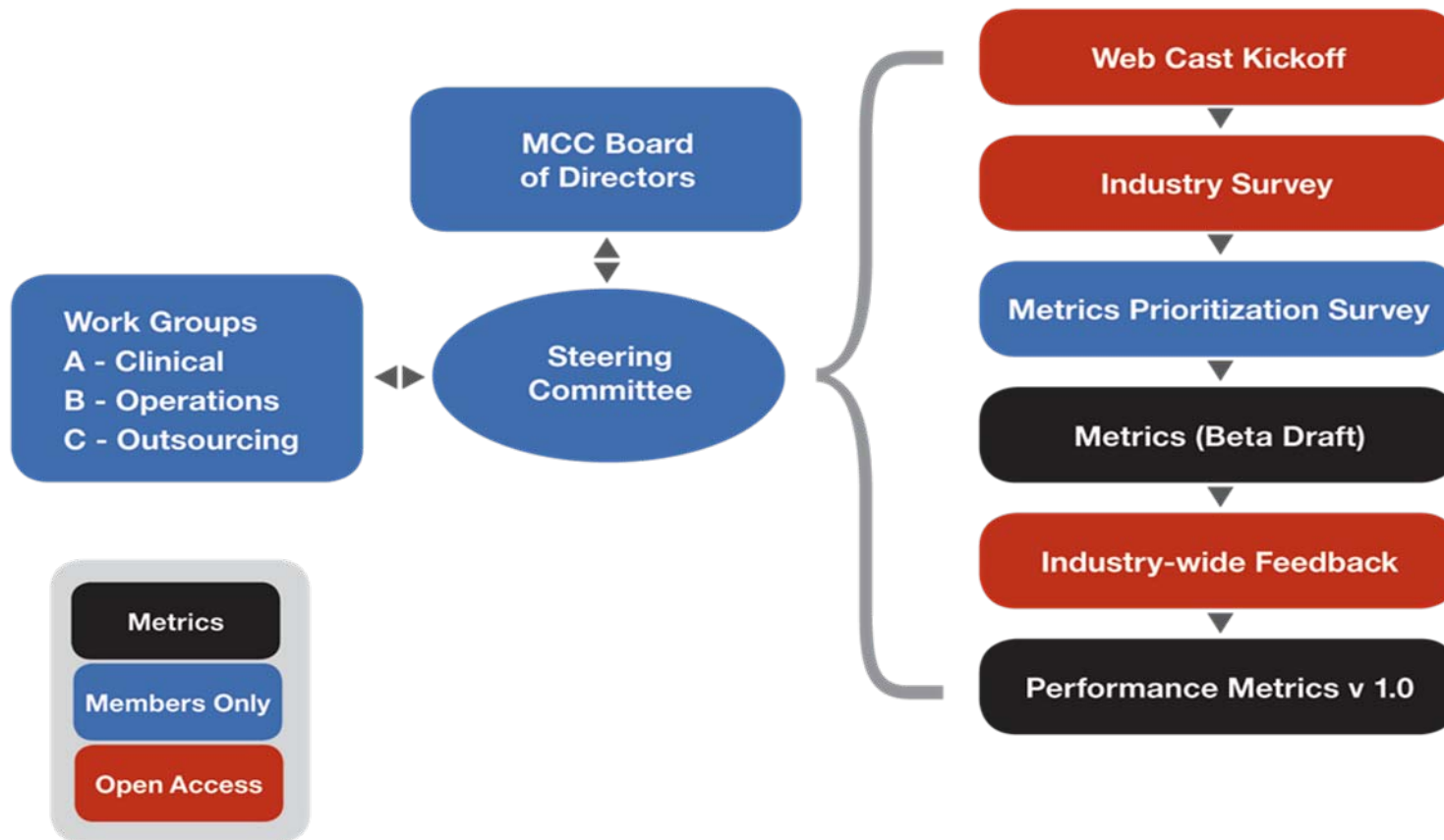
Agenda

- MCC Central Lab Performance Metrics version 1.1 & Review of Definition Refinement Changes
- How Metrics Have Improved Central Lab Deliverables for Sites / Sponsors
- MCC Lab Metrics Initiative Plans for 2009

MCC Central Laboratory Performance Metrics version 1.1

Sue Hwang
Amgen Inc.

Metrics Development Process



Living Metrics –key points

- Joint effort
 - Wide range of perspectives
 - Industry acceptance
- Catalyst for change for both parties
 - Improvement opportunities
 - Behavior changes
 - Facts and data for business decisions
- Review and modify as required
 - Continuous collaboration

MCC Central Lab Metrics Definition Refinement WG 1

MCC

**Abbott
Amgen
AstraZeneca
Eli Lilly**



**Covance
Esoterix
ICON
Mayo
MDS
PPD
Quintiles**

MCC Central Lab Metrics Definition Refinement WG 1

Sponsors		Central Labs		MCC
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Abbott	Julie Debus-Levy	PPD	Loc Nguyen	Guy Mascaro
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		Mayo	Jane Collins	

MCC Central Lab Performance Metrics version 1.1

Metric	Category	Metric Title	Definition
1	General Operations	Project management turnover	<p>Minimum: The percentage of the project management turnover in the central laboratory that have direct communication with sponsor for protocols.</p> <p>Additional analysis on a “for cause” basis: A list of project management turnover by name per sponsor and/or by protocol.</p>
2	Protocol Initiation	Percentage first supplies shipped on time to the first site for first patient	<p>Minimum: The percentage of protocols that have the first supplies to first site shipped date met based on the defined expectations between sponsor and central laboratory.</p> <p>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.</p>
3	Site Initiation	Percentage first supplies shipped on time for all sites (all regions)	<p>Minimum: The percentage of protocols that have the first supplies shipped date met for all sites (all regions) based on the defined expectations between sponsor and central laboratory.</p> <p>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.</p>

2. Protocol Initiation = first supplies to first site

- Rationale
 - Important deliverable is ability to meet protocol initiation milestone
 - Shipment of first supplies for a study equates to ready to receive, test, and report test results for that study
 - Time to finalize setup expands to time available for setup
 - Metric formula was clarified to match original intent
- Benefit Statement
 - Ability to complete setup activities in time for study start
 - Ability to deliver initial supplies on time to achieve first patient visit milestone
- Combined with Metric 3 = first supplies to all sites
 - Central labs ability to supply all global sites per sponsor's site initiation schedule



MCC Central Lab Performance Metrics version 1.1

Metric	Category	Metric Title	Definition
4	Data Cleaning	Percentage of queries from central laboratory to site based upon requisitions received	<p>Minimum: The number of queries generated between the central laboratory and the sites, compared to the number of requisitions received by a central laboratory.</p> <p>Additional analysis on a “for cause” basis:</p> <p>a. The number of queries generated between the central laboratory and the site, compared to the number of requisitions received for a site, protocol, sponsor, and central laboratory by business unit.</p> <p>b. The reasons which resulted in these calls by central laboratory defined by site, protocol, sponsor, and central laboratory by business unit.</p>
5	Data Cleaning	Average turnaround for resolution of queries from central laboratory to site	<p>Minimum: Average time required for resolution of queries from central laboratory to site based on the requisitions received by a central laboratory.</p> <p>Additional analysis on a “for cause” basis: The amount of time required to resolve these queries by reason for a site, protocol, sponsor, and central laboratory by business unit.</p>
6	Site Support Services	Percentage of queries from site to central laboratory based upon requisitions received and average turnaround time	<p>Minimum: The number of queries generated between the site and the central laboratory, compared to the number of requisitions received for a sponsor and central laboratory, and the average time to resolution.</p> <p>Additional analysis on a “for cause” basis: The number and type of queries generated between the site and the central laboratory, compared to the number of requisitions received by protocol.</p>

MCC Central Lab Performance Metrics version 1.1

Metric	Category	Metric Title	Definition
7	Site Support Services	Average turnaround time on queries from site to central laboratory	<p>Minimum: The average time required to resolve queries generated between the site and the central laboratory for a sponsor and central laboratory.</p> <p>Additional analysis on a “for cause” basis: The average time required to resolve queries generated between the site and the central laboratory for a protocol, compared to the number of requisitions, accessions, or sites.</p>
8	Safety	Percentage of panics that had both 1st attempts made and were successfully communicated to the sites within the defined turn around times	<p>Minimum: Percentage of panics that had both 1st attempts made and were successfully communicated to the sites within the defined turn around times- overall by sponsor and central laboratory.</p> <p>Additional analysis on a “for cause” basis: Percentage of panics not successfully attempted nor successfully provided within the defined turn around time for a site, protocol, sponsor and central laboratory by business unit.</p> <p>Note: “Attempts” and “Successfully” could be defined per Standard Operating Procedures or specific requests per sponsor.</p>
9	Laboratory Operations	Percentage specific test(s) reported within expected turnaround time	<p>Minimum: Percentage of specific test(s) as defined by the sponsor and service provider which reported “results available” or were reported to the investigator sites within the defined turnaround time as agreed upon by the sponsor and service provider - overall by protocol, sponsor and central laboratory.</p> <p>Additional analysis on a “for cause” basis: Percentage and median of specific test(s) as defined by the sponsor and service provider which were reported or “results available” to the investigator sites within the defined turnaround time as agreed upon by the sponsor and service provider per business unit by protocol, sponsor and central laboratory.</p> <p>Note: Median is based upon the percentage of tests reported “results available” in the expected turnaround time.</p>

MCC Central Lab Performance Metrics version 1.1

Metric	Category	Metric Title	Definition^
10	Laboratory Operations	Percentage tests not reportable	<p>Minimum: The percentage of tests not reportable for any reason by "general areas of concerns" overall by sponsor and central laboratory.</p> <p>Additional analysis on a "for cause" basis: The percentage of tests not reportable by "general areas of concerns" for a protocol, sponsor, central laboratory by business unit.</p> <p>Notes:</p> <ul style="list-style-type: none"> • Not Reportable is defined as tests cancelled for any reason (e.g. QNS, stability, etc). • The "general area of concerns" could be site, courier, receipt and laboratory / testing analysis with the appropriate cancellations placed in each category per central laboratory's processes. • A list of all "general areas of concern" should be included with this metric for reference.
11	Laboratory Operations	Percentage of shipments on time to sponsor directed third party	DELETED

11. On time shipments to 3rd party labs - Deleted

- Rationale - Metric was not an accurate reflection of central lab performance
- Referral labs - shipments are typically made to meet the TAT commitment of that test
- Labs for batch testing or handling (eg. Storage) - shipments are made on a pre-defined schedule
- Ad Hoc requests - shipment dates are negotiated at the time of request
- TAT performance is collected in metric 9
- Good internal metric for lab managers to monitor process
- Majority of central labs did not see a demand for this metric from sponsors

MCC Central Lab Performance Metrics version 1.1

Metric	Category	Metric Title	Definition^
12	Data Management	Percentage on time accepted file transfers	<p>Minimum: The percentage of “on time” accepted file transfers as defined by the sponsor and service provider for sponsor and central laboratory.</p> <p>Additional analysis on a “for cause” basis: The percentages of incremental / cumulative and final “on time” accepted file transfers as defined by the sponsor and service provider per protocol.</p>
13	Financial Management	Plan, Forecast and Actual Financial Report	<p>Minimum: An overview report provided by protocol, which compares the original forecasted budget (Request for Budget Pricing), the updated projected budget (after signature of the Statement of Work) and final 'actual' invoices for the protocol.</p> <p>Additional analysis on a “for cause” basis: This report would be defined between the sponsor and central laboratory to provide additional detail for a central laboratory service and/or per business unit.</p> <p>Notes:</p> <ul style="list-style-type: none"> • The central laboratory may use the defined categories on the attached spreadsheet. • Recommendation: A minimum annual historical portfolio variance report (original forecast, contracted budget vs. actual spend) by sponsor and central laboratory should be requested.
14	Financial Management	Comparison of budgeted and actual transportation costs by region and/or country	<p>Note: Transportation should be incorporated as a service area in the overview report in Metric #13 (refer to Budget Reconciliation Form).</p> <p>Minimum: The transportation costs will be added by region and/or country to each of the segments.</p> <p>Additional analysis on a “for cause” basis: The transportation costs could be further defined by type (e.g. ambient, frozen and combination).</p>
15	Quality Assurance	Percentage of audit findings closed within sponsor and central laboratory agreed upon timeframe	<p>Minimum: The percentage of the audit findings (including Financial, Quality Assurance and Computer Systems Quality) closed prior to or by the original timeline agreed upon between the sponsor and service provider by sponsor and central laboratory.</p> <p>Additional analysis on a “for cause” basis: The percentage of audit findings (including Financial, Quality Assurance and Computer Systems Quality) that require an adjustment to the timelines by the number of times (e.g. one time, two times, three times, etc.) by sponsor and central laboratory.</p>

MCC Central Lab Performance Metrics version 1.1

- Version 1.1 has been implemented!
 - WG1 effort on definition refinement concluded in January 2008
 - MCC inquiry sessions at IIR Partnerships conferences in January & April 2008
 - MCC Labs Steering Committee approval in March 2008
 - Launched in July 2008



MCC Central Laboratory Performance Metrics

How Metrics Have Improved Central Lab Deliverables - Sponsor perspective

Cynthia Lindemann

Eli Lilly and Company

Performance Metrics: History – Lilly's Original Goals

- A “Strong” Sponsor/Service Provider Relationship supported with performance metrics allowing mutual benefit
- Reduced “Relationship Roller Coaster” via performance metrics evaluations
- Continual stream of performance improvement and cycle time reduction through Performance metrics

Performance Metrics: History – Lilly’s First Actions









- Prior to 2003, all metric requests were “ad hoc”
- In 2003, Lilly began defining metrics to be requested from Central Laboratory Partnerships
 - The original list which was never implemented included a total of 50 metrics which covered all aspects of the business cycle from protocol set-up through on-study management to datalock.
- In 2004, Lilly was asked to join the Customer Advisory Board to focus on the establishment of standard industry-wide metrics. This later became the MCC.

Performance Metrics: Lilly's Current Status

- Lilly is a sponsoring member of the MCC
- Lilly is working with all our current Central Laboratory Partners (as well as other service providers) to implement the standardized metrics defined by the MCC
- Lilly continues to maintain previously defined metrics (established in 2005 and adapted as appropriate) for quarterly review and action until the majority of the MCC metrics are available across providers
- To date - all challenges which have arisen based on the metrics have resulted in positive outcomes

Quality Improvements through Metrics: Example 1 – Initial Metrics*

Metric	Category	Metric Title	Target^^
2	Protocol Initiation	Percentage first supplies shipped on time to the first site for first patient	Per Contract Lilly 100%

Q1 2005	Q2 2005	Q3 2005	Q4 2005	Q1 2006	Q2 2006	Q3 2006	Q4 2006	Q1 2007
-	92.6%	91.3%	93.3%	87.1%	88.3%	92.1%	78.5%	84.3%
								



*based on all four years of Lilly Standard Metrics across multiple service providers

Quality Improvements through Metrics: Example 1 – Next Steps

- Active Discussion with regard to process and expectations which led to:
 - Clear, concise definition of the metric
 - Explanation of Lilly process which requires set-up to occur in advance of the Kit Receipt Date not ‘just in time’ for the Kit Receipt Date
- Service provider(s) restructured standard timelines to allow more lead time
- Interim adjustment of Expectations and Measurement
- Clear, concise definition of the metric

Quality Improvements through Metrics: Example 1 – Past and Present

Metric	Category	Metric Title	Target^^
2	Protocol Initiation	Percentage first supplies shipped on time to the first site for first patient	Per Contract Lilly 95%

Q1 2005	Q2 2005	Q3 2005	Q4 2005	Q1 2006	Q2 2006	Q3 2006	Q4 2006	Q1 2007
-	92.6%	91.3%	93.3%	87.1%	88.3%	92.1%	78.5%	84.3%

Q2 2007	Q3 2007	Q4 2007	Q1 2008	Q2 2008	Q3 2008
93.0%	95.2%	96.23%	96.39%	88.90%	97.21%



*based on all four years of Lilly Standard Metrics across multiple service providers

Quality Improvements through Metrics: Example 1 – Outcomes

- Improvement of deliverable over time
- Continued Active Review of any goals not met to assess potential next steps / actions
- Current Goal: Return to and meet 100% Target

Quality Improvements through Metrics: Example 2 – Initial Metrics*

Metric	Category	Metric Title	Target^^
11 (old #12)	Data Management	Percentage on time accepted file transfers	>95% Lilly 100%

	Q1 2005	Q2 2005	Q3 2005	Q4 2005	Q1 2006	Q2 2006	Q3 2006	Q4 2006
Overall	-	96%	100%	100%	98%	100%	100%	100%

	Q1 2007	Q2 2007	Q3 2007	Q4 2007
Overall	90%	100%	99%	100%



*based on all four years of Lilly Standard Metrics across multiple service providers

Quality Improvements through Metrics: Example 2 – Next Steps

- Active Discussion with regard to perception that Data Transfer was not occurring as anticipated but metrics indicate success in most quarters which led to:
 - Further explanation of Lilly requirements
 - Detailed review of First File versus On-Study Deliverable timelines
- Service provider(s) reevaluating processes to adjust for challenges
- Interim adjustment of Expectations and Measurement
- Clear, concise definition of the metric

Quality Improvements through Metrics: Example 2 – Past and Present

Metric	Category	Metric Title	Target^^
11 (old #12)	Data Management	Percentage on time accepted file transfers	>95% Lilly 99%

	Q1 2005	Q2 2005	Q3 2005	Q4 2005	Q1 2006	Q2 2006	Q3 2006	Q4 2006
Overall	-	98% ❌	100% ✔️	100% ✔️	97% ❌	100% ✔️	100% ✔️	100% ✔️
Initial	-	-	100% ✔️	100% ✔️	92% ❌	100% ✔️	100% ✔️	100% ✔️
Ongoing	-	-	100% ✔️	100% ✔️	100% ✔️	100% ✔️	100% ✔️	100% ✔️

	Q1 2007	Q2 2007	Q3 2007	Q4 2007	Q1 2008	Q2 2008	Q3 2008
Overall	90% ❌	100% ✔️	99% ✔️	100% ✔️	100% ✔️	99% ✔️	96% ❌
Initial	67% ❌	0% ❌	96% ❌	88% ❌	100% ✔️	95% ❌	94% ❌
Ongoing	83% ❌	99% ✔️	99% ✔️	100% ✔️	100% ✔️	99% ✔️	98% ❌



*based on all four years of Lilly Standard Metrics across multiple service providers

Quality Improvements through Metrics: Example 1 – Outcomes

- Ongoing Discussion continues as improvement of deliverable remains a challenge:
 - Interim Adjustments to expectations
 - Continued Process Review and adjustment
- Current Goal: Return to and meet 100% Target

Why Start to or Continue to Utilize Performance Metrics?

- Enhanced Communication
- Greater Understanding of Processes and associated Expectations
- Improved Monitoring of Critical Deliverables
- Greater Focus on Achieving Meaningful Process Improvement
- Ability to Compare Across Industry

MCC Central Laboratory Performance Metrics

How Metrics Have Improved Central Lab Deliverables - Supplier perspective

Alissa Kerry

Covance Central Lab

History of MCC

Client demands for metrics

CVD launched initiative (2002)

Initiative should be detached from service provider

MCC formed

Industry metrics

Show me the metrics

**Encourages
fact-based
discussions
with clients**

**Builds trust,
which
strengthens
partnerships**

**Holds all
parties
accountable to
deliverables**

**Identifies
process
improvement
opportunities**

MCC Metric: Queries

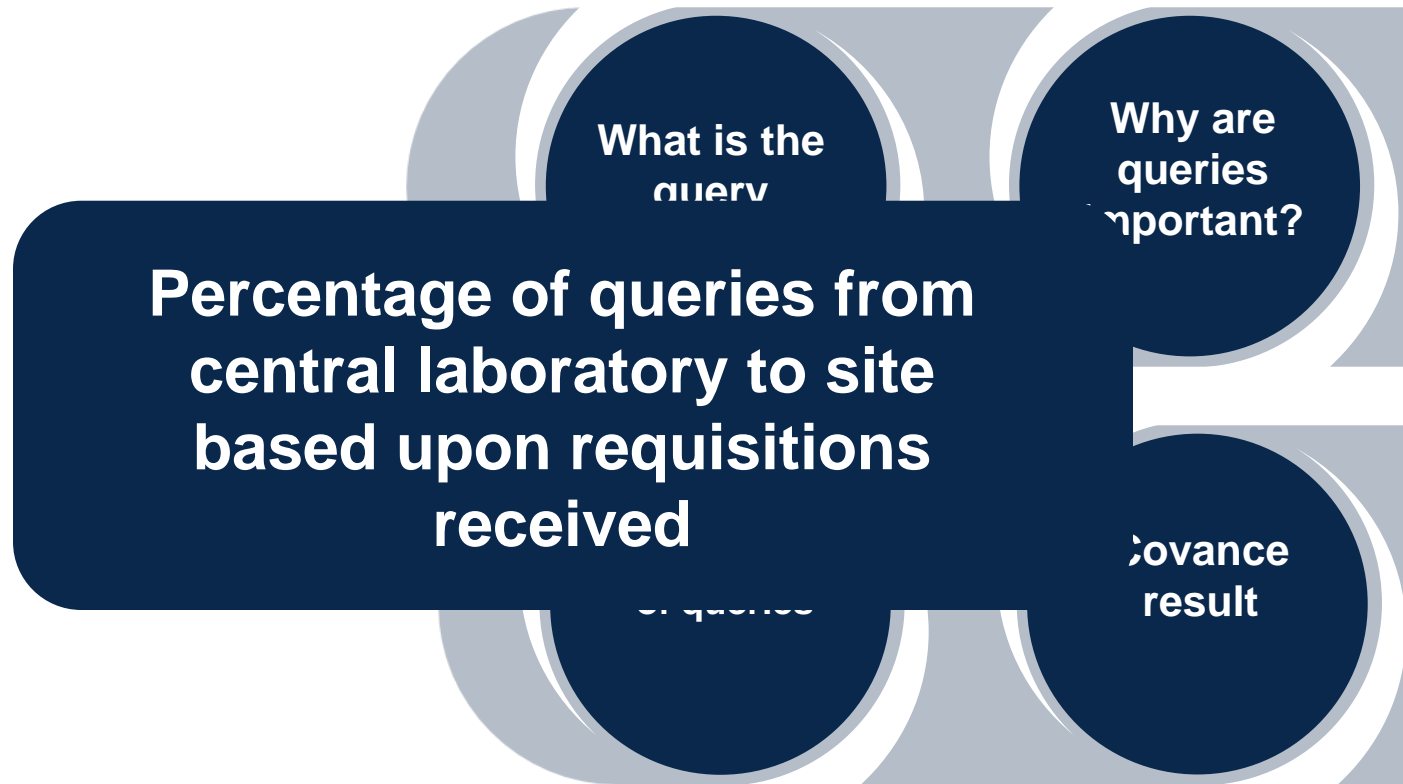
What is the
query
process?

Why are
queries
important?

Challenges
of queries

Covance
result

MCC Metric: Queries



Evaluation

Explored reasons for queries

“Just do it” and Six Sigma Projects

Hard to pinpoint when improvements took effect

Individual projects may need specific action

Actions

“ If the metric will not be used to adjust operations and business strategy, there is little point in gathering it. ”

Ralph Danrea, ITX Corporation

OPR project

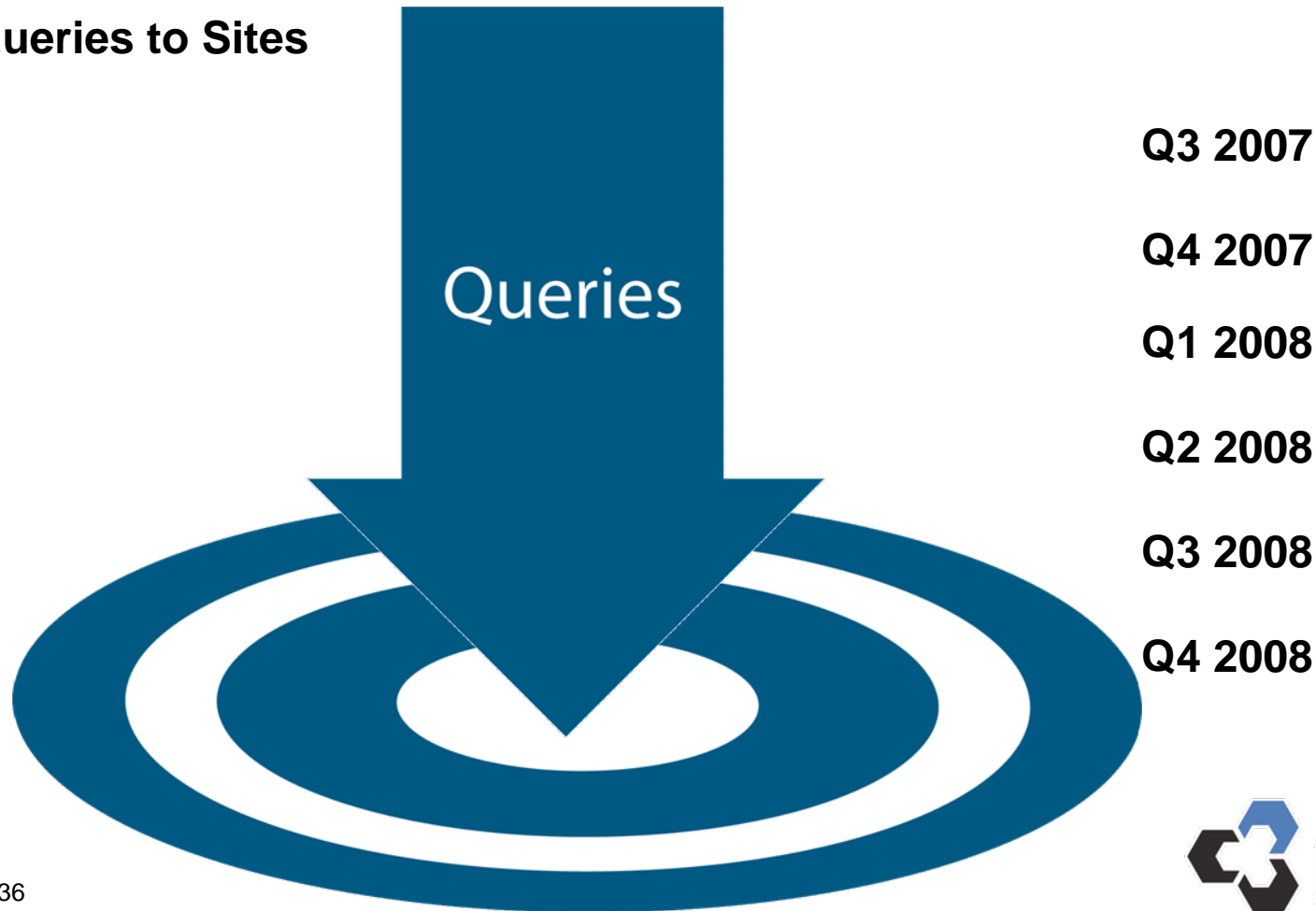
Kit expiry

Sex/DOB only on first 2 visits

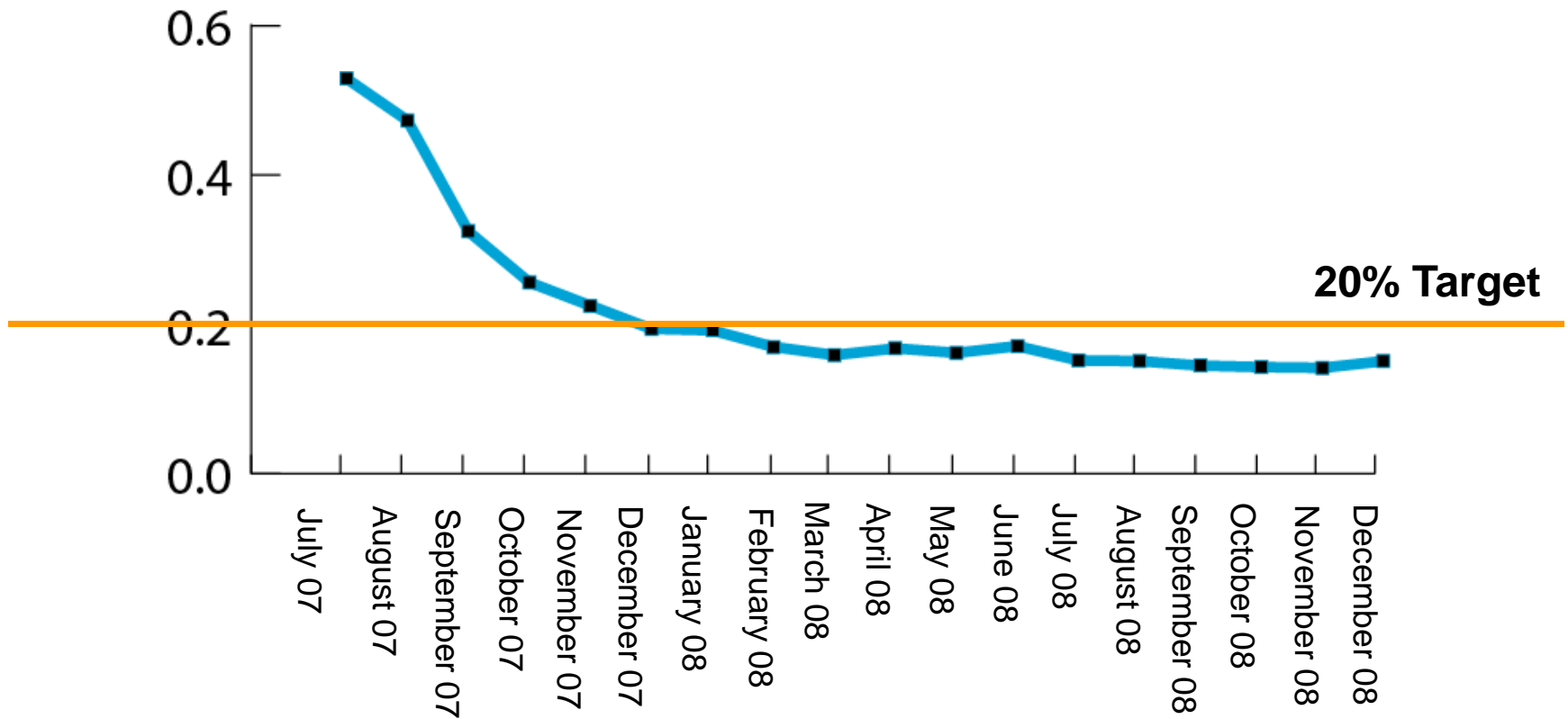
Study design meetings

Quarterly Results

Outbound Calls Queries to Sites



Results: Protocol Specific Example



Summary

Data

Exposes symptoms

Queries

One example of high level # to indicate opportunity for change

Metric

A measurement taken over a period of time that communicates a vital story about a process

MCC Central Laboratory Performance Metrics version 1.1

MCC Lab Metrics Initiative Plans for 2009

Linda Sullivan

MCC

Lab Metrics Initiative 2009 Activities

- Launch/relaunch MCC CL work groups:
 - Data collection tool WG
 - Create a standard data reporting template
 - Implementation / Shared Learning WG
 - Expand current case studies & build additional case studies
 - Develop ***How to use metrics to improve clinical trial performance*** white paper
 - Create ***New Member Welcome Packet*** and other training aids

Lab Metrics Initiative 2009 Activities

- MCC Lab Metrics WGs web-based meetings will begin in 2/2009
- Please contact Linda Sullivan at 317.848.2908 for additional information about participating in MCC activities