
Case Study - Implementation of the MCC Performance Metrics for Central Laboratory Strategic Partnerships: Sponsor and Service Provider Perspective

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Objectives

- Share both a sponsor and service provider practical example of the transition to a Performance Metrics Driven Organization
- Share experiences / outcomes for the benefit of others

Performance Metrics: Lilly's First Thoughts

- Performance Metrics are becoming critical to any Sponsor-Service Provider partnership to ensure consistent review and evaluation
- Performance Metrics utilized should be a balance of subjective and objective measures which apply directly to the business being evaluated
- The most important step is to begin; defining the “perfect” metric is an evolution
- Utilize available information and process....recreating the wheel reduces productivity and cycle time

Performance Metrics: Quintiles Laboratories First Thoughts

- Prior to the Metrics Champion Consortium...
 - Recognition of the value of metrics
 - Mixed and often inconsistent objectives
 - Varied and often long lists of requirements
 - Some real success with strategic partners
 - Not scalable without standardization thus costly for service providers

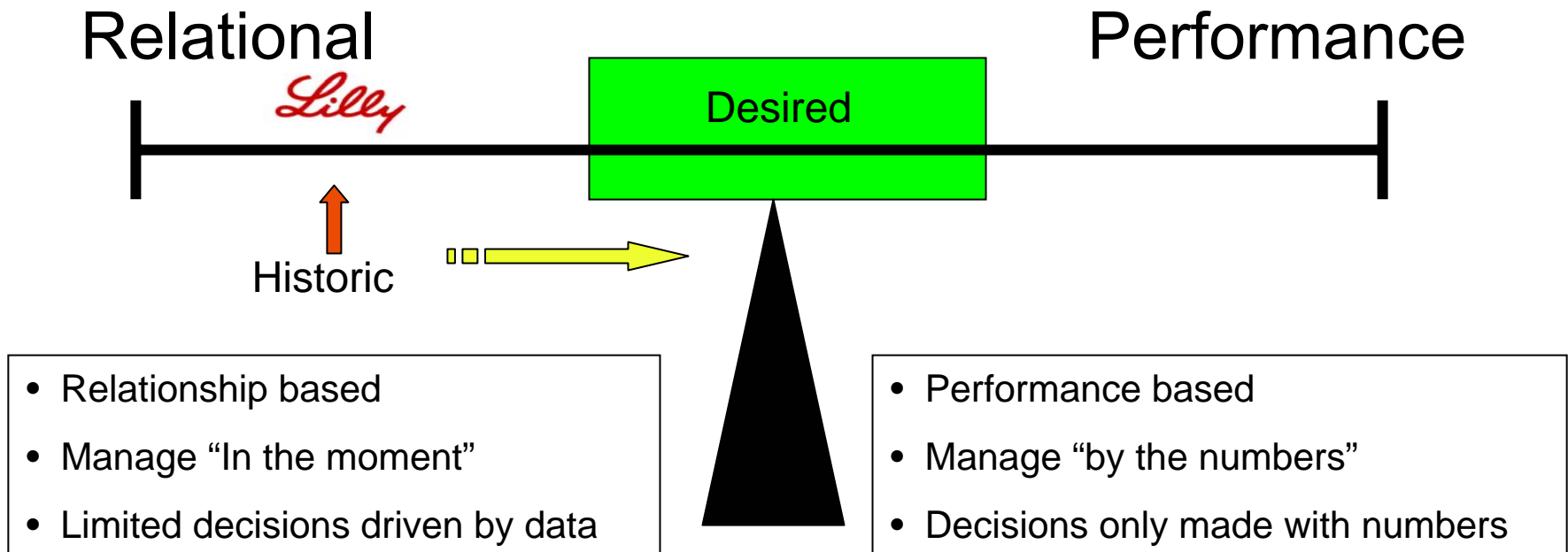
Performance Metrics: History – Lilly's First Steps

- Evaluate and understand internal structure / approach, gap analysis and goals:
 - Structure / Approach:
 - Lilly has a centralized department which manages all central laboratory, ECG and Imaging support for all teams and phases of protocol
 - Lilly has developed several well integrated partnerships in which both parties have a vested interest in success
 - Lilly seriously evaluated performance metrics only during Master Service Agreement negotiations
 - No standardized tools were applied to the management of the partnership; Lilly relied on the daily relationships (e.g. Project Associates, Coordinators) to do this
 - Lilly did not competitively bid protocols between partners



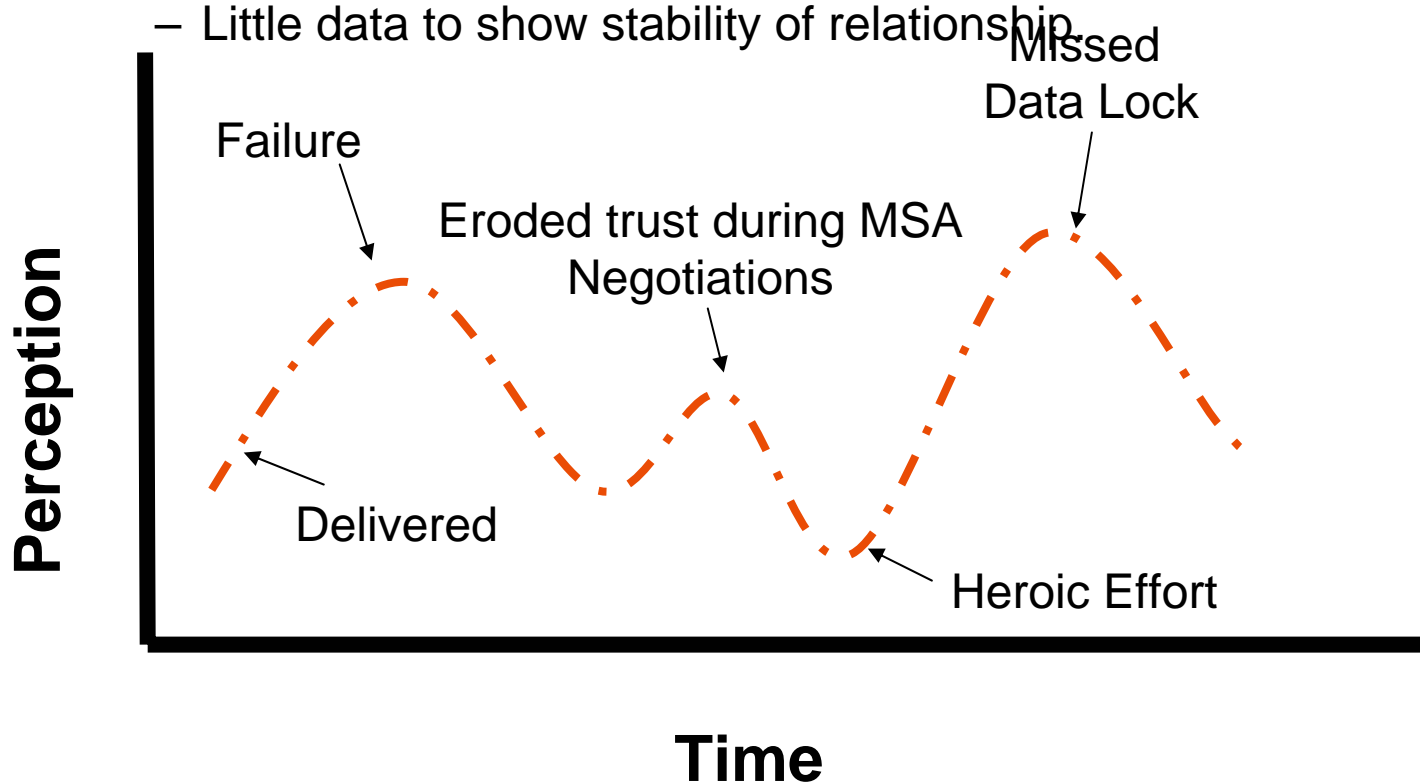
Performance Metrics: History – Lilly’s First Steps

- Gap Analysis:
 - Lilly wanted to move from relational based partnerships to a performance based partnerships



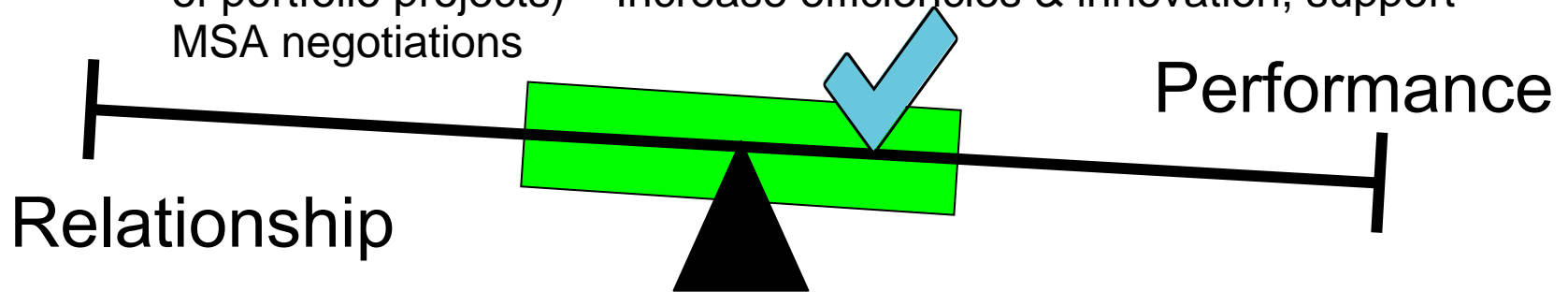
Performance Metrics: History – Lilly’s First Steps

- Gap Analysis:
 - Lilly wanted to move away from a “relational” roller coaster ride
 - **Conclusions:**
 - You are only as good as your last success or failure.
 - Little data to show stability of relationship.



Performance Metrics: History – Lilly's First Steps

- Gap Analysis:
 - Retain from current Lilly processes:
 - Centralized organization – increased efficiency internally and with service provider partners
 - Informal bench marking indicates a 20% to 30% greater productivity over decentralized competitors
 - Integrated relationships (within and between) – data standards, IT, processes
 - Add to achieve greater balance:
 - Performance Metrics – Drive Improvements, Track Relationships
 - Competitive bidding (All projects > \$500,00 and approximately 30% of portfolio projects) – Increase efficiencies & innovation, support MSA negotiations



Performance Metrics: History – Lilly's First Steps

- 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 idea through Performance metrics



Performance Metrics: History – Quintiles Laboratories First Steps

- Struggled to negotiate meaningful metrics in late 90's
- All metrics were one sided and only measured provider performance
- Required manual reports
- Data could only be compiled by project, not by sponsor
- Data sometimes produced more questions than answers

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 being hosted by Covance Central Laboratory Services to focus on the establishment of standard industry-wide metrics.

Performance Metrics: History – Lilly's First Actions



- During this time, we continued to pursue metric evaluations from our Central Laboratory Partners
 - The list of metrics which was agreed upon and generated included the following data:
 - **Customer Satisfaction:**
 - 360° degree customer satisfaction survey between teams
 - Relationship Management Meeting Structure: Strategic, Operational / Business Improvement and Weekly Operational Meetings

The MCC Metric which will replace current metric (if applicable) is listed in **purple** for reference.

Performance Metrics: History – Lilly's First Actions



– Operations Management:

- Work Order Processing
- Data Transfer On-Time and Error-Free (MCC Metric #12)
- Lab Errors and “Not Reportable” Samples / Tests (MCC metrics #9 and #10)
- Lab Reports Issued to the Sites (<24 hours, <48 hours) (MCC metric #9)
- Meet Set-Up timelines (MCC Metrics #2 and #3)
- Kits to site on-time (MCC Metric #3)
- Courier Performance
- Work Order within 3 days of award
- Executed work order within 5 days of receipt
- Number of change orders
- Average number of days for response on Change orders

The MCC Metric which will replace current metric (if applicable) is listed in purple for reference.

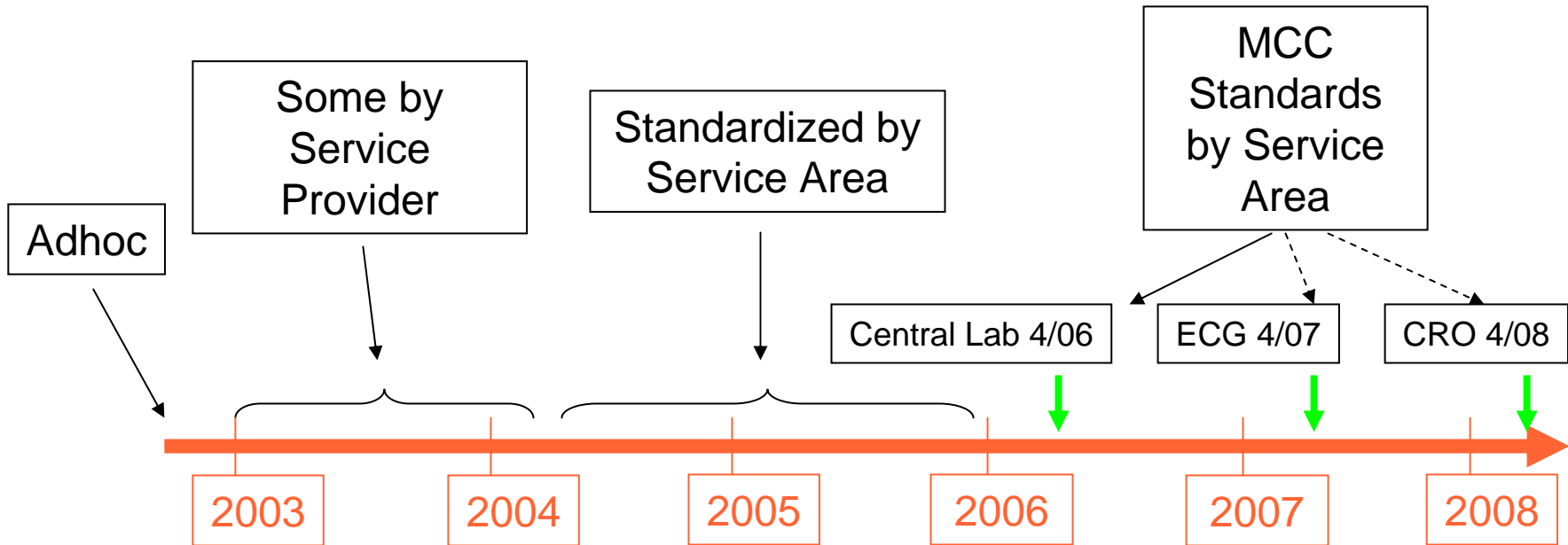
Performance Metrics: History – Lilly's First Actions



- **Innovations and Learning:**
 - Lessons learned
 - Key staff turn-over (MCC Metric #1)
 - Process Improvement Projects
- **Financial:** (MCC Metrics #13 and #14)
 - Business Volume (e.g. # of protocols, \$ Sales (not including transportation), Revenue YTD, Quarterly Revenue, Rolling annual revenue)
 - Accounts Receivables

The MCC Metric which will replace current metric (if applicable) is listed in purple for reference.

Performance Metrics: History – Lilly's First Actions



Result of the various activities:

Lilly has standard Service Provider Metrics for Each Service Area: Central Lab, ECG, Imaging, Banking

Conclusion:

It took a long time starting from Scratch!

Performance Metrics: History – Quintiles Laboratories First Actions

Strategic Goals:

- Provide data that is measurable and actionable
- Use data where both parties share the evaluation of performance
- Use metrics to improve performance of both parties

Tactical Goals:

- Review available data to see what information is available
- Use current data to report as many metrics as possible while enhancing system
- Invest in system to provide necessary data to allow us to report all metrics

Performance Metrics: Lilly's Current Status

- Lilly is a sponsoring member of the Metrics Consortium
- Lilly is working with our current Central Laboratory Partners to implement the standardized metrics defined by the Metrics Consortium
- Lilly will continue to maintain our previously defined metrics for quarterly review and action until the majority of the MCC metrics are available
- All challenges which have arisen based on the metrics have resulted in positive outcomes

MCC Metrics: Availability and Use for Lilly

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

Green indicates metric actively used and tracked by Lilly; Yellow indicates metric to be added in 2007

Performance Metrics: Quintiles Current Status

- Quintiles is a sponsoring member of the Metrics Consortium
- Quintiles is working with several of our sponsors to implement the standardized metrics defined by the Metrics Consortium

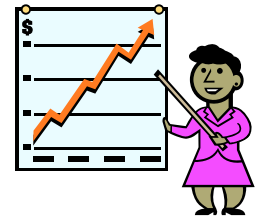
Performance Metrics: Quintiles Laboratories Current Status

1	General Operations	Project Management turnover during protocol	Currently tracking-manual process limiting scalability
2	Protocol Initiation	Average number of working days from statement of work signature to "database ready"	Currently tracking-currently manual process limiting scalability
3	Site Initiation	Percentage first supplies shipped on time	Currently tracking
4	Data Cleaning	Percentage of queries from central laboratory to site based on requisitions received	Data available but not currently requested. Working to automate tracking.
5	Data Cleaning	Average turnaround for resolution of queries from central lab to site	Data available but not currently requested. Working to automate tracking.
6	Site Support Services	Percentage of queries from site to central lab based on requisitions received	Not Currently Requested Longer - Term Availability
7	Site Support Services	Average turnaround time on queries from site to central laboratory	Not Currently Requested Longer - Term Availability
8	Safety	Percentage of panics successfully communicated to sites within defined turnaround time	Data available but not currently requested. Working to automate tracking.

Performance Metrics: Quintiles Laboratories Current Status

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10	Laboratory Operations	Percentage tests not reportable	Currently tracking
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12	Data Management	Percentage on time accepted file transfers	Currently tracking -currently manual process limiting scalability
13	Financial Management	Plan, Forecast, and Actual Financial Report	Currently tracking
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Performance Metrics: Outcomes*

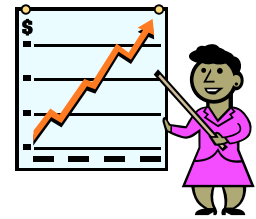


- Quarterly review of available MCC metrics and current Lilly metrics initiated the following:

- **MCC Metric #2 Challenge:** Timeline dates were not structured to meet Lilly expectations for “database ready”
 - Action: The service provider restructured their standard study start up timelines to meet Lilly’s expectations
 - Result: Provider agrees to have kits ready based upon agreed upon timelines vs. FPFV. Evaluation ongoing based on new process.
- **MCC Metric #3 Challenge:** Initial kit shipments to sites was not occurring as expected
 - Action: The service provider restructured their standard timelines to allow more lead time.
 - Result: More lead time built into start up process. Evaluation ongoing

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

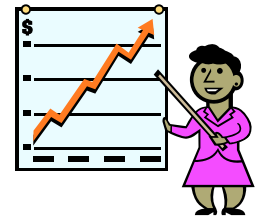
Performance Metrics: Outcomes*



- **MCC Metric #9 Challenge:** The percentage of test reported within the expected turnaround time meets Lilly’s requirements.
 - Action: This metric remains “on-track”; no action needed
 - Result: Team confidence that the information being provided by the central laboratory service provider to the sites is reaching the investigators in a timely fashion to help them ensure patient safety.
- **MCC Metric #10 Challenge:** The percentage of tests “not reportable” meets Lilly’s requirements.
 - Action: This metric remains “on-track”; no action needed
 - Result: Team confidence that the information being provided by the central laboratory service provider to the sites with regard to “not reportable tests” is within expected ranges of this activities being requested of them.

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

Performance Metrics: Outcomes*

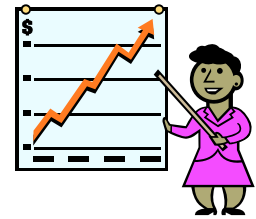


- **MCC Metric #12 Challenge:** Data Transfer meets Lilly’s requirements.
 - Action: The metric remains “on-track”; no action needed
 - Result: Team confidence that the data they require will be available as needed.

- **MCC Metric #12 Challenge:** >4 test transfers required for each new protocol and 7% of transfers has errors.
 - Action: Sponsor/QLAB working group developed process and transfer specs
 - Result: 1 test transfer sent prior to each new protocol and <1% of transfers have errors.

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

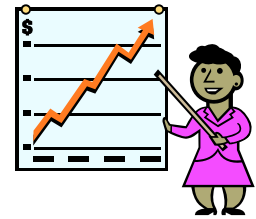
Performance Metrics: Outcomes *



- **MCC Metric #13 Challenge:** Financial tracking information meets Lilly’s requirements.
 - Action: This report allows the team to evaluate the current level of spending on the protocol and determine if any actions are required.
 - Result: Improved team awareness of study financial status
- **Non - MCC Metric Challenge:** Tracking turn around time on obtaining change order signature.
 - Action: Sponsor implemented the CNF process to expedite the change order signatory process.
 - Result: Improved ability of provider to invoice based on most current budget and reduced the number of budget revisions for minor changes

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

Performance Metrics: Outcomes *



- **Non - MCC Metric Challenge:** Tracking days outstanding on sponsor invoices.
 - Action: This report allowed the sponsor to see which invoices were outside MSA time period for payment.
 - Result: Sponsor reviewed invoice approval process. Evaluation ongoing.
- **Non - MCC Metric Challenge:** 360° survey yielded information that Project Managers and the CDSAS could improve communication between teams.
 - Action: A dedicated team of personnel focused on Lilly was created at the service provider to help ensure that the requirements of the CDSAs continue to be met.
 - Result: A healthier, more collaborative relationship

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

Performance Metrics: Lilly's Positive Financial Outcomes

Additionally, two major internal projects were driven by metrics:

Project	Current Metric	MCC Metric	~Savings
Sample Storage Management	Financial	#13 and #14	300,000
Scope of Work modification reduction	Financial	#13 and #14	200,000
Total Savings			500,000



Performance Metrics: Shared Lessons Learned Summary*

Being a metrics based organization has provided:

- Easier identification of areas of opportunity
- Better prioritization of the areas of focus
- Monetary savings
- Improved internal processes
- Improved external processes
- Enhanced integrated processes
- More constructive conversations with the sponsors / service providers
- Tools for improved team awareness of study financial status
- Enhanced Communication with Senior Management with regard to operational performance
- Critical to automate metrics process
- Only useful if used to take action

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

Performance Metrics: Summary of Benefits

- Measure of service provider performance
- Measure of own “internal” performance
- Review provides information for consistent, timely, informed and effective process enhancement / improvement
- Standardized metrics when fully implemented will help to reduce costs for all involved by eliminating customized metrics the associated inefficiencies

Performance Metrics: Future Challenges and Next Steps

- Complete Implementation of the MCC Metrics at preferred providers impacted by:
 - Previously defined metrics being collected and reviewed on a quarterly basis until the majority of MCC metrics are in place
 - Feedback from partners has been that additional sponsor uptake of the metrics is required by pharmaceutical counterparts in order to help them justify the costs associated with the IT work required to implement all the MCC metrics

