

Using Metrics to Improve the Management of Your Sponsor/Vendor Relationships

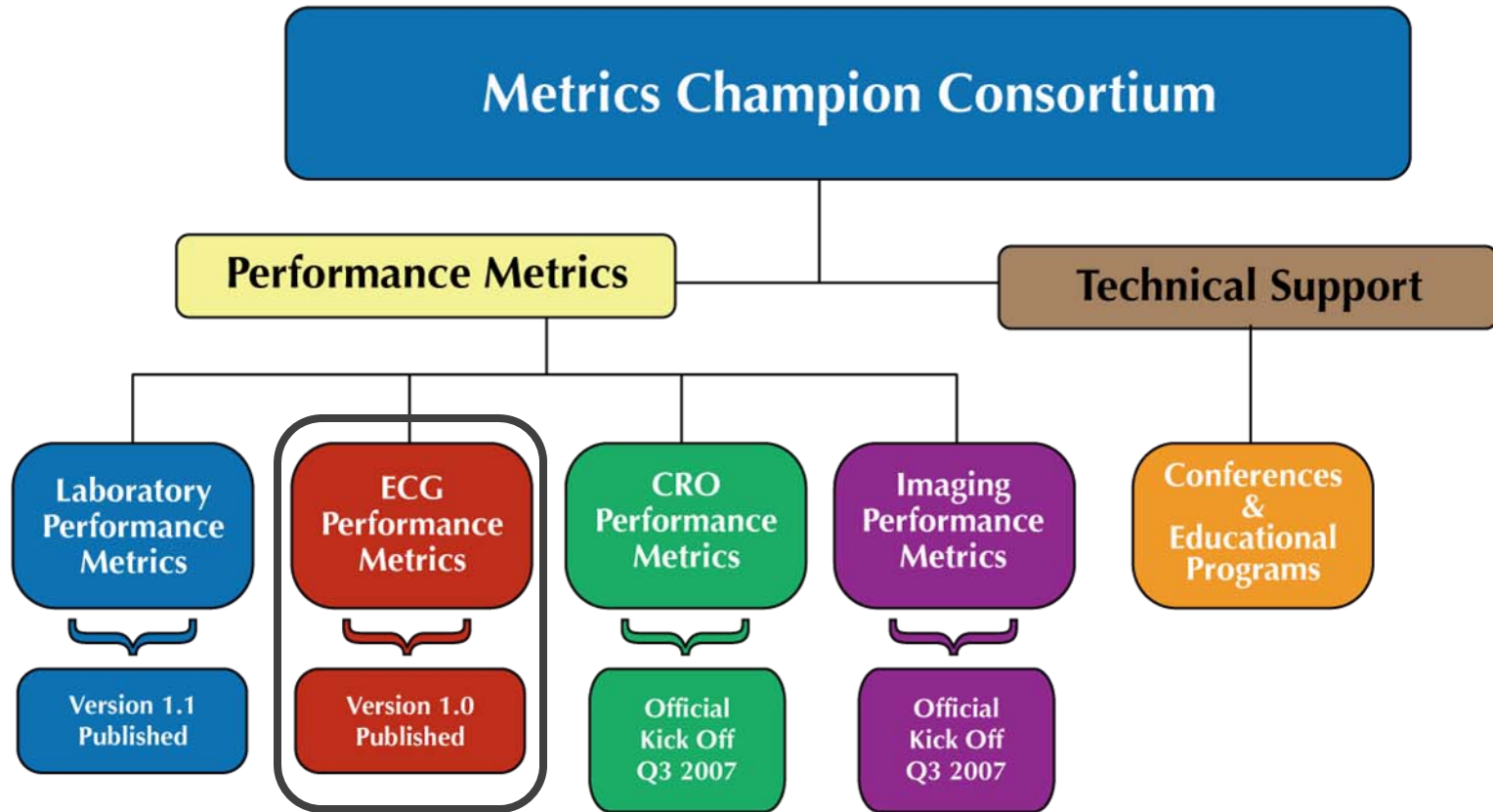
A Follow-up to the ECG Services Example

Steven Asbury – Eli Lilly & Company

*January 2009
Las Vegas, NV*

Proposed Agenda

- What benefits have Lilly/Quintiles seen since deciding to collaborate in utilizing the MCC Metrics?
- Quality improvements through Metrics
- What improvements have been made due to the review of the metrics?
- Risks/Rewards of using metrics to improve the Sponsor/Vendor Relationship.



Why Decide to Collaborate in Utilizing Performance Metrics?

If Performance Metrics are the questions we ask of our business and our Partnerships, then Effective Collaboration can ensure we ask the right Questions



Why Decide to Collaborate in Utilizing Performance Metrics?

Asking The Right Questions Leads To:

- Identification of Sponsors' and Core Lab's Business Requirements
- Enhanced Understanding of Processes
- Improved Monitoring of Critical Deliverables
- Greater Focus on Achieving Meaningful Process Improvement
- Ability to Compare Across Industry
- Enhanced Communication

How did we utilize the MCC forum to develop these metrics

- Collaborative Input From Multiple Vendors, Sponsors, and Equipment Manufacturers
- Multi-Disciplinary approach through Working Group structure ensured wide range of views
- Oversight and Final Decisions by the ECG Steering Committee
- Existing Structure for Metrics development (From Previous Laboratory Metrics Initiative)

NOW: Need more pharma input to complete implementation of metrics and attempt to create variability metrics.

ECG Metrics Structure

Metric	Metric Title	Definition	Formula/Example	Unit of Measure	Reporting Frequency	Target
3	Percentage of on-time ECG equipment shipments to sites	<p>Minimum: The percentage of sites who received their ECG equipment by the agreed upon receipt date (based on defined expectations between the sponsor and core lab).</p> <p>NOTE: Timelines must be discussed, established proactively and agreed to by both parties to make this a meaningful metric.</p> <p>Additional analysis on a "for cause" basis: A listing of protocols, countries and sites that did not meet the ECG equipment receipt date agreed upon by the sponsor and core lab.</p>	<p>Formula: (Total N of sites that received equipment by the expected date / Total N of sites with first equipment required) x 100</p> <p>Specific Example: 1000 sites initiated; 990 received machines as expected (10 did not).</p> <p>Result: $990/1000 \times 100 = 99\%$ received machines within expectations.</p>	Total N and Percentage (%)	Quarterly	>95%
		<p>General Benefit Statement</p>	<p>You will be informed regarding the core lab's ability to finalize the predefined database, prepare and ship ECG supplies and deliver what is required for the site to achieve first patient visit. In addition, you can extrapolate if the core lab can provide the required start-up supplies per the timeline. Lastly, you can assess the sponsor's ability to provide receipt dates to the core lab which are reasonable to accommodate shipping times for countries, including addressing Customs/Import concerns associated with these countries. This will assist the sponsors and core labs in understanding the caveats in shipping to different regions of the world.</p>			

ECG Metrics Structure

Metric	Metric Title	Definition	Formula/Example	Unit of Measure	Reporting Frequency	Target
3	<i>Percentage of on-time ECG equipment shipments to sites</i>	<p>Minimum: The percentage of sites who received their ECG equipment by the agreed upon receipt date (based on defined expectations between the sponsor and core lab). NOTE: Timelines must be discussed, established proactively and agreed to by both parties to make this a meaningful metric. Additional analysis on a "for cause" basis: A listing of protocols, countries and sites that did not meet the ECG equipment receipt date agreed upon by the sponsor and core lab.</p>	<p>Formula: (Total N of sites that received equipment by the expected date / Total N of sites with first equipment required) x 100 Specific Example: 1000 sites initiated; 990 received machines as expected (10 did not). Result: 990/1000 x 100 = 99% received machines within expectations.</p>	Total N and Percentage (%)	Quarterly	>95%
		General Benefit Statement	<p>You will be informed regarding the core lab's ability to finalize the predefined database, prepare and ship ECG supplies and deliver what is required for the site to achieve first patient visit. In addition, you can extrapolate if the core lab can provide the required start-up supplies per the timeline. Lastly, you can assess the sponsor's ability to provide receipt dates to the core lab which are reasonable to accommodate shipping times for countries, including addressing Customs/Import concerns associated with these countries. This will assist the sponsors and core labs in understanding the caveats in shipping to different regions of the world.</p>			

ECG Metrics Structure

Metric	Metric Title	Definition	Formula/Example	Unit of Measure	Reporting Frequency	Target
3	Percentage of on-time ECG equipment shipments to sites	<p>Minimum: <i>The percentage of sites who received their ECG equipment by the agreed upon receipt date (based on defined expectations between the sponsor and core lab).</i></p> <p>NOTE: <i>Timelines must be discussed, established proactively and agreed to by both parties to make this a meaningful metric.</i></p> <p>Additional analysis on a "for cause" basis: <i>A listing of protocols, countries and sites that did not meet the ECG equipment receipt date agreed upon by the sponsor and core lab.</i></p>	<p>Formula: (Total N of sites that received equipment by the expected date / Total N of sites with first equipment required) x 100</p> <p>Specific Example: 1000 sites initiated; 990 received machines as expected (10 did not).</p> <p>Result: 990/1000 x 100 = 99% received machines within expectations.</p>	Total N and Percentage (%)	Quarterly	>95%
		<p>General Benefit Statement</p>	<p>You will be informed regarding the core lab's ability to finalize the predefined database, prepare and ship ECG supplies and deliver what is required for the site to achieve first patient visit. In addition, you can extrapolate if the core lab can provide the required start-up supplies per the timeline. Lastly, you can assess the sponsor's ability to provide receipt dates to the core lab which are reasonable to accommodate shipping times for countries, including addressing Customs/Import concerns associated with these countries. This will assist the sponsors and core labs in understanding the caveats in shipping to different regions of the world.</p>			

ECG Metrics Structure

Metric	Metric Title	Definition	<i>Formula/Example</i>	Unit of Measure	Reporting Frequency	Target
3	Percentage of on-time ECG equipment shipments to sites	<p>Minimum: The percentage of sites who received their ECG equipment by the agreed upon receipt date (based on defined expectations between the sponsor and core lab).</p> <p>NOTE: Timelines must be discussed, established proactively and agreed to by both parties to make this a meaningful metric.</p> <p>Additional analysis on a "for cause" basis: A listing of protocols, countries and sites that did not meet the ECG equipment receipt date agreed upon by the sponsor and core lab.</p>	<p>Formula: <i>(Total N of sites that received equipment by the expected date / Total N of sites with first equipment required) x 100</i></p> <p>Specific Example: <i>1000 sites initiated; 990 received machines as expected (10 did not).</i></p> <p>Result: <i>990/1000 x 100 = 99% received machines within expectations.</i></p>	Total N and Percentage (%)	Quarterly	>95%
		General Benefit Statement	<p>You will be informed regarding the core lab's ability to finalize the predefined database, prepare and ship ECG supplies and deliver what is required for the site to achieve first patient visit. In addition, you can extrapolate if the core lab can provide the required start-up supplies per the timeline. Lastly, you can assess the sponsor's ability to provide receipt dates to the core lab which are reasonable to accommodate shipping times for countries, including addressing Customs/Import concerns associated with these countries. This will assist the sponsors and core labs in understanding the caveats in shipping to different regions of the world.</p>			

ECG Metrics Structure

Metric	Metric Title	Definition	Formula/Example	<i>Unit of Measure</i>	Reporting Frequency	Target
3	Percentage of on-time ECG equipment shipments to sites	<p>Minimum: The percentage of sites who received their ECG equipment by the agreed upon receipt date (based on defined expectations between the sponsor and core lab). NOTE: Timelines must be discussed, established proactively and agreed to by both parties to make this a meaningful metric. Additional analysis on a "for cause" basis: A listing of protocols, countries and sites that did not meet the ECG equipment receipt date agreed upon by the sponsor and core lab.</p>	<p>Formula: (Total N of sites that received equipment by the expected date / Total N of sites with first equipment required) x 100 Specific Example: 1000 sites initiated; 990 received machines as expected (10 did not). Result: 990/1000 x 100 = 99% received machines within expectations.</p>	<i>Total N and Percentage (%)</i>	Quarterly	>95%
		General Benefit Statement	<p>You will be informed regarding the core lab's ability to finalize the predefined database, prepare and ship ECG supplies and deliver what is required for the site to achieve first patient visit. In addition, you can extrapolate if the core lab can provide the required start-up supplies per the timeline. Lastly, you can assess the sponsor's ability to provide receipt dates to the core lab which are reasonable to accommodate shipping times for countries, including addressing Customs/Import concerns associated with these countries. This will assist the sponsors and core labs in understanding the caveats in shipping to different regions of the world.</p>			

ECG Metrics Structure

Metric	Metric Title	Definition	Formula/Example	Unit of Measure	Reporting Frequency	Target
3	Percentage of on-time ECG equipment shipments to sites	<p>Minimum: The percentage of sites who received their ECG equipment by the agreed upon receipt date (based on defined expectations between the sponsor and core lab). NOTE: Timelines must be discussed, established proactively and agreed to by both parties to make this a meaningful metric. Additional analysis on a "for cause" basis: A listing of protocols, countries and sites that did not meet the ECG equipment receipt date agreed upon by the sponsor and core lab.</p>	<p>Formula: (Total N of sites that received equipment by the expected date / Total N of sites with first equipment required) x 100 Specific Example: 1000 sites initiated; 990 received machines as expected (10 did not). Result: 990/1000 x 100 = 99% received machines within expectations.</p>	Total N and Percentage (%)	Quarterly	>95%
		<p>General Benefit Statement</p> <p>You will be informed regarding the core lab's ability to finalize the predefined database, prepare and ship ECG supplies and deliver what is required for the site to achieve first patient visit. In addition, you can extrapolate if the core lab can provide the required start-up supplies per the timeline. Lastly, you can assess the sponsor's ability to provide receipt dates to the core lab which are reasonable to accommodate shipping times for countries, including addressing Customs/Import concerns associated with these countries. This will assist the sponsors and core labs in understanding the caveats in shipping to different regions of the world.</p>				

ECG Metrics Structure

Metric	Metric Title	Definition	Formula/Example	Unit of Measure	Reporting Frequency	Target
3	Percentage of on-time ECG equipment shipments to sites	<p>Minimum: The percentage of sites who received their ECG equipment by the agreed upon receipt date (based on defined expectations between the sponsor and core lab).</p> <p>NOTE: Timelines must be discussed, established proactively and agreed to by both parties to make this a meaningful metric.</p> <p>Additional analysis on a "for cause" basis: A listing of protocols, countries and sites that did not meet the ECG equipment receipt date agreed upon by the sponsor and core lab.</p>	<p>Formula: (Total N of sites that received equipment by the expected date / Total N of sites with first equipment required) x 100</p> <p>Specific Example: 1000 sites initiated; 990 received machines as expected (10 did not).</p> <p>Result: 990/1000 x 100 = 99% received machines within expectations.</p>	Total N and Percentage (%)	Quarterly	>95%
		General Benefit Statement	<p>You will be informed regarding the core lab's ability to finalize the predefined database, prepare and ship ECG supplies and deliver what is required for the site to achieve first patient visit. In addition, you can extrapolate if the core lab can provide the required start-up supplies per the timeline. Lastly, you can assess the sponsor's ability to provide receipt dates to the core lab which are reasonable to accommodate shipping times for countries, including addressing Customs/Import concerns associated with these countries. This will assist the sponsors and core labs in understanding the caveats in shipping to different regions of the world.</p>			

ECG Metrics Structure

Metric	Metric Title	Definition	Formula/Example	Unit of Measure	Reporting Frequency	Target
3	Percentage of on-time ECG equipment shipments to sites	<p>Minimum: The percentage of sites who received their ECG equipment by the agreed upon receipt date (based on defined expectations between the sponsor and core lab). NOTE: Timelines must be discussed, established proactively and agreed to by both parties to make this a meaningful metric. Additional analysis on a "for cause" basis: A listing of protocols, countries and sites that did not meet the ECG equipment receipt date agreed upon by the sponsor and core lab.</p>	<p>Formula: (Total N of sites that received equipment by the expected date / Total N of sites with first equipment required) x 100 Specific Example: 1000 sites initiated; 990 received machines as expected (10 did not). Result: 990/1000 x 100 = 99% received machines within expectations.</p>	Total N and Percentage (%)	Quarterly	>95%
		<p>General Benefit Statement</p>		<p><i>You will be informed regarding the core lab's ability to finalize the predefined database, prepare and ship ECG supplies and deliver what is required for the site to achieve first patient visit. In addition, you can extrapolate if the core lab can provide the required start-up supplies per the timeline. Lastly, you can assess the sponsor's ability to provide receipt dates to the core lab which are reasonable to accommodate shipping times for countries, including addressing Customs/Import concerns associated with these countries. This will assist the sponsors and core labs in understanding the caveats in shipping to different regions of the world.</i></p>		

MCC ECG Performance Metrics

Metric	Title	Metric	Title
1	Average number of days from ECG study award to contract signature	9	% of ECGs received from one study that were interpretable by the core lab
2	Average number of days from signed ECG technical specifications document (TSD) signature to vendor ready to receive ECGs	10	% of manual adjustments of automated QT annotations from one study (semi-automatic “computer assisted” method with visual inspection and manual adjustment whenever necessary)
3	% of on-time ECG equipment shipments to sites	11	% of ECG equipment failure
4	% of sites who conduct a successful test ECG transmission prior to 1st subject visit	12	Average turnaround time on replacing faulty ECG equipment
5	% of ECGs reported to Investigator Sites within agreed turnaround time	13	% of on-time, accepted ECG file transfers
6	% of ECG data queries from vendor to site	14	Key ECG core lab personnel turnover during protocol
7	Turnaround time on resolution of ECG site queries from central vendor	15	% of ECG core lab audit/assessment findings closed within agreed timelines
8	% of ECG alerts successfully communicated to sites within defined turnaround time	16	Average % of variance maintained in the ECG budget

MCC ECG Performance Metrics

Metric	Title	Metric	Title
1	Average number of days from ECG study award to contract signature	9	% of ECGs received from one study that were interpretable by the core lab
2	Average number of days from signed ECG technical specifications document (TSD) signature to vendor ready to receive ECGs	10	% of manual adjustments of automated QT annotations from one study (semi-automatic "computer assisted" method with visual inspection and manual adjustment whenever necessary)
3	% of on-time ECG equipment shipments to sites	11	% of ECG equipment failure
4	% of sites who conduct a successful test ECG transmission prior to 1st subject visit	12	Average turnaround time on replacing faulty ECG equipment
5	% of ECGs reported to Investigator Sites within agreed turnaround time	13	% of on-time, accepted ECG file transfers
6	% of ECG data queries from vendor to site	14	Key ECG core lab personnel turnover during protocol
7	Turnaround time on resolution of ECG site queries from central vendor	15	% of ECG core lab audit/assessment findings closed within agreed timelines
8	% of ECG alerts successfully communicated to sites within defined turnaround time	16	Average % of variance maintained in the ECG budget

MCC ECG Performance Metrics

Metric	Title	Metric	Title
1	Average number of days from ECG study award to contract signature	9	% of ECGs received from one study that were interpretable by the core lab
2	Average number of days from signed ECG technical specifications document (TSD) signature to vendor ready to receive ECGs	10	% of manual adjustments of automated QT annotations from one study (semi-automatic "computer assisted" method with visual inspection and manual adjustment whenever necessary)
3	% of on-time ECG equipment shipments to sites	11	% of ECG equipment failure
4	% of sites who conduct a successful test ECG transmission prior to 1st subject visit	12	Average turnaround time on replacing faulty ECG equipment
5	% of ECGs reported to Investigator Sites within agreed turnaround time	13	% of on-time, accepted ECG file transfers
6	% of ECG data queries from vendor to site	14	Key ECG core lab personnel turnover during protocol
7	Turnaround time on resolution of ECG site queries from central vendor	15	% of ECG core lab audit/assessment findings closed within agreed timelines
8	% of ECG alerts successfully communicated to sites within defined turnaround time	16	Average % of variance maintained in the ECG budget

MCC ECG Performance Metrics

Metric	Title	Metric	Title
1	Average number of days from ECG study award to contract signature	9	% of ECGs received from one study that were interpretable by the core lab
2	Average number of days from signed ECG technical specifications document (TSD) signature to vendor ready to receive ECGs	10	% of manual adjustments of automated QT annotations from one study (semi-automatic "computer assisted" method with visual inspection and manual adjustment whenever necessary)
3	% of on-time ECG equipment shipments to sites	11	% of ECG equipment failure
4	% of sites who conduct a successful test ECG transmission prior to 1st subject visit	12	Average turnaround time on replacing faulty ECG equipment
5	% of ECGs reported to Investigator Sites within agreed turnaround time	13	% of on-time, accepted ECG file transfers
6	% of ECG data queries from vendor to site	14	Key ECG core lab personnel turnover during protocol
7	Turnaround time on resolution of ECG site queries from central vendor	15	% of ECG core lab audit/assessment findings closed within agreed timelines
8	% of ECG alerts successfully communicated to sites within defined turnaround time	16	Average % of variance maintained in the ECG budget

MCC ECG Performance Metrics

Metric	Title	Metric	Title
1	Average number of days from ECG study award to contract signature	9	% of ECGs received from one study that were interpretable by the core lab
2	Average number of days from signed ECG technical specifications document (TSD) signature to vendor ready to receive ECGs	10	% of manual adjustments of automated QT annotations from one study (semi-automatic "computer assisted" method with visual inspection and manual adjustment whenever necessary)
3	% of on-time ECG equipment shipments to sites	11	% of ECG equipment failure
4	% of sites who conduct a successful test ECG transmission prior to 1st subject visit	12	Average turnaround time on replacing faulty ECG equipment
5	% of ECGs reported to Investigator Sites within agreed turnaround time	13	% of on-time, accepted ECG file transfers
6	% of ECG data queries from vendor to site	14	Key ECG core lab personnel turnover during protocol
7	Turnaround time on resolution of ECG site queries from central vendor	15	% of ECG core lab audit/assessment findings closed within agreed timelines
8	% of ECG alerts successfully communicated to sites within defined turnaround time	16	Average % of variance maintained in the ECG budget

Expectations, and how they changed

- Performance Metrics are a “punishment” tool?
 - Participation in forum allowed the free exchange of views before the finalization
- Standardized metrics will allow measurement tool across core labs
 - Not such a good idea without detailed information regarding study
- Performance Metrics have shown potential for an enormous learning opportunity regarding core labs and sponsors.

Quality Improvements through Metrics

Example 1 – Initial Metrics












Metric Title	Target
Percentage of ECGs Reported within Agreed Turnaround Time	>95%

1	2	3	4	5	6	7	8	9	10	Av.
88.7%	92.1%	90.7%	96.4%	93.0%	92.0%	84.4%	85.9%	94.9%	91.5%	90.3%

Quality Improvements through Metrics

Example 1 – Initial Metrics

Metric Title	Target
Percentage of ECGs Reported within Agreed Turnaround Time	>95%

1	2	3	4	5	6	7	8	9	10	Av.
88.7% 	92.1% 	90.7% 	96.4% 	93.0% 	92.0% 	84.4% 	85.9% 	94.9% 	91.5% 	90.3% 

Quality Improvements through Metrics

Example 1 – Initial Metrics

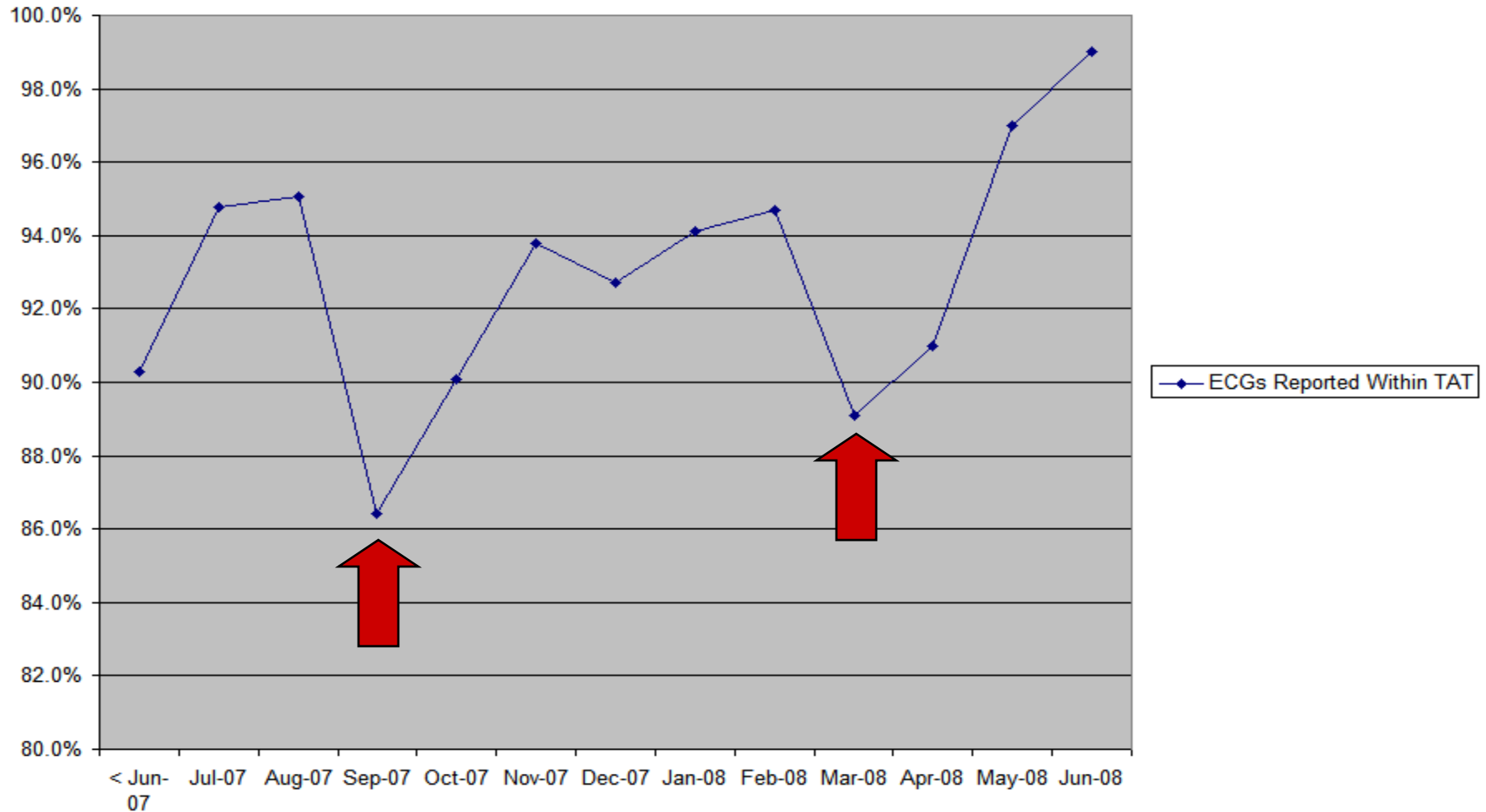
Metric Title	Target
Percentage of ECGs Reported within Agreed Turnaround Time	>95%

1	2	3	4	5	6	7	8	9	10	Av.
88.7%	92.1%	90.7%	96.4%	93.0%	92.0%	84.4%	85.9%	94.9%	91.5%	90.3%

Quality Improvements through Metrics

Example 1 – Monthly Tracking

ECGs Reported Within TAT



Quality Improvements through Metrics

Example 1 – Past and Present

Metric Title	Target
Percentage of ECGs Reported within Agreed Turnaround Time	>95%

1	2	3	4	5	6	7	8	9	10	Av.
88.7%	92.1%	90.7%	96.4%	93.0%	92.0%	84.4%	85.9%	94.9%	91.5%	90.3%

1	2	3	4	5	6	7	8	10	11	12	13	14	Av.	NL Av.
100%	100%	100%	82%	95%	100%	100%	96%	100%	100%	100%	100%	100%	99%	99%

Quality Improvements through Metrics

Example 1 – What Changed?

Discussions led to:

- Understanding of how Lilly differed from normal QECG processes
 - Did not account for ECGs not reported back to site in automated reporting system
 - Did not account for weekends/holidays
- Process/System changes to configure systems to meet Lilly expectations
- Better understanding of Lilly expectations and Quintiles systems

Quality Improvements through Metrics

Example 2 – Initial Metrics












Metric Title	Target
Percentage of On-time ECG Equipment Shipments to Sites	>95%

1	2	3	4	5	6	7	8	9	10	Av
0%	100%	100%	100%	100%	0%	33.3%	12.5%	100%	100%	53.7%

Quality Improvements through Metrics

Example 2 – Initial Metrics

Metric Title	Target
Percentage of On-time ECG Equipment Shipments to Sites	>95%

1	2	3	4	5	6	7	8	9	10	Av
0%	100%	100%	100%	100%	0%	33.3%	12.5%	100%	100%	53.7%
										

Quality Improvements through Metrics

Example 2 – Initial Metrics

Metric Title	Target
Percentage of On-time ECG Equipment Shipments to Sites	>95%

1	2	3	4	5	6	7	8	9	10	Av
0%	100%	100%	100%	100%	0%	33.3%	12.5%	100%	100%	53.7%

Quality Improvements through Metrics

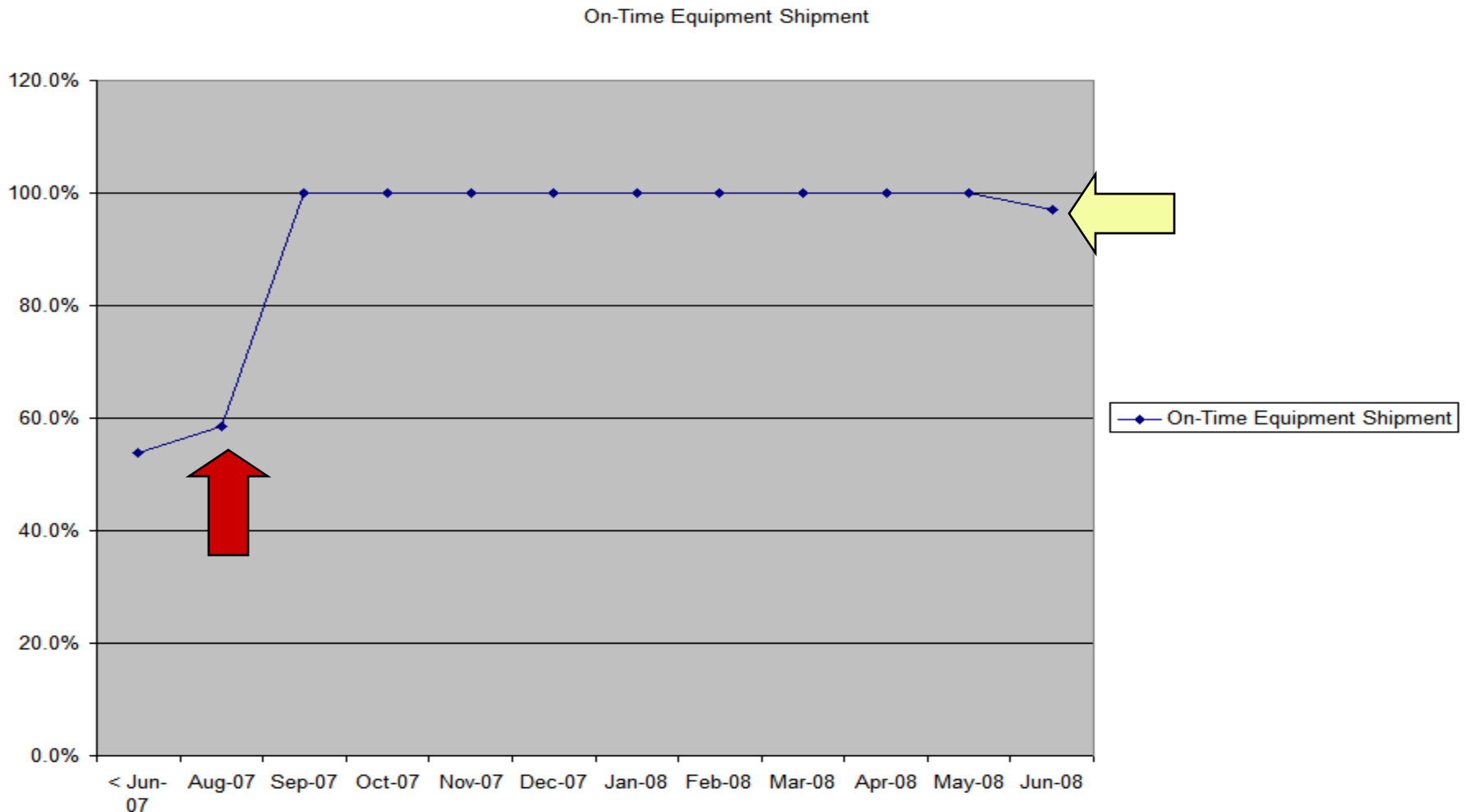
Example 2 – Initial Metrics

Metric Title	Target
Percentage of On-time ECG Equipment Shipments to Sites	>95%

1	2	3	4	5	6	7	8	9	10	Av
0%	100%	100%	100%	100%	0%	33.3%	12.5%	100%	100%	53.7%

Quality Improvements through Metrics






Example 2 – Monthly Tracking



Quality Improvements through Metrics

Example 2 – Past and Present

Metric Title	Target
Percentage of On-time ECG Equipment Shipments to Sites	>95%

1	2	3	4	5	6	7	8	9	10	Av
0% 	100%	100%	100%	100%	0% 	33.3% 	12.5% 	100%	100%	53.7% 

1	2	3	4	5	6	7	8	9	10	11	12	13	14	Av.	NL AV
NA	NA	NA	NA	100%	NA	NA	NA	NA	NA	NA	100%	NA	95.5%	97.1%	100%

Quality Improvements through Metrics

Example 2 – What Changed?

Discussions led to:

- Understanding of how Lilly communicates Equipment Shipment dates
 - Provided multiple dates
 - Ensured everyone understood the ramifications of multiple dates and meaning of dates provided
- Clarification of what should be communicated in the metrics
 - Studies using site owned equipment need not be counted
- Watching ‘difficult regions’ which are causing issues

Quality Improvements through Metrics

Example 3 – Initial Metrics

Metric Title	Target
Percentage of ECG Queries from Vendor to Site	<20%

1	2	3	4	5	6	7	8	9	10	Av
4.3%	13.6%	1.2%	2.4%	14.0%	15.3%	86.7%	62.0%	6.3%	0.4%	5.7%

Quality Improvements through Metrics

Example 3 – Initial Metrics

Metric Title	Target
Percentage of ECG Queries from Vendor to Site	<20%

1	2	3	4	5	6	7	8	9	10	A
4.3%	13.6%	1.2%	2.4%	14.0%	15.3%	86.7%	62.0%	6.3%	0.4%	5.7%

Quality Improvements through Metrics

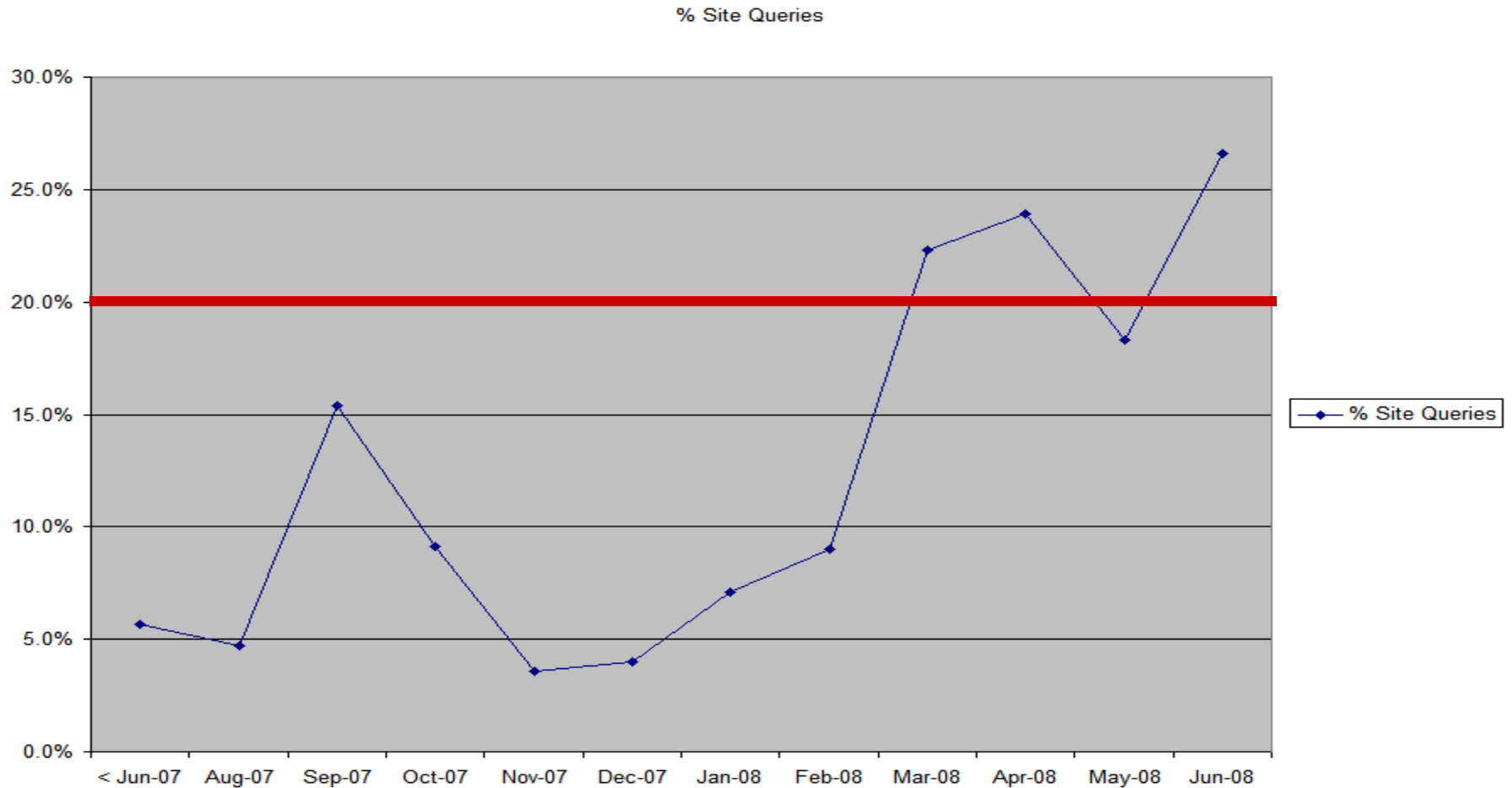
Example 3 – Initial Metrics

Metric Title	Target
Percentage of ECG Queries from Vendor to Site	<20%

1	2	3	4	5	6	7	8	9	10	Av
4.3%	13.6%	1.2%	2.4%	14.0%	15.3%	86.7%	62.0%	6.3%	0.4%	5.7%

Quality Improvements through Metrics

Example 3 – Monthly Tracking



Quality Improvements through Metrics

Example 3 – Past and Present

Metric Title	Target
Percentage of ECG Queries from Vendor to Site	<20%

1	2	3	4	5	6	7	8	9	10	Av
4.3%	13.6%	1.2%	2.4%	14.0%	15.3%	86.7%	62.0%	6.3%	0.4%	5.7%

1	2	3	4	5	6	7	8	9	10	11	12	13	14	Av	NL
41%	129%	8%	164%	50%	40%	12%	52%	13%	7%	20%	26%	0%	0%	27%	11%

Quality Improvements through Metrics

Example 3 – What Changed?

Still Trying to Determine!!

- Bad Site Selection?
- Study Indication Leading to Lack of Detail?
- Poor Training?
 - Quintiles ECG Training
 - Lilly Training
 - CRO Training
 - Web Training
 - CD Training
- What is Most Common Issue?
- Individual Sites or Across Sites?

Quality Improvements through Metrics

Example 3 – What Changed?

Still Trying to Determine:

- Bad Site Selection?
- Study Indications *More Prevalent in Certain Indications*
- Poor Training?
 - Quintiles ECG Training
 - Live Training
 - CRO Training
 - Web Training
 - CD Training
- What is Most Common Issue? *Correlated to Specific DE Fields*
- Individual Sites or Across Sites? *Individual Sites*

Need to Investigate

NO Trends

Risks of Using Performance Metrics

- Failing to identify what the key performance areas really are and wasting time
- Only accepting the metrics on Initial “Face Value” and not looking at underlying reasons
- Sharing metrics without providing explanations
- Failing to understand the processes which lead to the metrics

Rewards of Using Performance Metrics

- **Improved Performance**
- **Improved Communication**
 - Communication leads to understanding of processes
 - Communication leads to understanding of how change affects areas within organization
 - Leads to honest and open communication
- **Improved Process**
- **Improved Delivery**
- **Improved Relationship**

Key Requirements

- **Open, honest communication**
- **A Structured Approach i.e. The MCC**
- **Recognition that both Vendor and Sponsor have areas for improvement**
- **Understanding of both partners positions**
- **Willingness to seek Mutual Process Improvement**
- **Acceptance that Process Improvement can apply to everyone**



Please contact Guy Mascaro or Linda Sullivan at 317.848.2908 for additional information about participating in MCC activities.

www.metricschampion.org