

 **ECG**  
metrics champion

*Lilly*  **QUINTILES**<sup>®</sup>

**Case Study**



**Eli Lilly and Quintiles Case Study:**  
**Using MCC ECG Performance Metrics to Improve  
Sponsor, Site, and Core Lab Clinical Trial Operations**

## Metrics Champion Consortium - Overview

Today's drug development industry is under increased pressure to improve its research and development performance/strategies by reducing drug development times and costs, while at the same time dramatically increasing productivity and maintaining quality.<sup>1</sup> Biotechnology and pharmaceutical organizations that are currently achieving efficient clinical trial cycle times attribute their success to the following "best practices"<sup>1</sup>:

- Maintaining focus on core competencies
- Prioritizing the utilization of resources
- Outsourcing services

The utilization of standardized performance metrics by the drug development industry to reduce clinical development times and to improve clinical trial deliverables is essential to its success. Sponsors and ECG Core Labs need to effectively manage and track their resources, including people, time, and money, as each has an impact on productivity and efficiency over the course of a clinical trial.

### Building Partnerships Around Standardized Performance Metrics

Biotechnology, pharmaceutical, and service provider organizations have joined together to form a not-for-profit organization, the Metrics Champion Consortium (MCC), where member organizations work collaboratively to develop and implement standardized performance metrics which aim to improve the efficiency and effectiveness of clinical trials. Implementing standardized performance metrics benefits sponsor and service provider organizations by enabling them to compare clinical trial performance across all of a sponsor's studies, even if they utilize multiple service providers. Together, sponsors and service providers can review performance with the aim to identify both best practice scenarios and opportunities for improvement. Once opportunities for improvement are identified, sponsor/service provider partners can review the specific protocols that determine the process in question and determine appropriate action steps to improve performance.

To date, the MCC has developed and released two sets of standardized performance metrics: Central Laboratory Performance Metrics (released in 2006) and ECG Performance Metrics (released Q4 of 2007). Throughout the metrics development and implementation process, the MCC provides a safe harbor 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.

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

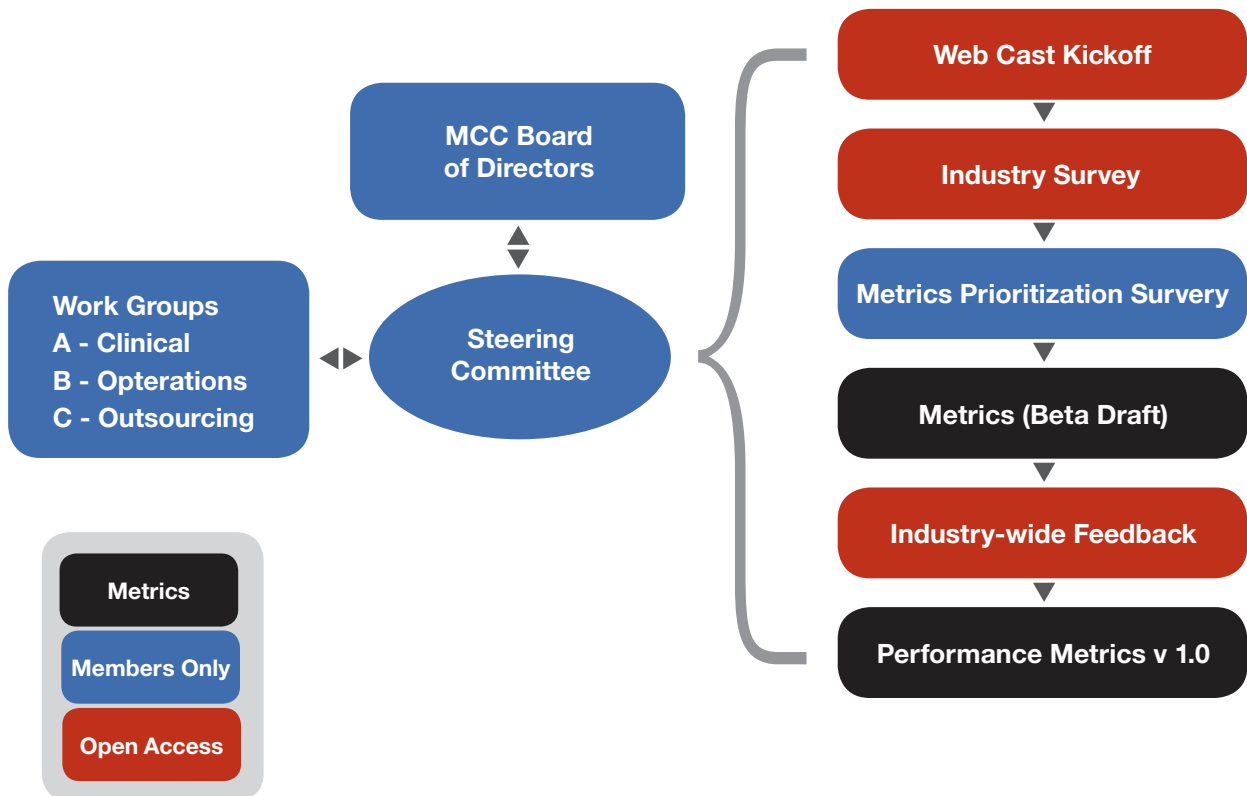
## MCC ECG Metrics – Mission Statement

To develop and support a baseline set of ECG performance metrics provided by service providers within the biotechnology and pharmaceutical industry with the intent to jointly encourage the sponsors, service providers, investigative sites, and equipment manufacturers in gaining performance improvement, effectiveness, efficiency, and appropriate levels of controls.

## MCC ECG Metrics Development Process

In 2006, a group of Sponsors, ECG Core Labs, and other ECG-related Service Providers began developing a set of standardized MCC ECG Performance Metrics. The group worked together on a Steering Committee and in three Working Groups to develop a draft set of standardized ECG performance metrics [Figure 1]. In October 2007, after reviewing industry feedback, the MCC released the ECG Performance Metrics version 1.0.

Figure 1. MCC Metrics Development Process Model



## Why Did Lilly and Quintiles Decide to Collaborate in Utilizing the MCC ECG Performance Metrics?

**Premise:** If performance metrics are the questions organizations ask of their businesses and their partnerships, then effective collaboration ensures they are asking the **right** questions.

### **From the sponsor perspective, asking the right questions leads to**

- Better understanding of the services their core lab provides
- Enhanced understanding of their core lab's processes
- Improved monitoring of their core lab's ability to meet critical timelines
- Ability to compare results across all studies (even across multiple core labs)
- Ability to pinpoint areas of interest & utilize both sponsor and core lab knowledge bases to improve processes
- Enhanced partnership relationships through improved communication among all parties

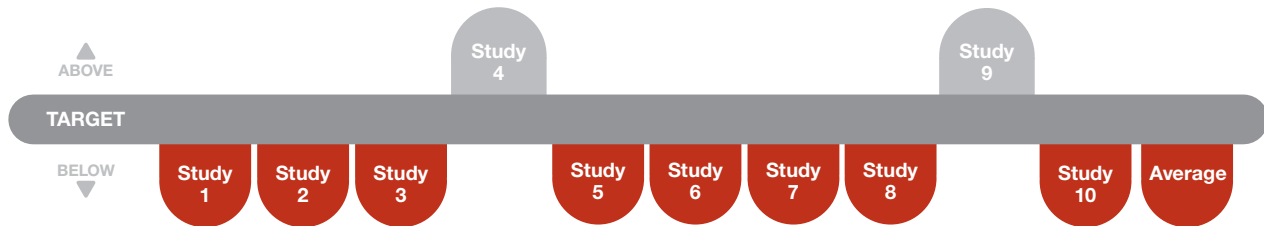
### **From the service provider perspective, asking the right questions leads to**

- Identification of their client's business requirements
- Enhanced understanding of their client's processes
- Improved monitoring of their client's critical deliverables
- Greater focus on achieving meaningful process improvement
- Higher customer satisfaction

## Results: Quality Improvements Through Review of Metrics

### Example 1: Percentage of ECGs Reported within Agreed Turnaround Time

Definition	Formula/Example	Unit of Measure	Reporting Frequency	Target
<p><b>Minimum:</b> The percentage of ECGs that have met the agreed upon turnaround time from ECG receipt to successful notification of the results to the site. The TAT is defined and agreed upon between the sponsor and core lab and may be different for every protocol.</p> <p><b>Additional analysis on a “for cause” basis:</b> A listing of ECGs that did not meet the expected turnaround time and the rationale for missing this target, broken out by protocol and/or site.</p>	<p><b>Formula:</b> (Total N of ECGs that met the expected turnaround time ÷ Total N of ECGs received) x 100</p>	Total N and Percentage (%)	Monthly	>95%



#### Review Steps

- Examined the “below target” studies and determined that many of the studies missed their turnaround times by less than 1 hour of agreed turnaround time
- Determined that hand-offs between Quintiles Operations and Clinical departments were not completed efficiently enough to allow ECGs to meet the expected turnaround time
- Compared the Lilly protocols vs Quintiles process and discovered that the Lilly protocol and the Quintiles system were not compatible
  - Lilly collects triplicates of ECGs but only requires that only 1 of the 3 copies is reported to Investigative Sites
  - Quintiles’ autofax system is not set up to fax only 1 of 3 reports – it is an “all or none” system – Quintiles has to use a manual faxing process to accommodate Lilly’s protocol

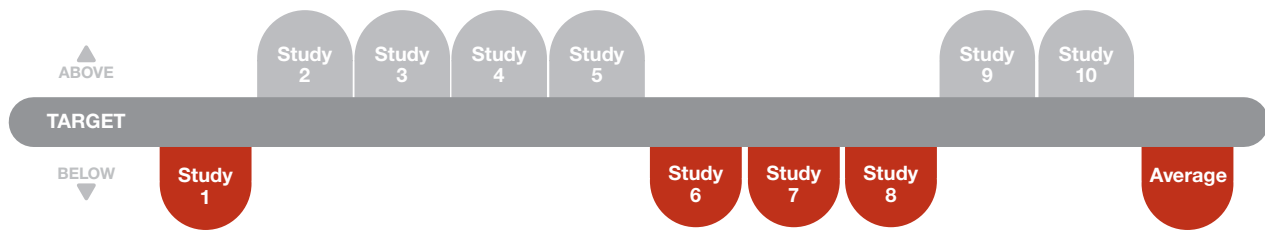
#### Action Step

- Quintiles is working to automate the handoffs between departments within Quintiles to allow their ECG processing to flow more efficiently
- Quintiles is updating the “autofax” system to accommodate Lilly’s protocols

## Results: Quality Improvements Through Review of Metrics

### Example 2: Percentage of On-time ECG Equipment Shipments to Sites

Definition	Formula/Example	Unit of Measure	Reporting Frequency	Target
<p><b>Minimum:</b></p> <p>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><b>Formula:</b></p> <p>(Total N of protocols with first equipment shipped date met ÷ Total N of protocols with first equipment required) x 100</p>	Total N and Percentage (%)	Quarterly	>95%



#### Review Steps

- Studies 1 & 6: Reviewed the protocols and determined that these studies had their own equipment thus no equipment was being shipped to sites, demonstrating the need to fully understand the studies that are being reported and understanding what the metrics are telling you
- Studies 7 & 8: Reviewed data and found a problem in the process by which the “on-time” date was established - Lilly set optimistic start dates which were revised prior to the launching the study; Quintiles was using the initial date provided on the initial form submitted by Lilly, not the updated start dates

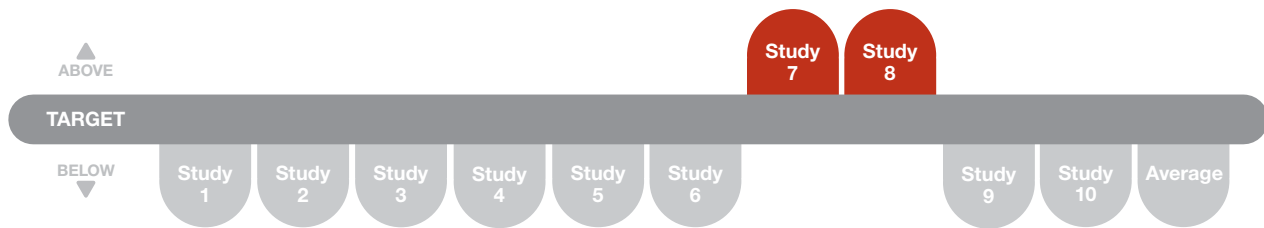
#### Action Step

- Quintiles will clarify the reporting of these metrics by indicating “Not applicable” for studies where site-owned equipment is used
- Lilly is no longer setting optimistic start dates on the form; Lilly is establishing realistic start dates and communicating them to Quintiles

## Results: Quality Improvements Through Review of Metrics

### Example 3: Percentage of ECG Queries from Vendor to Site

Definition	Formula/Example	Unit of Measure	Reporting Frequency	Target
<p><b>Minimum:</b></p> <p>The number of queries generated between the core lab and the site, compared to the number of ECGs received for a sponsor and core laboratory</p>	<p><b>Formula:</b></p> <p>(Total N of queries generated between the core laboratory and the site ÷ Total N of ECGs received) x 100</p>	Total N and Percentage (%)	Quarterly	<20%



#### Review Steps

- Studies 7 & 8: Both studies are Oncology studies; Traditionally, oncology study sites do not focus on the ECG/Cardiac safety component of clinical studies
- High number of queries related to the system generating multiple queries when a single ECG has missing, inconsistent, or unexpected information

#### Action Steps

- Lilly and Quintiles will be reviewing the study data by site to determine which sites need to be retrained to submit ECGs with complete information – thus reducing the query workload for the sites and Quintiles
- Lilly will review results to identify how effective different site training methodologies (in person vs webconference vs taped training) are to determine the best option

## How Key Players' Perceptions Changed During the MCC Performance Metrics Development and Implementation Process

### Initial Expectations

- **Sponsors:** Interested in utilizing standardized performance metrics as a standardized measurement tool for evaluating ECG core labs across the industry
- **Service providers:** Concerned that the MCC performance metrics would be used as a “punitive” tool

### Changes in Expectations

- **Sponsors:** While using these across the industry is still appealing, it was recognized that this may not be the best use for the metrics; However, developing the metrics and reviewing the results led to an enormous opportunity to learn about ECG core labs procedures, as well as performance at the core labs, investigative sites and sponsor locations
- **Service providers:** Participation in the MCC forum allowed the free exchange of views before the metric are finalized, reassured vendors that their views on the utility of the metrics were considered; Through this participation and the discussions that have ensued it is being seen that they are not being used punitively but rather leading to a better understanding of how companies can work together

## Key Requirements for Successfully Developing and Implementing Performance Metrics

- Open, honest communication (A Neutral Forum)
- A structured approach (ie The MCC)
- The recognition that both Vendor and Sponsor have areas for improvement
- A recognition of both partners positions
- The willingness to seek mutual process improvement
- Acceptance that process improvement can apply to all parties

## MCC ECG Performance Metrics v 1.0

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
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 Percentage of variance maintained in the ECG budget



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