

MCC ECG Performance Metrics version 2.0 Announcement

The MCC Cardiopulmonary Performance Metrics Steering Committee and the MCC ECG Implementation Working Group would like to take this opportunity to thank everyone for their participation in the MCC ECG Performance Metrics initiative over the last several years; and especially over the last two years as we have worked on refining Version 1.1 of the ECG metrics to create Version 2.0 of the metrics. The revision of the metrics to version 2.0 resulted in the addition of new ECG metrics, revision of some metrics, removal of a few metrics, and planning a path forward for the use of these metrics across new service lines. With that being said, we would like to introduce the new and improved MCC ECG Performance Metric version 2.0.

MCC ECG Performance Metrics v2.0			MCC ECG Performance Metrics v2.0		
Metric	Metric Type	Metric Title	Metric	Metric Type	Metric Title
1	Cycle Time	Average number of days from study award to contract signature	11	Quality	a. Percentage of equipment failure as determined by site b. Percentage of equipment failure as determined by site that is a true failure of equipment
2	Cycle Time	Average number of days from signed technical specifications document (TSD) to core lab ready to receive samples	12	Cycle Time	Average turnaround time for replacing faulty equipment
3	Timeliness	Percentage of on-time equipment shipments to sites	13	Timeliness	Percentage of on-time, accepted file transfers
4	Cycle Time	Average and median time from collection of sample at the site to receipt at core lab	14	Efficiency / Cost	
5	Tracking	Number of Samples Processed within Reporting Period	15	Efficiency / Cost	a. Percent spend with current budget b. Change from initial budgeted amount to current/final budgeted amount
6	Cycle Time	Average and median time for queries to be raised by the core lab	16 ECG 1	Quality	a. Percentage of ECGs that have suspect quality as determined by the core lab b. Percentage of ECGs in which no parameters could be assessed c. Percentage of ECGs in which only the interval duration measurements could not be assessed
7	Quality	Percentage of data queries from core lab to site	17 ECG 2	Quality	Percentage of manual adjustments of automated annotations for all intervals
8	Cycle Time	a. Turnaround time on resolution of site queries from core lab (resolved queries) b. Outlier Analysis of query resolution time (resolved queries) c. Listing of queries outstanding >2 weeks (unresolved queries)			
9	Cycle Time	Average and median time for core labs to enter query resolution provided by the site into system			
10	Timeliness	a. Percentage of final reports issued to sites within agreed turnaround time b. Percentage of alerts successfully communicated to sites within defined turnaround time			



©2011 Metrics Champion Consortium, Inc. All rights reserved

A more detailed listing of the metrics that includes the exact definition, formula for determining the metric results, unit of measure, reporting frequency, target, benefit statement, who is being measured and a listing of companion metrics for each individual metric (metrics that are related) can be found on the Metric Champion Consortium's website, on the Member Homepage . Please note that you will need your MCC user name and password (<http://metricschampion.org/members/default.aspx>). Additionally, if you would like to see the exact changes that have occurred within each metric, a marked up version can be found on the Cardiopulmonary Initiative area of the MCC website.

When the MCC ECG Performance Metrics were introduced to the industry, they were developed and implemented in the hope that they would be utilized by sponsor companies and ECG core labs to identify areas where we could improve clinical trials collecting centralized ECGs; create better processes at the sponsors, investigative sites and core labs; understand how the decisions made and processes implemented by the sponsors affect the work core labs do; allow common understanding of core lab processes; and develop a common understanding of processes between the core labs and sponsors. While the ultimate goal of the metrics was to improve processes, the penultimate goal was to allow a common ground for discussions to occur between the sponsors and core labs for process improvement and general understanding of the processes within each

organization that affect the management of centralized ECGs. We feel this has been accomplished and believe that more improvements can be realized using the newest version of the MCC ECG Performance Metrics. Also, in the coming year(s) we can offer the industry even better metrics to address clinical trial performance at the investigative sites, core labs and sponsors in the areas of electrocardiograms, ambulatory blood pressure monitoring (ABPM), spirometry, and echocardiography.

As with the previous versions of the MCC ECG Performance metrics, the metrics included in Version 2.0 are meant to be a menu of standardized metrics that the core labs can provide. It is expected that no one sponsor will request every metric included in the listing. However, the use of the metrics as a menu should lead to discussions between the core lab and sponsor to determine which metrics are most important to both parties, and this will lead to a better understanding of the processes involved at the core lab as well as giving the core lab a better understanding of the aspects the sponsor feels are important within a clinical trial.

With this communication, we would like to take the opportunity to:

- Introduce Version 2.0 of the ECG Performance Metrics
 - Describe what has changed and why these changes were made,
 - Roll out the newest Process Flow Diagram to demonstrate the generic process for centralized ECG processes and highlight where the current ECG Performance Metrics are applied,
 - Roll out the new and improved *recommended* ECG Performance Metrics Reporting Tool
- Highlight recent changes to the MCC ECG Performance Metrics Website
 - Addition of a discussion area to be used to address questions and comments that arise during the implementation and integration of Version 2.0 of the ECG Performance Metrics
 - Addition of an online wiki to better define terms used in the ECG Performance Metrics
- Explain how the metrics were broken out into 'Core Metrics' and 'ECG Metrics', why this was done and how we plan to develop an expanded set of **Cardiopulmonary** Performance Metrics to be used for other service lines such as ABPM, spirometry and echocardiography.
- Outline where we intend to go over the next few years.

We hope you take the time to join us in this initiative and participate to the fullest extent your time will allow so together we can develop and define service line metrics that can lead to a better understanding of the collection of data across clinical studies.

MCC Cardiopulmonary Performance Metrics Steering Committee

Steve Asbury (Chair)	Eli Lilly and Company	Katherine Luca-Nicholson	BioMedical Systems
Adel Nada, MD/David Carter, MD	Abbott Laboratories	Debbie Walton	Merck
Corina Dota, MD	AstraZeneca International		
Jeff Heilbraun	CoreLab Partners		
Pierre Jordaan, MD	Novartis Institute for Biomedical Research		
Jeff Litwin, MD	ERT		

What has changed and why were the changes made?

Old Metric #*	New Metric #	Metric Title
1	1	Average number of days from study award to contract signature
2	2	Average number of days from signed technical specifications document (TSD) to core lab ready to receive samples
3	3	% of on-time equipment shipments to sites
	4	Average and median time from collection of sample at the site to receipt at core lab
	5	Number of Samples Processed within Reporting Period
	6	Average and median time for queries to be raised by the core lab
6	7	% of data queries from core lab to site
7 & new	8	a. Turnaround time on resolution of site queries from core lab (resolved queries) b. Outlier Analysis of query resolution time (resolved queries) c. Listing of queries outstanding >2 weeks (unresolved queries)
	9	Average and median time for core labs to enter query resolution provided by the site into system
5, 8	10	a. % of final reports issued to sites within agreed turnaround time b. % of alerts successfully communicated to sites within defined turnaround time
11 & new	11	a. % of equipment failure as determined by site b. % of equipment failure as determined by site that is a true failure of equipment
12	12	Average turnaround time for replacing faulty equipment
13	13	% of on-time, accepted file transfers
16 & new	14	a. % spend with current budget b. Change from initial budgeted amount to current/final budgeted amount
	15	% of invoice payments received by the core lab within the agreed upon turnaround time
9 & new	16 ECG 1	a. % of ECGs that have suspect quality as determined by the core lab b. % of ECGs in which no parameters could be assessed c. % of ECGs in which only the interval duration measurements could not be assessed
10	17 ECG 2	% of manual adjustments of automated annotations for all intervals

* ECG v 1.1 metrics # 4, 14 & 15 are not included in v 2.0

Numbering Changes:

When looking at version 2.0 of the metrics, it becomes very obvious that the numbering has changed. There are two reasons for this change. The metrics in Version 2.0 have now been renumbered to reflect when they occur along the process map – e.g. the contracting metric occurs before the final budget variance metric.

The second thing you will notice is that the metrics have been broken into two parts:

- 1) Core Metrics (metrics 1-15)
- 2) ECG-Specific Metrics (metrics 16-17)

The Core Metrics are metrics that will be applicable across many different service lines - this change was made to allow us to expand our Performance metrics to include service lines such as ABPM, spirometry and echocardiography. By having a set of core metrics, we can be assured that the creation of systems and processes to gather these metrics at the core labs are consistent and easier to manage; and it allows us to dedicate our time in developing only the metrics that are best suited for each new service line. The ECG Performance Metrics version 2.0 is comprised of the 15 Core Metrics + the 2 ECG-Specific Metrics. Once we create other service line metrics (discussed below), you will have the option to select Core Metrics across a variety of service areas plus service line specific metrics (e.g. ECG-Specific Metrics, ABPM-Specific Metrics, etc.)

Including the Median Data as well as the Mean Data:

Many of the metrics now include both the mean value for a metric as well as the median value for the metric. The group felt that receiving only the mean value could be misleading as only one or a few results could greatly skew the data reported. By obtaining both the mean and median values, it is expected that you would be able to better ascertain if the result is skewed by a few disparate data points.

Newly Added Metrics:

While reviewing the metrics included in version 1.1, it was determined that there were several areas where we did not collect metrics which could provide an even better picture of the process. Therefore, metrics were added to address these gaps.

New Metrics	
4	Average and median time from collection of sample at the site to receipt at core lab
5	Number of Samples Processed within Reporting Period
6	Average and median time for queries to be raised by the core lab
8b	Outlier Analysis of Query Resolution Time
8c	Listing of Queries Outstanding >2 Weeks
9	Average and Median Time for Core Lab to Enter Query Resolution Provided by Site into System
11b	% of Equipment Failure as Determined by Site that is True Failure of Equipment
14a	% Spend within Current Budget
15	% of invoice payments received by the core lab within the agreed upon turnaround time
16b	% of ECGs in which No Parameters (Morphology or Intervals) Could Be Assessed
16c	% of ECGs in which Only the Morphology Could Be Assessed

- **Average and Median Time from Collection of the Sample at the Site to Receipt at the Core Lab (metric 4):** While reviewing the metrics that were available in version 1.1, it was apparent that we did not collect any information that addressed the beginning of the data collection process. The group felt that delays in the process often start when sites are not diligent in getting data obtained on clinical trial participants to the core labs in a timely manner. This in turn results in delays in getting reports back to the sites since the process cannot begin until the core lab has the data. Therefore, this metric was added as a way for sponsors and core labs to identify sites that are not complying with protocol requirements. The metric will allow a more proactive approach to addressing delays in the receipt of the samples at the core lab which allows the core lab review process to begin.
- **Number of Samples Processed with Reporting Period (metric 5):** This tracking metric was added because it is important to know and understand the total amount of work the core lab is processing for each study, as well as across all studies, the core lab is conducting for a sponsor. This understanding allows the sponsor gain perspective when looking at the other metric results.
- **Average and Median Time for Queries to be Raised by the Core Lab (metric 6):** This metric was added so the sponsor and core lab can assess whether the core lab is generating queries in a timely manner, which greatly affects the amount of time it takes to get the analysis processes underway (once the site responds to these queries). By tracking this information process changes can be made to ensure that samples are being addressed in a timely manner.
- **Outlier Analysis of Query Resolution Time (metric 8b):** This metric was added so the sponsor can identify sites that are not responding to queries within a reasonable amount of time (resolution takes >7 calendar days to be received). Identification of slow responding sites can lead to discussions with the sites to explain why queries need to be addressed and, hopefully, result in query resolution receipt in a more rapid manner.
- **Listing of Queries Outstanding >2 Weeks (metric 8c):** This metric will highlight sites that are not resolving queries issued by the core labs (those that are still outstanding to be resolved). By identifying these sites, discussions can occur with the sites to ensure that they are resolving queries as quickly as possible so the data can be generated and resulted to the site and/or the sponsor. Additionally, site monitors can be alerted to problems at these sites and review procedures during site visits.
- **Average and Median Time for Core Lab to Enter Query Resolution Provided by Site into System (metric 9):** This metric was added to monitor the amount of time it takes the core lab to enter query resolutions from the sites, which begins the clock on the reporting of data to the sites and/or the sponsors. By monitoring this metric, the core lab can address any systematic delays in getting query responses entered into their systems.
- **Percentage of Equipment Failure as Determined by Site that is True Failure of Equipment (metric 11b):** This metric was added to allow the sponsor to know the frequency that equipment truly fails and be able to contrast this with the number of times a site deems that the equipment has failed. Seeing a low percentage of true equipment failures (as compared to equipment failure as determined by the site) could indicate that either the core lab's helpdesk is not able to effectively troubleshoot issues over the telephone, or it could indicate that a site is unwilling to work with the core lab to address user issues when working with the devices.
- **Percent Spend within Current Budget (metric 14a):** This metric was added to provide the sponsor with a real time view of where the study budget stands in regards to the budgeted amount of the existing budget. Having this information will assist in tracking the progress of the study as well as provide an indicator if the study will fall below or above the contracted amount.
- **Percentage of Invoice Payments Received by the Core Lab Within the Agreed Upon Turnaround Time (metric 15):** This metric was added to help sponsors and core labs understand the efficiency of the sponsor's payment process and the quality of invoices issued by the core lab. The underlying cause for delay of payment may be related to a problem with the sponsor's payment process and/or errors in the invoicing process at the core lab.
- **Percentage of ECGs in which No Parameters (Morphology or Intervals) Could be Assessed (metric 16b):** This metric was added so the sponsor and core lab can know the percentage of ECGs that were

not analyzable at all. By identifying sites that are collecting unevaluable ECGs, the sponsor can proactively retrain the sites to ensure that quality ECGs are being recorded in the future.

- **Percentage of ECGs in which Only the Morphology Could be Assessed (metric 16c):** This metric was added so the sponsor and core lab can know the percentage of ECGs that could be partially assessed, meaning the interval values could not be assessed. By identifying sites that are collecting partially evaluable ECGs, the sponsor can proactively retrain the sites to ensure that quality ECGs are being recorded in the future.

Metrics Removed:

Based on discussions during the ECG Metrics Implementation Working Group and the Cardiopulmonary Metrics Steering Committee meetings, it was determined that several metrics were not being used or deemed as providing limited or no use. Therefore, the following metrics were removed in Version 2.0.

- **Percentage of Site Who Conduct a Successful Test ECG Transmission:** The group agreed that the core labs should monitor this to ensure that sites are attempting a test transmission. However, in most cases this is not useful to know during the study unless there is an issue with transmission of the ECG data. In the event that a site is having transmission troubles, it is important for the core labs to be able to let the sponsor know if the site did not attempt a test ECG. Additionally, most sites have conducted enough studies with the equipment used that they do not require test transmissions, though it is very useful.
- **Key ECG Core Lab Personnel Turnover During Protocol:** This metric was removed because the group felt it is a very small number (if at all), and when it comes to Project Manager turnover it is not a real issue as long as the appropriate training occurs at the core lab. Regarding over reader turnover, it is important to know, but should be handled and communicated proactively instead of waiting to report this information within the monthly metrics.
- **Percentage of ECG Core Lab Audit/Assessment Findings Closed with Agreed Timelines:** Sponsors track this differently (different groups within the sponsor and different ways of tracking) and the sponsors should determine when the items are closed and not rely on the core labs determination of them being closed.

Version 1.1 Metrics That Have Had Major Changes

(Metrics 1-15 were all changed so they are not specific to ECGs alone, to indicate that study-specific metrics as well as overall metrics across all studies be provided, as well as minor wording changes). The following metrics had major changes:

- **Average Number of Days from Study Award to Contract Signature (metric 1):** Only minor changes were made to this metric (such as changing 'days' to 'calendar days', and not including studies placed on hold).
- **Average Number of Days from Signed Technical Specifications Document (TSD) to Core Lab Ready to Receive Samples (metric 2):** Only minor changes were made to this metric (such as changing 'days' to 'calendar days', and not including studies placed on hold).
- **Percentage of On-Time Equipment Shipments to Sites (metric 3):** Only major change is to provide an explanation of delays within the 'for cause' analysis.
- **Percentage of Data Queries from Core Lab to Site (metric 7):** Only minor changes were made to this metric (such as changing the frequency to monthly and including the exact query verbiage in the 'for cause' analysis).
- **Turnaround Time on Resolution of Site Queries From Core Lab (metric 8a – see metrics 8b and 8c in the listing of new metrics above):** Only minor changes other than asking for the median time in addition to the mean time. The reporting frequency was also changed to monthly
- **Percentage of Equipment Failure as Determined by Site (metric 11a – see metric 11b in the listing of new metrics above):** Defined 'equipment failure' as a failure that requires the equipment to be replaced; not equipment issues that can be addressed through troubleshooting calls. We have also added a note to indicate that 'not all equipment that is deemed by the site to be faulty is truly faulty.'

- **Percentage of On-Time, Accepted File Transfers (metric 13):** Defined what is considered to be an 'accepted file transfer'.
- **Change from Initial Budgeted Amount to Current/Final Budgeted Amount (metric 14b – see metric 14a in the listing of new metrics above):** This metric has been completely rewritten to indicate the true variance seen between the initial budgeted amount to the current and final budgeted amount. This metric will now indicate how well a sponsor can communicate the needs/expectations while requesting a budget as well as the core lab's ability to provide an accurate initial budget based on the sponsor's request. This metric was changed as the metric found in version 1.1 was difficult to understand and implement in a way that provided understandable data.
- **Percentage of ECGs that Have Suspect Quality as Determined by Core Lab Processes (metric 16a – see metric 16b and 16c in the listing of new metrics above):** This metric replaced 'Percentage of ECGs Received from one Study that were Uninterpretable'. The definition was clarified to indicate ECGs that had quality concerns that could impact the over read at the core lab (such as improper lead placement, baseline wander, artifact, noise, etc.) based on the core lab's or sponsor's process for determining 'suspect quality'. This metric also specifies that morphologies that exist that do not allow interpretation should not be included as unevaluable.
- **Percentage of Manual Adjustments of Automated Annotations for All Intervals (metric 17):** This metric was modified to capture all interval measurements, not just QT.

[Where do ECG Performance Metrics Version 2.0 metrics address touch points within the centralized ECG process at the core labs?](#)

The MCC has developed a generic process flow diagram for the management of centralized ECGs within clinical trials and identified which steps version 2.0 of the metrics address. It should be noted that each metric has been defined in general terms to highlight the type of metric that is being requested. The MCC developed this process flow diagram to assure that we have developed metrics that address the important touch points within the process and to gain a visual representation of each type of metric that we are requesting to determine if we are lacking in any specific metric type. Here are the metric types and the definition of each type of metric:

Cycle Time (CT): Measures how long it takes to complete a task (i.e. # of days)

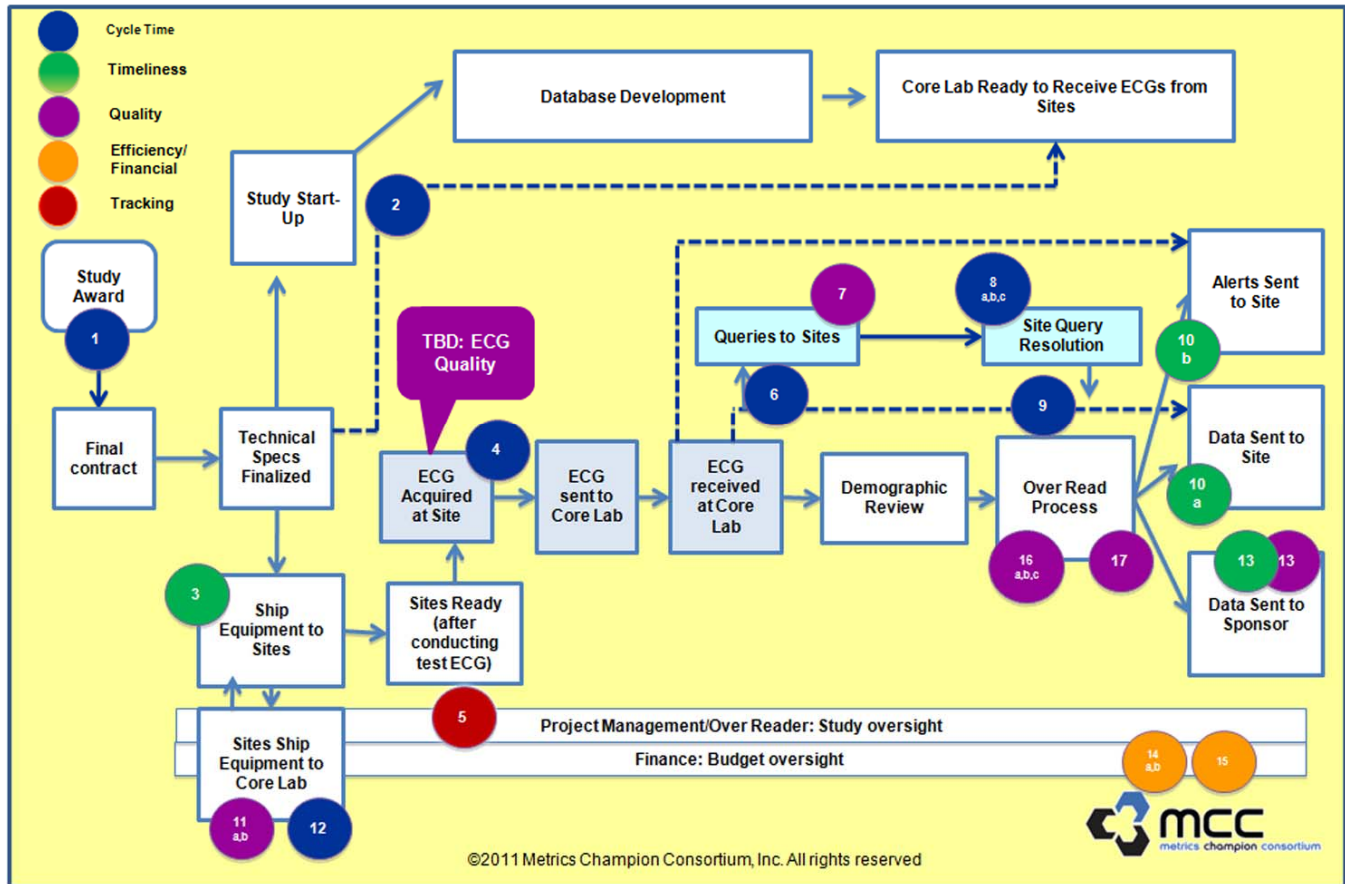
Timeliness (T): Measures whether a milestone was achieved on-time (i.e. within agreed upon turnaround time)

Quality (Q): Measures the number of errors in completing a task

Efficiency/Financial (E): Measures the resources required to complete a task

Tracking (TR): Measures a volume of work that is being managed

ECG Metrics v2.0 on Process Map



A power point version of the ECG Performance Metrics (v. 2.0) can be found on the MCC Member Homepage. Please note that you will need your MCC user name and password (<http://metricschampion.org/members/default.aspx>).

How should the core labs provide the metrics to the sponsors they work with?

Next to establishing and implementing performance metrics, defining a standardized methodology for the core labs to share these metrics with their sponsors is the most important aspect of creating a standardized, consistent process of communicating this information. Due to overwhelming feedback, the MCC ECG Performance Metric Teams have redesigned the recommended MCC ECG Performance Metrics Reporting Tool to assist in communicating this information. The metrics reporting tool has been redesigned in an attempt to provide more information regarding whether or not the metrics are meeting the target (using a green, yellow, and red color coding scheme) and an arrow scheme to indicate if the metrics have improved, remained the same or declined from the previous reporting period. The reporting tool also now has a comment column and the core labs should utilize this column to provide metric information that is pertinent to the sponsor.

Here is an example of the MCC ECG Performance Metrics Reporting Tool:

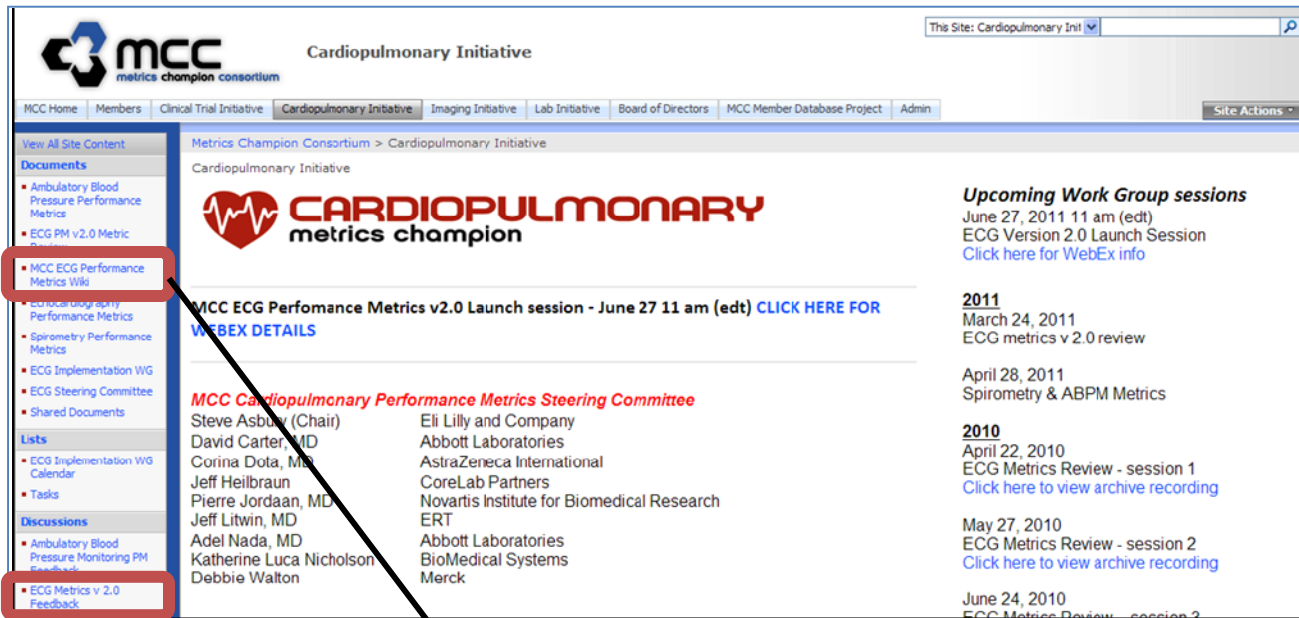
MCC ECG Performance Metric #16 – ECG Acquisition Quality												
Metric	Sub-Metric	Metric Title	Unit of Measure	Target	Row Information	Study 1	Study 2	Study 3	Study 4	Study 5	Sponsor Average	Core Lab Average for All Sponsors
16 ECG 1	16a	Percentage of ECGs that have Suspect Quality as Determined by the Core Lab	Percentage (%)	<0.5	Number with Suspect Quality	2	3	0	13	43	61	
					Total Number	500	800	900	2380	600	5180	
					Metric Value	0.40%	0.38%	0.00%	0.55%	7.17%	1.18%	0.32%
					Comparison to Last Period	↑	↔	↓	↔	↑	↓	
					Comments <ul style="list-style-type: none"> Study 4 - Site 8 had 13 ECGs that had incorrect chest lead placement. Study 5 - Site 53 collected 40 ECGs that had electrical interference. 							

The complete reporting tool example for the ECG Performance Metrics (v. 2.0) can be found on the MCC Member Homepage.. Please note that you will need your MCC user name and password (<http://metricschampion.org/members/default.aspx>).

[Where can I find additional information about the ECG metrics?](#)

The MCC has added two features to their website that will assist in ensuring there is a common understanding of terms used in the ECG performance metrics (the MCC ECG Performance Metrics Wiki) and a place where virtual discussions and questions can occur related to the implementation and use of the ECG Performance Metrics (the ECG Metrics v 2.0 Feedback area within the Discussions section). It should be noted that these additions to the MCC Website can be found on the Metric Champion Consortium’s website under the ECG Initiative. Please note that you will need your MCC user name and password (<http://metricschampion.org/members/default.aspx>).

In the screen shot below you can see where each of these can currently be found within the ECG Initiative page of the MCC website...



The screenshot shows the MCC website interface. In the left sidebar, two items are highlighted with red boxes: 'MCC ECG Performance Metrics Wiki' and 'ECG Metrics v 2.0 Feedback'. A black arrow points from the 'MCC ECG Performance Metrics Wiki' link to a red box labeled 'Wiki' below the screenshot. Another black arrow points from the 'ECG Metrics v 2.0 Feedback' link to a red box labeled 'ECG metrics 2.0 feedback' below the screenshot. The main content area of the screenshot displays the 'MCC ECG Performance Metrics v2.0 Launch session - June 27 11 am (edt) CLICK HERE FOR WEBEX DETAILS' and lists the members of the 'MCC Cardiopulmonary Performance Metrics Steering Committee'.

ECG metrics 2.0 feedback

Wiki

The MCC ECG Performance Metrics Wiki is currently located on the Cardiopulmonary initiative page, but will eventually be moved to the Member's Homepage. The wiki will be used to define terms that are used within the MCC metrics and MCC initiatives to ensure that a common definition is known to everyone who utilizes the metrics. While the wiki is currently located within the ECG Initiative page, members can add wiki terms and/or definitions to the contents. However, once it is moved to the Member's Homepage, only an administrator will be able to add terms and definitions, so if you feel something needs to be added you can submit a discussion topic to the ECG Metrics v 2.0 Feedback page (described below) requesting that a term and/or definition be added or updated.

The ECG Metrics v 2.0 Feedback page will be used to gather questions and/or thoughts regarding the implementation or utilization of the MCC ECG Performance Metrics version 2.0. The Steering Committee will regularly review the discussions occurring on this site and will use this to address questions and comments that arise and drive discussions in future Implementation Working Group Meetings and future revisions of the MCC ECG Performance Metrics. This will become a valuable tool in sharing implementation strategies and issues among the Working Group as well as highlighting areas where we can improve the metrics that we have developed; and we hope that everyone will begin to use this portion on the MCC website.

[Where do we go from here and what can we look forward to in the future?](#)

With the finalization of version 2.0 of the MCC ECG Performance Metrics, we feel that this version will be stable over the next few years. However, the Steering Committee still has a desire to establish ECG acquisition quality metrics as we believe this is an area that is not fully addressed by the ECG Performance Metrics. Therefore, throughout 2011 the Steering Committee will continue the quest of determining if and how ECG acquisition metrics can be obtained and reported. While this endeavor has begun, we are still in the early discussions regarding this, but we are hoping that some decisions can be reached in 2011 and when more information is available this information will be shared with the Implementation Working Group.

Since the version 1.1 of the metrics has been rolled out, several core labs have incorporated the production of these metrics into their standard services. Likewise, some sponsors companies have begun to use these metrics to gain a better understanding of the ECG services within their studies. These services are not only related to the

core lab's service, but also to how the sponsor is working, performance at the investigative sites and the quality of the ECG equipment produced by different manufacturers. Based on the implementation of these metrics several case studies were developed to demonstrate how the metrics were implemented and the benefit the metrics have created. However, the MCC is very interested in developing additional case studies that demonstrate how your organizations have implemented the MCC ECG Performance Metrics, and we would be willing to assist in creating case studies to demonstrate how this was accomplished and what benefits you have gained. Case studies can either be papers that are shared on the MCC website or in journals, or presented at conferences. Please let Linda Sullivan know if you would be interested in sharing your experience using the MCC ECG Performance Metrics and the MCC will assist you in putting a case study together.

The focus of 2011 will now move toward creating a set of metrics to address other service lines where no standard metrics exist. This will be accomplished by using the core metrics (metrics 1-15) to address the general service line capabilities, while creating service line-specific metrics to establish metrics for these service lines. After discussions within the Implementation Working Group and the Steering Committee, we have decided to move forward with the creation of ambulatory blood pressure monitoring (ABPM) and spirometry metrics at the same time; and later continue to look into the possibility of creating a set of echocardiography metrics.

Jeff Heilbraun (CoreLab Partners) and Katherine Luca-Nicholson (BioMedical Systems) will use their vast expertise in these fields to lead the initiative to develop ABPM and spirometry metrics; and we are hopeful that they will receive much participation from the Implementation Working Group members. The development of these metrics began at the April 28, 2011 meeting and the hope is that the first version of the ABPM and spirometry metrics will be rolled out late this year or early next year.

Once again the Cardiopulmonary Performance Metrics Steering Committee would like to thank all of the MCC members; and especially those who have participated in creating Version 2.0 of the MCC ECG Performance Metrics, and we hope that your participation will continue as we move into the development of the expanded set of **Cardiopulmonary Performance Metrics** over the next year!! We look forward to the development of a standardized set of performance metrics for ABPM and spirometry but more importantly we look forward to the wonderful interaction of individuals from sponsors and core labs which enable us all to collect information that will lead to the betterment of data we are obtaining in clinical trials.

Sincerely,

MCC Cardiopulmonary Performance Metrics Steering Committee

Steve Asbury (Chair)	Eli Lilly and Company	Katherine Luca-Nicholson	BioMedical Systems
Adel Nada, MD/David Carter, MD	Abbott Laboratories	Debbie Walton	Merck
Corina Dota, MD	AstraZeneca International		
Jeff Heilbraun	CoreLab Partners		
Pierre Jordaan, MD	Novartis Institute for Biomedical Research		
Jeff Litwin, MD	ERT		

Metric	Metric Type	Metric Title
1	Cycle Time	Average number of days from study award to contract signature
2	Cycle Time	Average number of days from signed technical specifications document (TSD) to core lab ready to receive samples
3	Timeliness	% of on-time equipment shipments to sites
4	Cycle Time	Average and median time from collection of sample at the site to receipt at core lab
5	Tracking	Number of Samples Processed within Reporting Period
6	Cycle Time	Average and median time for queries to be raised by the core lab
7	Quality	% of data queries from core lab to site
8	Cycle Time	a. Turnaround time on resolution of site queries from core lab (resolved queries) b. Outlier Analysis of query resolution time (resolved queries) c. Listing of queries outstanding >2 weeks (unresolved queries)
9	Cycle Time	Average and median time for core labs to enter query resolution provided by the site into system
10	Timeliness	a. % of final reports issued to sites within agreed turnaround time b. % of alerts successfully communicated to sites within defined turnaround time
11	Quality	a. % of equipment failure as determined by site b. % of equipment failure as determined by site that is a true failure of equipment
12	Cycle Time	Average turnaround time for replacing faulty equipment
13	Timeliness	% of on-time, accepted file transfers
	Quality	
14	Efficiency / Financial	a. % spend with current budget b. Change from initial budgeted amount to current/final budgeted amount
15	Efficiency / Financial	% of invoice payments received by the core lab within the agreed upon turnaround time
16 ECG 1	Quality	a. % of ECGs that have suspect quality as determined by the core lab b. % of ECGs in which no parameters could be assessed c. % of ECGs in which only the interval duration measurements could not be assessed
17 ECG 2	Quality	% of manual adjustments of automated annotations for all intervals