

# MCC ECG Performance Metrics v2.0

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Linda Sullivan  
VP Operations  
Metrics Champion Consortium





# MCC Mission

The Metrics Champion Consortium (MCC) is an open, multidisciplinary, non-profit organization comprised of biotechnology, pharmaceutical, medical device and service provider organizations.

**Our mission** is to help sponsor and service provider organizations involved in the pharmaceutical, biotechnology and medical device industries improve their overall clinical trial development processes through the utilization of MCC standardized clinical trial performance metrics (time, cost & quality) by:

- ❖ Supporting the ongoing collaborative development of standardized performance metrics and process improvement tools
- ❖ Encouraging the continuous implementation of the metrics and tools among MCC members
- ❖ Providing a collaborative learning environment for members to share best practices, discuss challenges and industry trends
- ❖ Offering live and online educational opportunities to support the use of performance metrics and tools in member organizations



# MCC Members

Abbott Laboratories  
Actelion Pharma  
Acorda Therapeutics  
AG Mednet  
AstraZeneca\*  
BARC Global Central Lab  
Bayer Healthcare  
Beaufort CRO  
BioClinica  
Biogen Idec  
Biomarin Pharmaceuticals  
Biomedical Systems  
CardiaBase  
Cardio Analytics  
Cardiocore  
Celgene  
Cerexa  
CHDI  
Clinical Reference Laboratory  
Clinical Systems Ltd.  
Clinsys Clinical Research

Cognizant  
Corelab Partners  
Covance  
Covidien  
CSL Limited  
Customized Improvement Strategies  
DecisionView  
Duke Clinical Research Institute  
ERT\*  
Esoterix Clinical Trial Services  
Eurofins Medinet  
ExecuPharm  
Forte Research Systems  
GE Healthcare  
Genentech  
Genzyme  
Halloran Consulting Group  
i3  
iCardiac Technologies  
ICON

Imaging Endpoints  
INC Research  
Incyte  
Intrinsic Imaging  
Ixico  
Lilly\*  
M2S  
MEDIDATA GmbH  
Medidata Solutions  
Medtronic  
Merck  
MLM Labs  
New England Research Institute  
Novartis  
Novella Clinical  
Paragon Biomedical  
Parexel / Perceptive Informatics  
Pfizer\*  
PharmaNet\*  
PPD\*  
PRA International

QD-Quality & Training Solutions  
Quest Diagnostics  
Quintiles\*  
RadMD  
Regeneron  
Roche\*  
Seattle Genetics  
Sunovion Pharmaceuticals  
Synarc  
Virtual Scopics  
WorldCare Clinical

\* MCC Board of Directors

**70+ members  
and growing!**



## Message from the MCC Cardiopulmonary Performance Metrics Steering Committee

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.

Thank you for the opportunity to introduce the new and improved MCC ECG Performance Metric version 2.0.

***PLEASE NOTE: A more detailed listing of the metrics, including the exact definition, formula, target, benefit statement, and a listing of companion metrics for each individual metric (metrics that are related) is available to MCC Members on the MCC website's Member Homepage .***

The MCC ECG Performance Metrics (v1.0) were introduced to the industry in 2007. This set of standardized performance metrics, selected and defined by MCC members (sponsors and ECG core labs), were implemented in the hope that they would be utilized by sponsor companies and ECG core labs to:

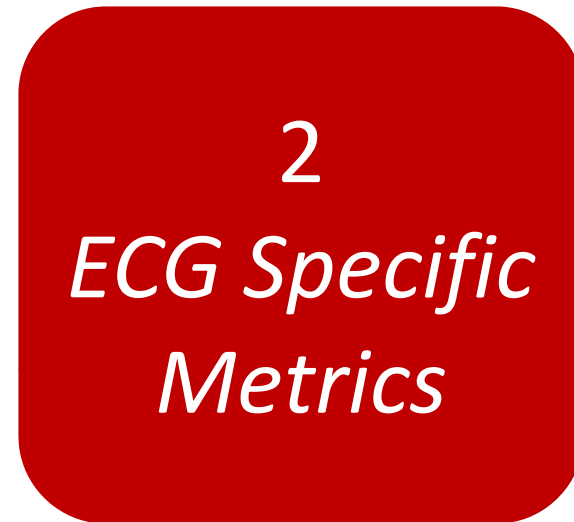
- identify areas where we could improve clinical trials collecting centralized ECGs;
- create better processes at the sponsors, investigative sites and core labs;
- understand how the decisions made and processes implemented by the sponsors affect the work core labs do;
- allow common understanding of 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. MCC Members feel this has been accomplished and believe that more improvements can be realized using the newest version of the MCC ECG Performance Metrics.

In the coming year(s) we plan to develop similar 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.

Sponsors should work with their core labs to determine which metrics are most important to both parties and should be used in their programs. The discussion about which metrics to use can provide both parties with a better understanding of the processes involved at the core lab and give the core lab a better understanding of the aspects the sponsor feels are important within a clinical trial.



Metrics that may be applicable across different service lines (ABPM, Spirometry, etc)

## **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 / Cost / Financial (E)**

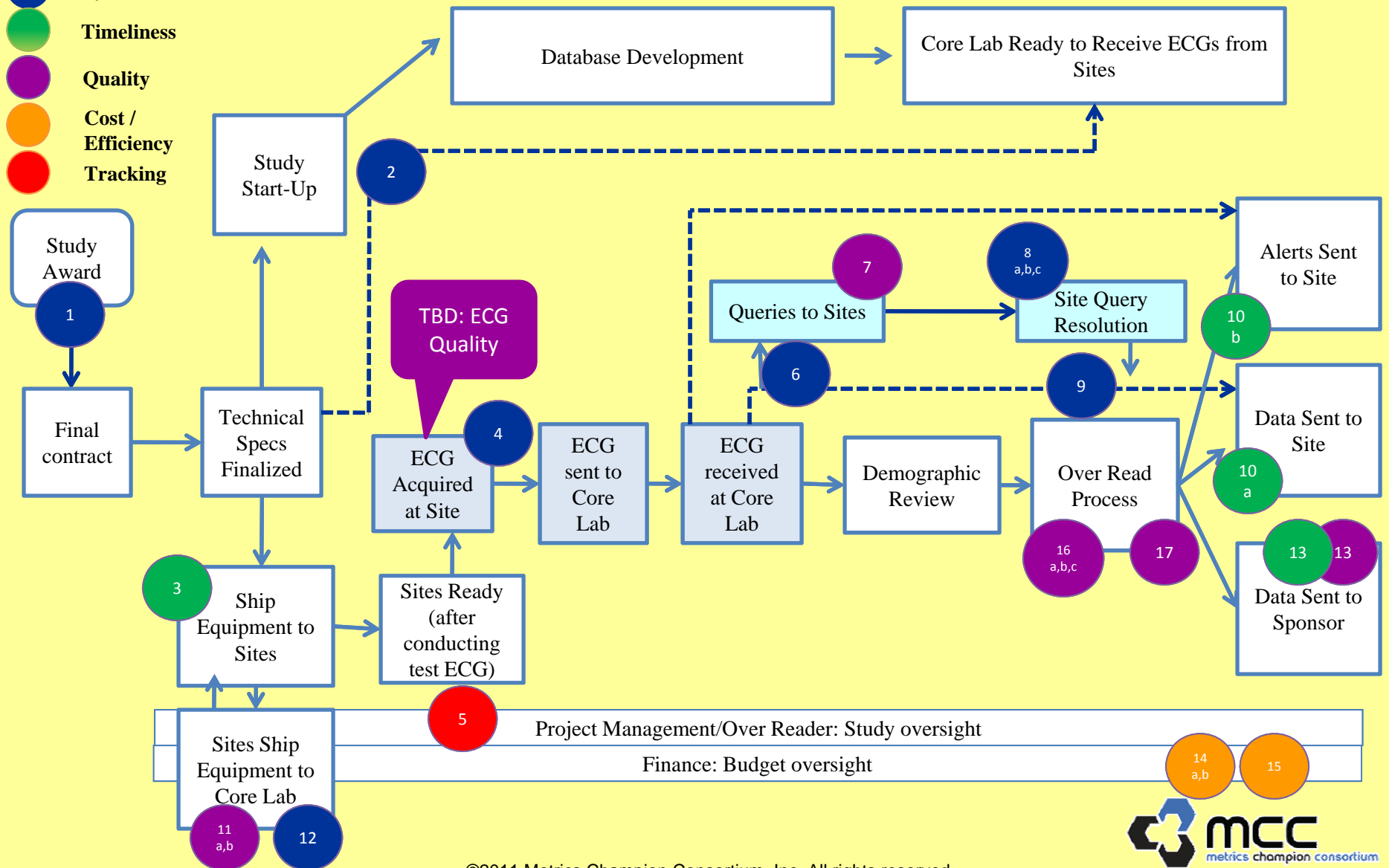
Measures the resources required to complete a task

## **Tracking (TR)\***

Measures a volume of work that is being managed

\* Metric for tracking purposes only – not performance metric

- Cycle Time
- Timeliness
- Quality
- Cost / Efficiency
- Tracking

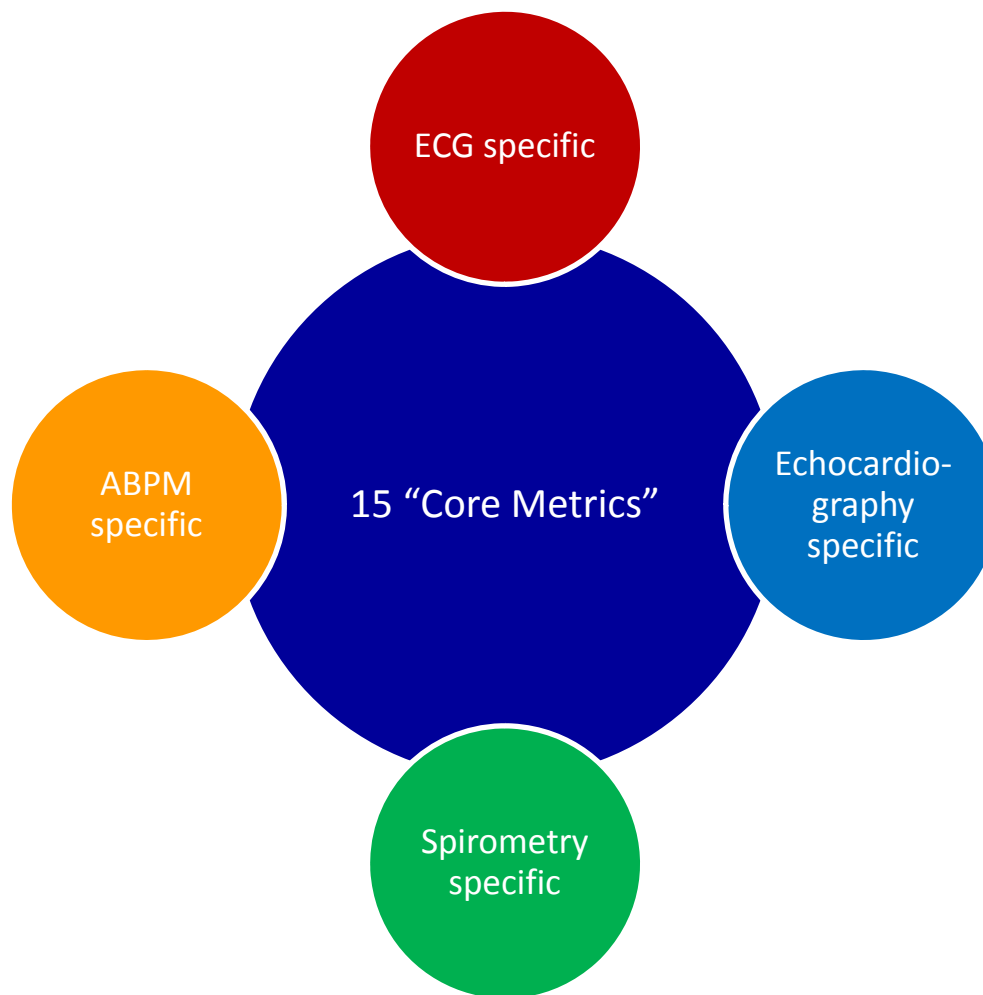


| Metric | Metric Type | Metric Title   |
|--------|-------------|--|
| 1      | Cycle Time  | Average number of days from study award to contract signature  |
| 2      | Cycle Time  | Average number of days from signed technical specifications document (TSD) to core lab ready to receive samples  |
| 3      | Timeliness  | Percentage 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     | Percentage of data queries from core lab to site   |
| 8      | Cycle Time  | <ul style="list-style-type: none"> <li>a. Turnaround time on resolution of site queries from core lab (resolved queries)</li> <li>b. Outlier Analysis of query resolution time (resolved queries)</li> <li>c. Listing of queries outstanding &gt;2 weeks (unresolved queries)</li> </ul> |
| 9      | Cycle Time  | Average and median time for core labs to enter query resolution provided by the site into system   |
| 10     | Timeliness  | <ul style="list-style-type: none"> <li>a. Percentage of final reports issued to sites within agreed turnaround time</li> <li>b. Percentage of alerts successfully communicated to sites within defined turnaround time</li> </ul>  |

| Metric      | Metric Type       | Metric Title  |
|-------------|-------------------|---|
| 11          | Quality           | <ul style="list-style-type: none"> <li>a. Percentage of equipment failure as determined by site</li> <li>b. Percentage of equipment failure as determined by site that is a true failure of equipment</li> </ul>  |
| 12          | Cycle Time        | Average turnaround time for replacing faulty equipment  |
| 13          | Timeliness        | Percentage of on-time, accepted file transfers  |
|             | Quality           |   |
| 14          | Efficiency / Cost | <ul style="list-style-type: none"> <li>a. Percent spend with current budget</li> <li>b. Change from initial budgeted amount to current/final budgeted amount</li> </ul>   |
| 15          | Efficiency / Cost | Percentage of invoice payments received by the core lab within the agreed upon turnaround time  |
| 16<br>ECG 1 | Quality           | <ul style="list-style-type: none"> <li>a. Percentage of ECGs that have suspect quality as determined by the core lab</li> <li>b. Percentage of ECGs in which no parameters could be assessed</li> <li>c. Percentage of ECGs in which only the interval duration measurements could not be assessed</li> </ul> |
| 17<br>ECG 2 | Quality           | Percentage of manual adjustments of automated annotations for all intervals   |

| Anatomy of a MCC ECG Performance Metric   |   |                          |   |  |
|---|---|--------------------------|---|--|
| Metric #  | Metric Type   | Metric Title             | Definition<br>(see Wiki for detailed definitions)   | Formula / Example  |
|   | CT, T, Q,<br>E, TR  |                          |   | Formula:<br><br>Specific Example:  |
| Additional Analysis on a "for cause" basis  |   |                          | Who's Being Measured?   | Business Driver(s) /<br>Benefit Statement                                      |
| List of "drill down" metrics that should be reviewed when the metric is not within established target |   |                          | CORE LAB, SITE, SPONSOR   | Statement about why this metric is important /the reason for utilizing metric. |
| Unit of Measure   | Target  | Reporting Frequency      | Companion Metrics   |  |
| Calendar days, % etc.   | Threshold target or acceptable range.<br><br>Exceeding target triggers additional analysis on a "for cause" basis | Monthly, Quarterly, etc. | The term "companion metrics" refers to the concept that many MCC metrics should be examined in combination with other MCC metrics ... together they give you a more complete picture of performance |  |

***Note to MCC Members: The detailed descriptions of the metrics are posted on the MCC website's Member Homepage .***





# MCC Plans to Expand Use of Metrics To Other Services Areas – Coming Soon!

| Core Metrics | ECG Metrics                               | ABPM Metrics            | Spirometry Metrics            |
|--------------|---|-------------------------|-------------------------------|
| Metric 1     | X   | ??                      | ??                            |
| Metric 2     | X   |                         |                               |
| Metric 3     | X   |                         |                               |
| Metric 4     | X   |                         |                               |
| Metric 5     | X   |                         |                               |
| Metric 6     | X   |                         |                               |
| Metric 7     | X   |                         |                               |
| Metric 8     | X   |                         |                               |
| Metric 9     | X   |                         |                               |
| Metric 10    | X   |                         |                               |
| Metric 11    | X   |                         |                               |
| Metric 12    | X   |                         |                               |
| Metric 13    | X   |                         |                               |
| Metric 14    | X   |                         |                               |
| Metric 15    | X   |                         |                               |
|              | ECG – specific metrics<br>Metrics 16 & 17 | ABPM – specific metrics | Spirometry – specific metrics |



Interested in learning about joining the MCC?

Visit <http://www.metricschampion.org> or  
contact Linda Sullivan ([lsullivan@metricschampion.org](mailto:lsullivan@metricschampion.org))