



## Discussion: Industry-wide Efforts to Develop and Implement Standardized Clinical Trial Performance Metrics to Drive Process Improvement

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*IQPC 10<sup>th</sup> Lean Six Sigma for Pharmaceutical, Biotech and Medical Device Excellence*

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<http://www.metricschampion.org>



# *Today's Discussion*

Learn how a group of pharmaceutical, biotechnology and CROs are collaborating to define and implement a standardized set of clinical trial performance metrics with the intent to *drive performance improvement of the drug development process.*



# Discussion Questions

- MCC standardized performance metrics and blinded industry database:
  - who will participate and what will be captured?
  - how will it be shared?
- ***MCC Companion Metrics*** – how does your organization utilize metrics to assess performance and drive behavior?
- Quality scoring tools – what areas deserve focus to establish industry quality standards?
- Can focus on a fixed set of metrics detract from process improvement discovery?

- Creating standardized clinical trial performance metrics and an industry benchmarking database
- Participating in an industry based Sponsor/CRO Process Improvement Work Group
- Utilizing new approaches to measuring the quality of site assessment, protocol writing and other clinical trial activities



# *Utilizing a collaborative approach to developing standardized metric definitions*





## *Building Partnerships Around Standardized Performance Metrics*

The Metrics Champion Consortium (MCC) is a not-for-profit organization comprised of biotechnology, pharmaceutical and service provider organizations who work collaboratively to develop and implement standardized performance metrics with the intent of jointly improving the efficiency and effectiveness of managing and tracking resources needed to successfully run clinical trials.



# *MCC Member Organizations*

**Abbott Laboratories**

**AstraZeneca**

**BARC Global Central Lab**

**BioClinica**

**Biogen Idec**

**Biomedical Systems**

**Cardio Analytics**

**Cardiocare**

**Carefusion**

**Cerexa**

**CHDI**

**Clinsys Clinical Research**

**Covance**

**Duke Clinical Research  
Institute**

**ERT**

**Esoterix Clinical Trial  
Services**

**Eurofins Medinet**

**ExecuPharm**

**Genentech**

**Genzyme**

**i3**

**ICON**

**Imaging Endpoints**

**INC Research**

**Incyte**

**Lilly**

**M2S**

**MacroGenics**

**Medidata Solutions**

**Medtronic**

**Merck**

**New England Research Institute**

**Novartis**

**Paragon Biomedical**

**Perceptive Informatics**

**Pfizer**

**PharmaNet**

**PPD**

**Quest Diagnostics**

**RadMD**

**RadPharm**

**Regeneron**

**Research Point**

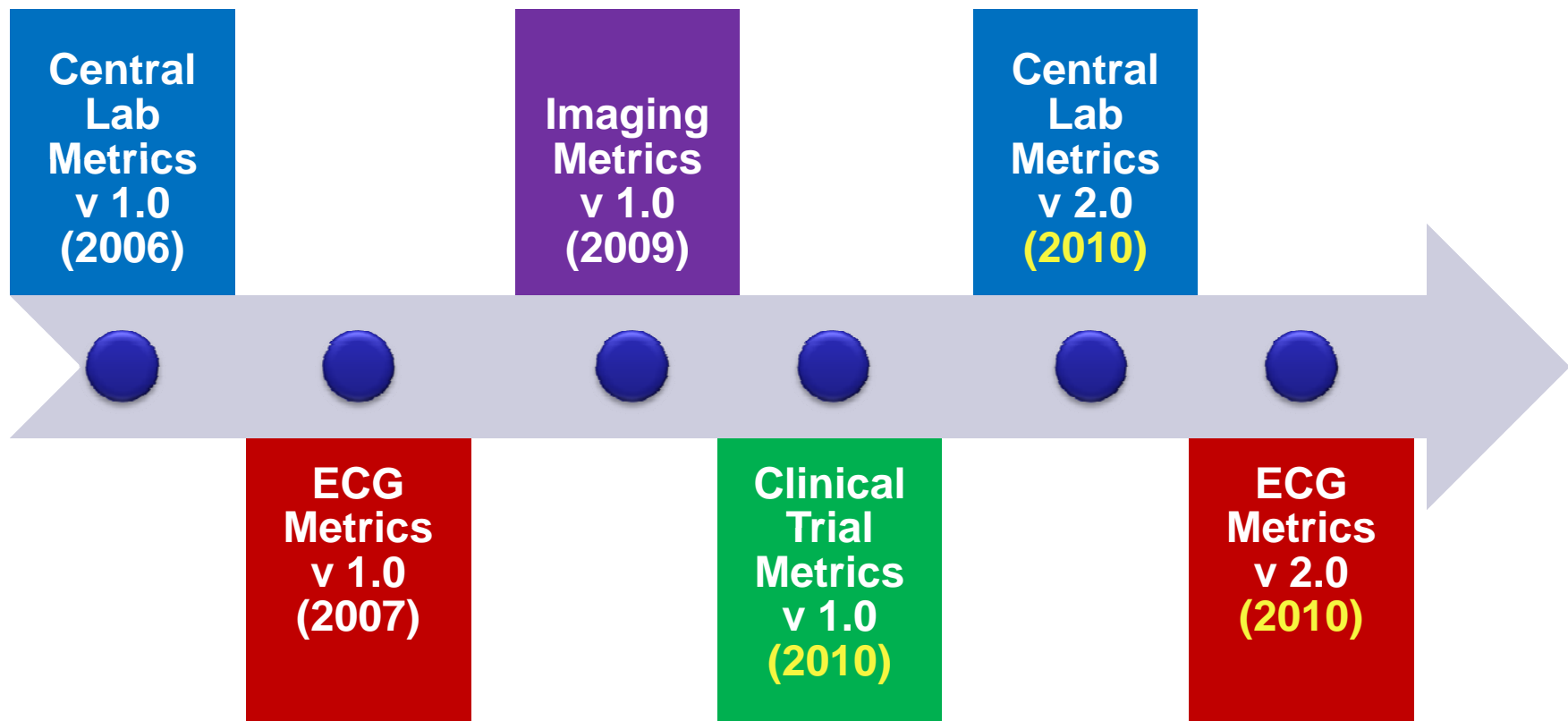
**Synarc**

**Virtual Scopics**

**WorldCare Clinical**



# Metrics Development Timeline



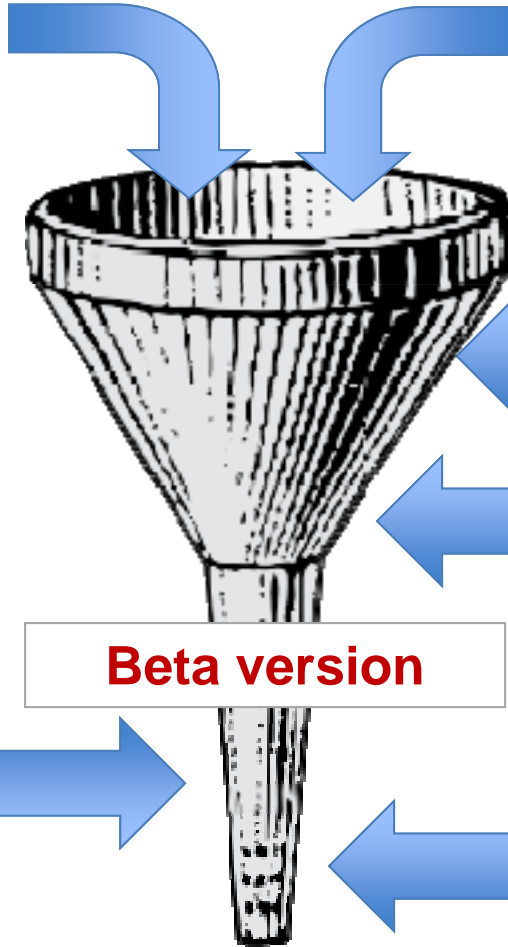


# MCC Metrics Development Process

## Brainstorm Metrics Lists

- Industry meetings
- Surveys

Gather Existing Metrics  
MCC SC & WG members



Create Process Maps  
MCC SC & WG members

Screen Metrics With  
Mapping Tool  
MCC SC & WG members

Solicit Industry  
Feedback

Revise Metrics  
MCC SC & WG members

**Metrics version 1.0**



# *Metric Characteristics*

- Key indicators of performance and allow for “additional for cause analysis”
- Clearly defined measurement criteria
- Provide benefit to Sponsor and Service Provider (must add value)
- “Soft” relationship metrics will be added in future versions



# *Types of Performance Metrics*

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

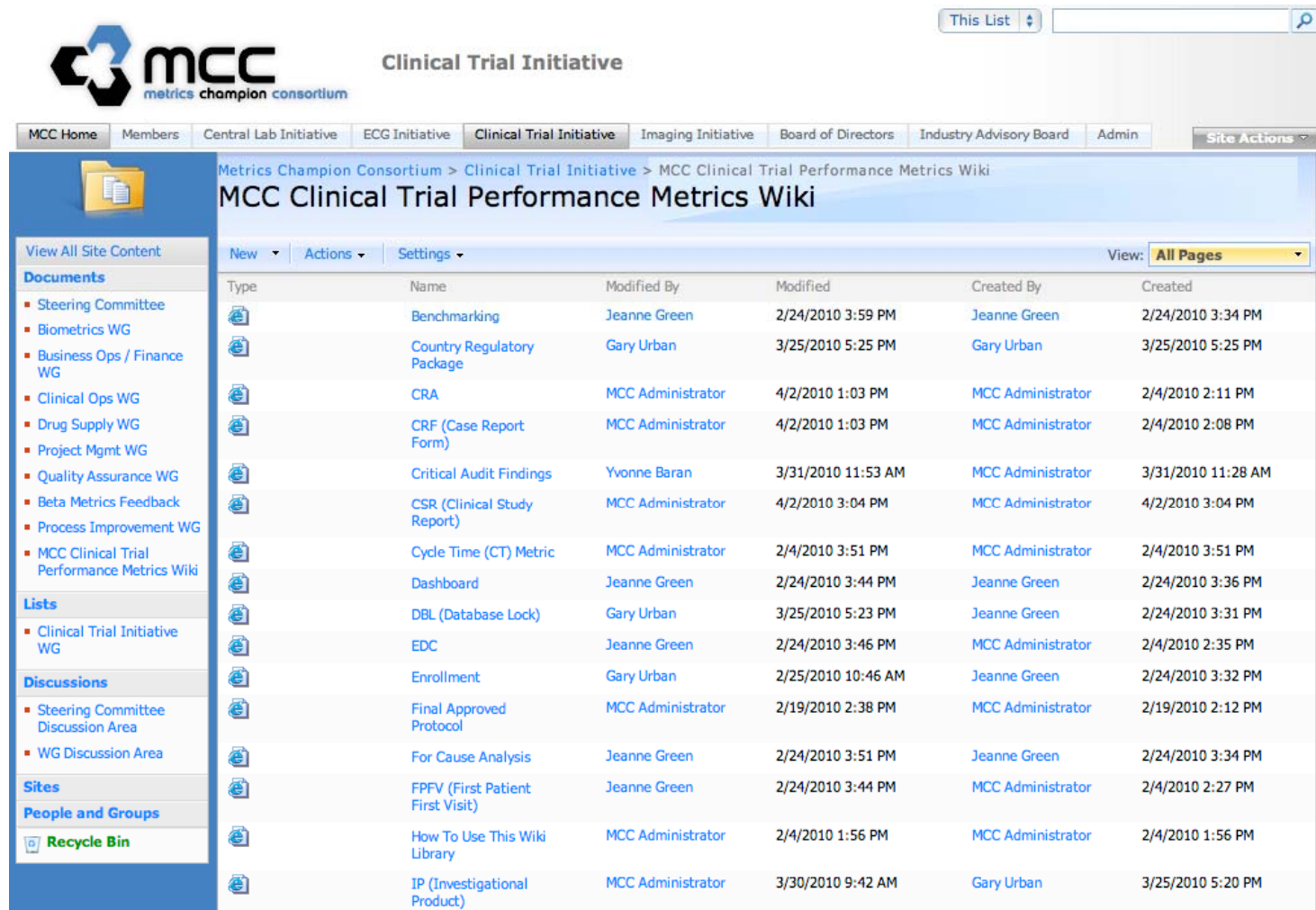
**Timeliness (T):** Measures whether a milestone was achieved on-time (i.e. within agreed upon turnaround time)

**Quality (Q):** Measures the number of errors in completing a task or completion of quality-related activity

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

# Example: MCC Clinical Trial Performance Metrics v 1.0 DRAFT

Metric #	Metric Type	Metric Title	Category	Metric Indicator	Part of Study
25	T	% subjects enrolled	Patient Screening and Retention	LEADING Indicator	Study Conduct
<b>Definition (see Wiki for detailed definitions)</b>		<b>Formula / Example</b>		<b>Reporting Detail</b>	
% subjects enrolled at point in time (actual date of 25, 50, 75%) vs. target date  <b>See MCC Wiki for definitions</b>		Formula: $X/Y (100) = \% \text{ subjects enrolled}$ $X = \# \text{ of subjects enrolled}$ $Y = \text{total \# of subjects anticipated to be enrolled}$  Example: A total of 35 subjects are enrolled at point time vs. an expected 32 enrolled subjects at point in time. $35/32 \times 100 = 109\%$		Study / Country / Region / Therapeutic Area / Portfolio levels  <b>Unit of Measure</b>  %	
<b>Business Driver(s) / Benefit Statement</b>		<b>Additional Analysis on a "for cause" basis</b>		<b>Reporting Frequency</b>	<b>Target</b>
Meeting or exceeding enrollment targets ensures trial timelines are met. It may be acceptable for the metric to trend toward the lower end of the target early in the enrollment period. Below target metrics indicate the need for risk management/intervention. A trend toward the upper end of the target may indicate a need to mitigate the risk of over-enrollment.		% of sites activated; Screen failure rate vs. expected; Actual vs. Planned Enrollment once LPLV is achieved. Formula: $(\# \text{ Months for Actual Enrollment} - \# \text{ Months Planned for Enrollment}) / \# \text{ Months Planned for Enrollment} \times 100 = \% \text{ additional time required for enrollment. } 18-12=6/12 \times 100 = 50\%$		Weekly or monthly, dependent upon planned enrollment period	> = 90% (Green) 75%-90% (Yellow) < 75% (Red)
<b>Companion Metrics</b>	MCC metrics # 3, 5, 11, 14, 17, 24, 34				



The screenshot shows the MCC Clinical Trial Performance Metrics Wiki interface. At the top, there is a navigation bar with the MCC logo and the text "Clinical Trial Initiative". Below this is a secondary navigation bar with tabs for "MCC Home", "Members", "Central Lab Initiative", "ECG Initiative", "Clinical Trial Initiative" (selected), "Imaging Initiative", "Board of Directors", "Industry Advisory Board", and "Admin". A "Site Actions" dropdown menu is also visible.

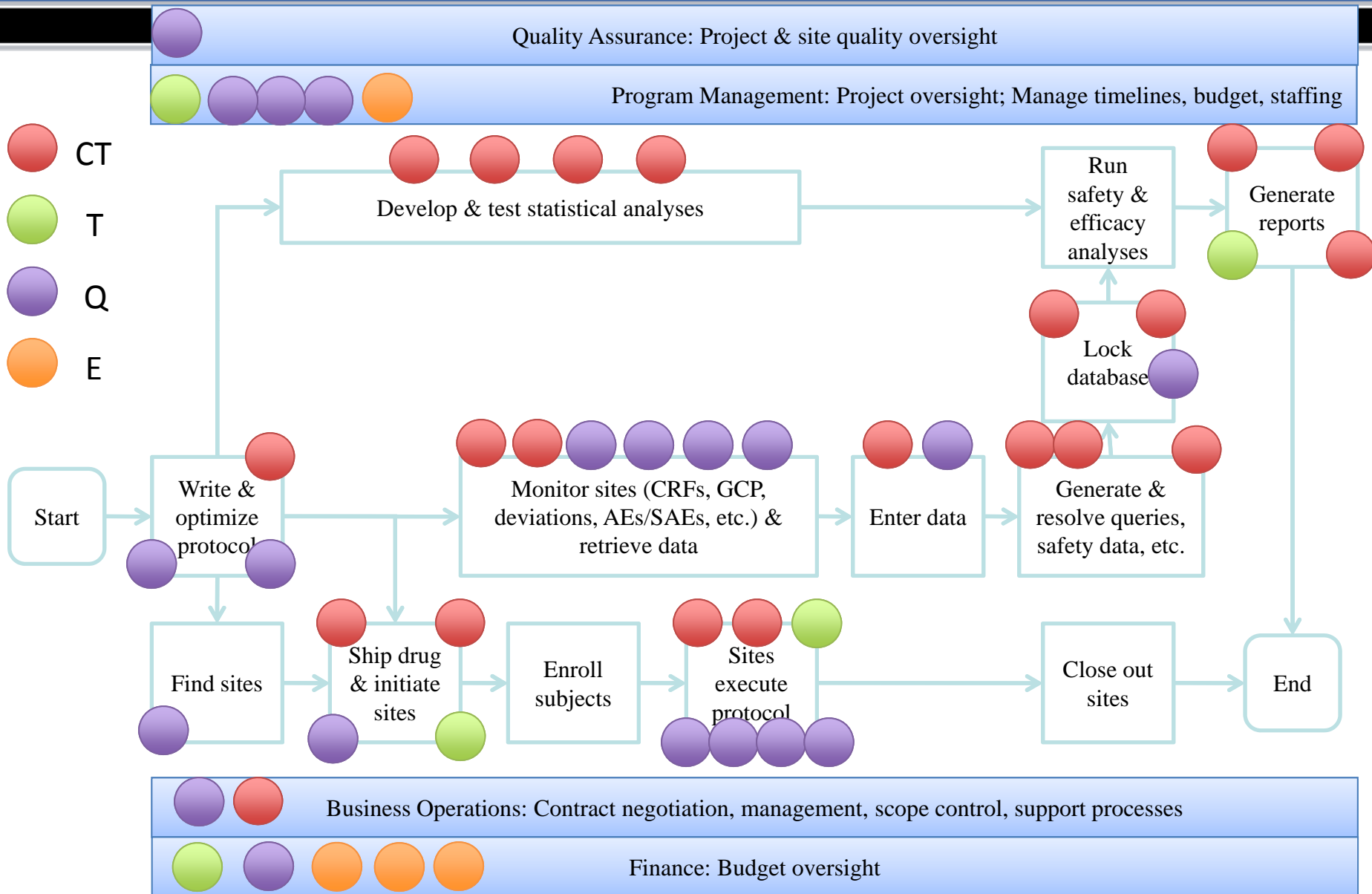
The main content area displays the title "MCC Clinical Trial Performance Metrics Wiki" and a breadcrumb trail: "Metrics Champion Consortium > Clinical Trial Initiative > MCC Clinical Trial Performance Metrics Wiki". Below the title, there are tabs for "New", "Actions", and "Settings". A "View:" dropdown menu is set to "All Pages".

The main content is a table listing various documents. The table has the following columns: Type, Name, Modified By, Modified, Created By, and Created. The data rows are as follows:

Type	Name	Modified By	Modified	Created By	Created
	Benchmarking	Jeanne Green	2/24/2010 3:59 PM	Jeanne Green	2/24/2010 3:34 PM
	Country Regulatory Package	Gary Urban	3/25/2010 5:25 PM	Gary Urban	3/25/2010 5:25 PM
	CRA	MCC Administrator	4/2/2010 1:03 PM	MCC Administrator	2/4/2010 2:11 PM
	CRF (Case Report Form)	MCC Administrator	4/2/2010 1:03 PM	MCC Administrator	2/4/2010 2:08 PM
	Critical Audit Findings	Yvonne Baran	3/31/2010 11:53 AM	MCC Administrator	3/31/2010 11:28 AM
	CSR (Clinical Study Report)	MCC Administrator	4/2/2010 3:04 PM	MCC Administrator	4/2/2010 3:04 PM
	Cycle Time (CT) Metric	MCC Administrator	2/4/2010 3:51 PM	MCC Administrator	2/4/2010 3:51 PM
	Dashboard	Jeanne Green	2/24/2010 3:44 PM	Jeanne Green	2/24/2010 3:36 PM
	DBL (Database Lock)	Gary Urban	3/25/2010 5:23 PM	Jeanne Green	2/24/2010 3:31 PM
	EDC	Jeanne Green	2/24/2010 3:46 PM	MCC Administrator	2/4/2010 2:35 PM
	Enrollment	Gary Urban	2/25/2010 10:46 AM	Jeanne Green	2/24/2010 3:32 PM
	Final Approved Protocol	MCC Administrator	2/19/2010 2:38 PM	MCC Administrator	2/19/2010 2:12 PM
	For Cause Analysis	Jeanne Green	2/24/2010 3:51 PM	Jeanne Green	2/24/2010 3:34 PM
	FPFV (First Patient First Visit)	Jeanne Green	2/24/2010 3:44 PM	MCC Administrator	2/4/2010 2:27 PM
	How To Use This Wiki Library	MCC Administrator	2/4/2010 1:56 PM	MCC Administrator	2/4/2010 1:56 PM
	IP (Investigational Product)	MCC Administrator	3/30/2010 9:42 AM	Gary Urban	3/25/2010 5:20 PM

On the left side of the interface, there is a sidebar with a "View All Site Content" link and several sections: "Documents" (listing various workgroups like Steering Committee, Biometrics WG, etc.), "Lists" (listing Clinical Trial Initiative WG), "Discussions" (listing Steering Committee Discussion Area, WG Discussion Area), "Sites", and "People and Groups". At the bottom of the sidebar is a "Recycle Bin" link.

# MCC Clinical Trial Performance Metrics v 1.0 DRAFT

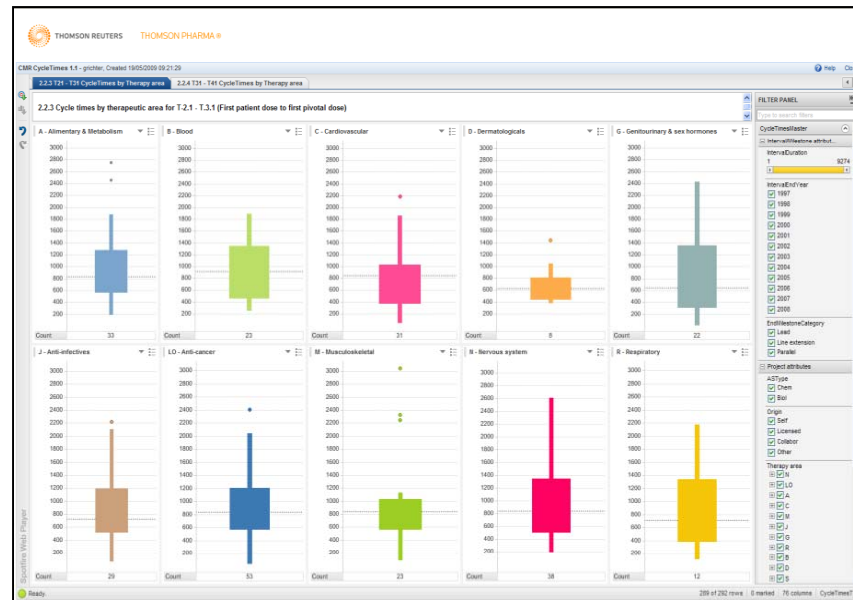




## *MCC Member Blinded Database*

- MCC Board of Directors established an alliance partnership with CMR International, a Thomson Reuters business
- The Alliance Partnership, with the guidance of MCC Members, is developing the database repository reporting platform utilizing Spotfire Analytics software
- MCC Member organizations must contribute data in order to access database reports

- Spotfire data visualization and analytics tool
- Interactive platform





# *Using metrics to drive process improvement*





## *MCC Process Improvement WG*

Process Improvement WG tasked with following purpose:

- Review Beta metrics to ID significant gaps in coverage of the clinical trial process
- Assess each proposed metric to:
  - determine how it could be used for process improvement
  - ensure data formats support process improvement activities
- Create *How to use the metrics for process improvement* guidance paper

- Focused on study start up process –

**High Quality  
Protocol**

+

**Good Site  
Selection**

=

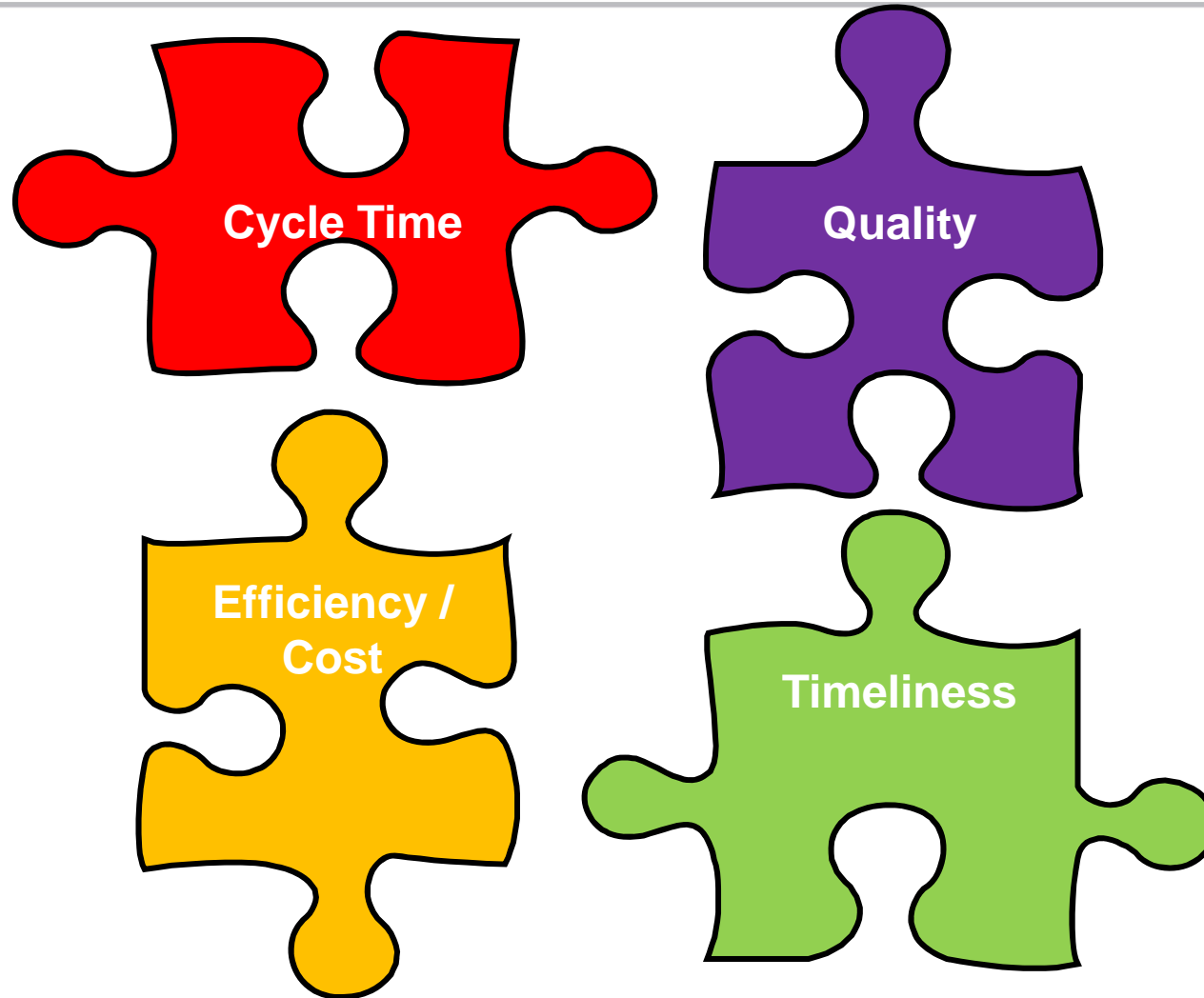
**High Chance of  
Successful Trial**



- Concerned that focusing only on time-related metrics can lead to sub-optimization

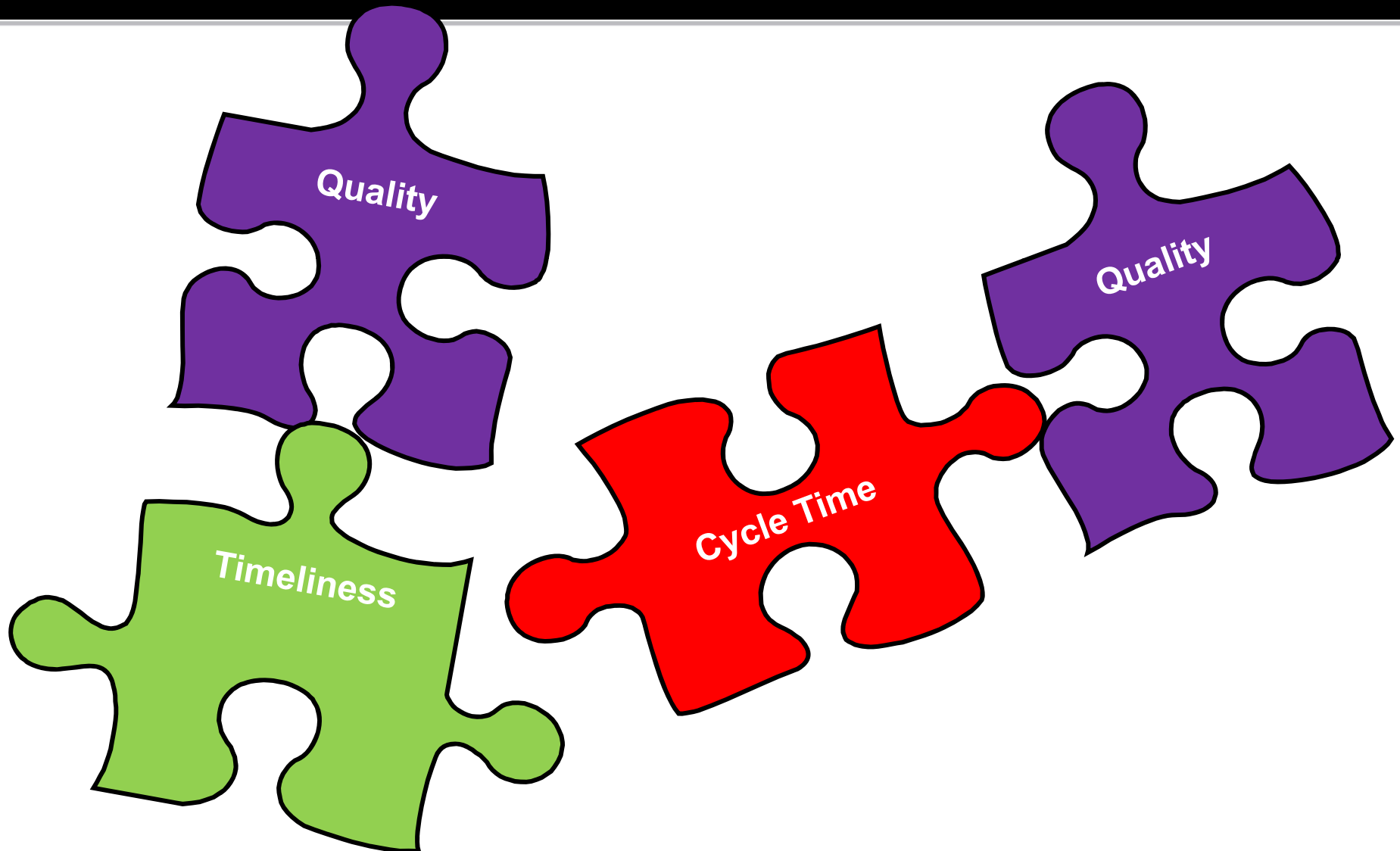


# Types of MCC Performance Metrics

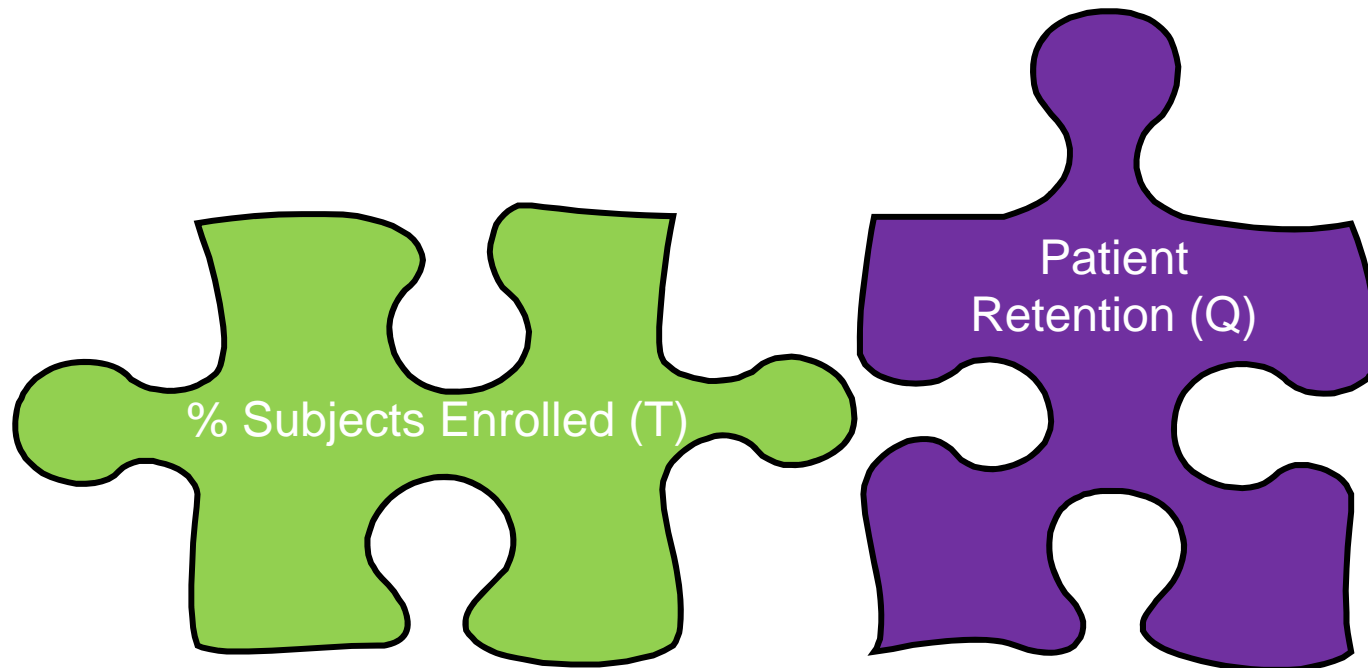




# *MCC Companion Performance Metrics*



Example: MCC Patient Screening and Recruitment Companion Metrics





# MCC Companion Performance Metrics – Study Start-up

- Study start up process important to trial success

**High Quality  
Protocol**

+

**Good Site  
Selection**

=

**High Chance of  
Successful Trial**



- Industry measures study start-up time-related metrics which can lead to sub-optimization
- Defined two new metrics:
  - Protocol Quality
  - Site Selection Quality



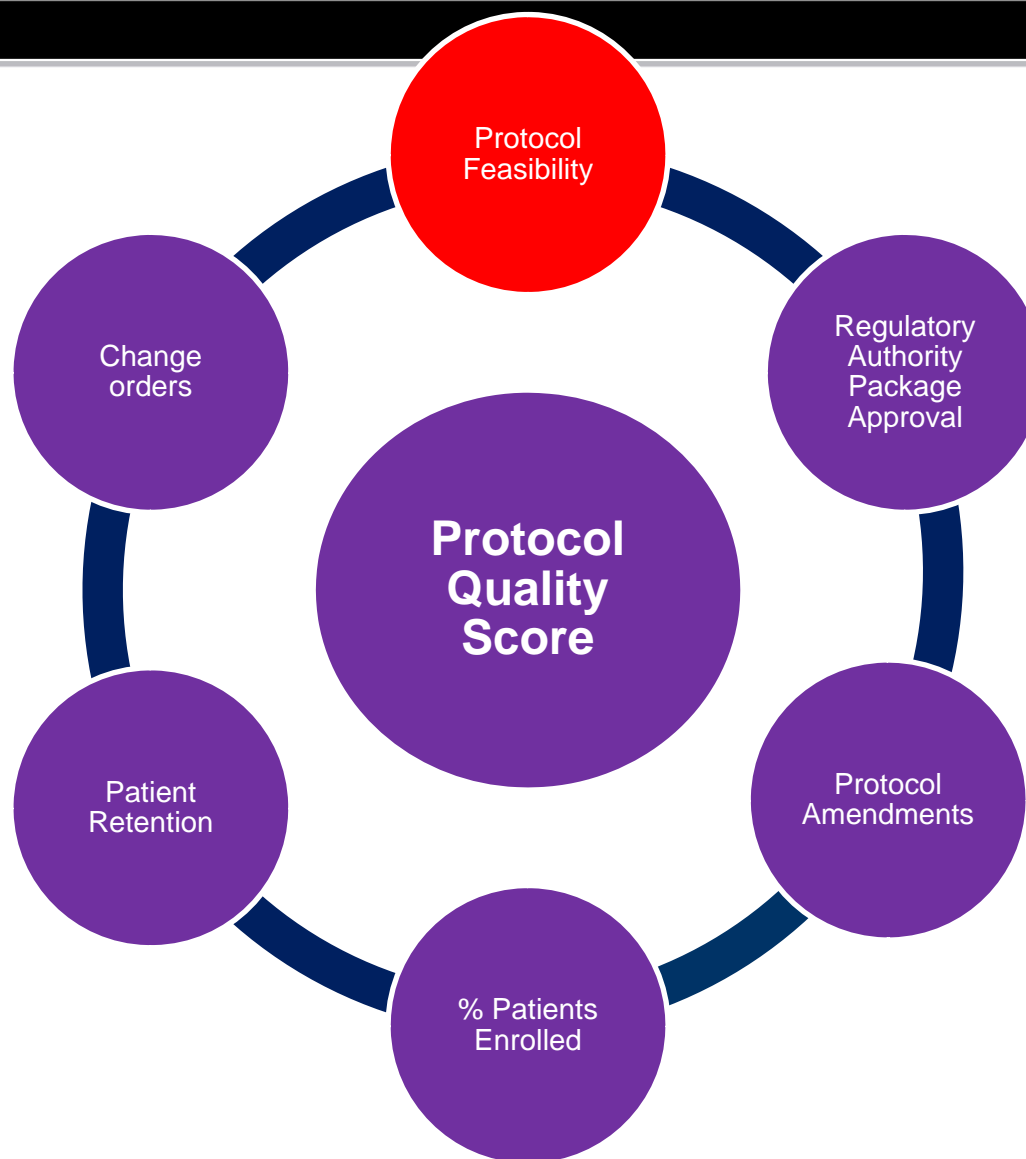
# *New MCC Quality Tools*

## Key Features:

- Provides Protocol Development and Site Selection teams with specialized quality scoring tools
- Team completes quality survey to determine how the protocol or sites selected score against the appropriate quality criteria
- If the quality score is below expectations, the team should consider addressing the areas they scored poorly on and redoing the survey to get a higher score



# MCC Protocol Quality Tool – User Pilots





# MCC Site Selection Quality Tool – User Pilots





# *MCC Quality Scoring Approach*

- Quality is difficult to measure – but important for success
- The act of measuring should modify behaviour:
  - Is the team doing what is needed to produce the best protocol?
  - Does a site lack skills and need specific training?
  - Are there enough high quality sites selected in country X?
- Interest in developing additional Quality Scoring Approach for Site Performance, CRFs and CSRs



## *Discussion Questions*

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- Can focus on a fixed set of metrics detract from process improvement discovery?



## *How can my company get involved?*

For additional information about joining the MCC, visit

<http://www.metricschampion.org>

or

contact Linda Sullivan at

lsullivan@metricschampion.org