



## **UPDATE FROM THE MCC**

***Understanding How Pharmaceutical,  
Biotechnology and CROs Develop Standardized  
Metrics to Drive Process Improvement and Boost  
Partnership Performance in Clinical Trials***

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***6<sup>th</sup> Annual Clinical Performance Metrics & Benchmarking Summit  
21 September 2010 Philadelphia, PA USA***



<http://www.metricschampion.org>

- MCC Overview
- Collaborative approach to developing standardized metric definitions
- MCC Clinical Trial Performance Metrics v1.0 (*new*)
- MCC Companion Metrics (*new*)
- MCC Process Improvement Quality Tools (*new*)
- Next Steps
- Q&A



## *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**

**CardiaBase**

**Cardio Analytics**

**Cardiocare**

**Carefusion**

**Cerexa**

**CHDI**

**Clinical Reference Laboratory**

**Clinsys Clinical Research**

**CoreLab Partners**

**Covance**

**Duke Clinical Research Institute**

**Eli Lilly**

**ERT**

**Esoterix Clinical Trial Services**

**Eurofins Medinet**

**ExecuPharm**

**Genzyme**

**i3**

**iCardiac Technologies**

**ICON**

**Imaging Endpoints**

**INC Research**

**Incyte**

**Intrinsic Imaging**

**Ixico**

**M2S**

**MacroGenics**

**Medidata Solutions**

**Medtronic**

**Merck**

**New England Research Institute**

**Novartis**

**Paragon Biomedical**

**Parexel / Perceptive Informatics**

**Pfizer**

**PharmaNet**

**PPD**

**PRA International**

**Quest Diagnostics**

**RadMD**

**Regeneron**

**Research Point**

**Roche / Genentech**

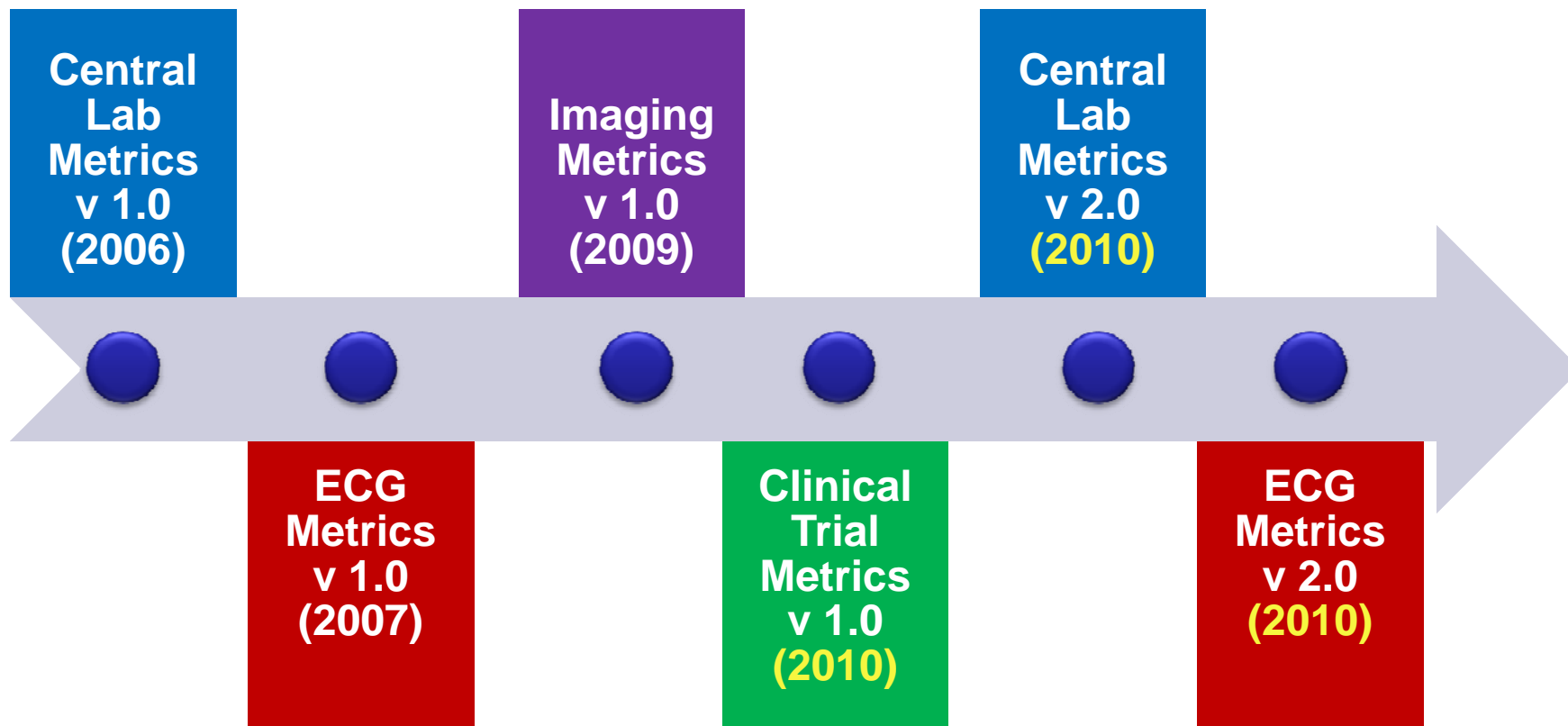
**Synarc**

**Virtual Scopics**

**WorldCare Clinical**



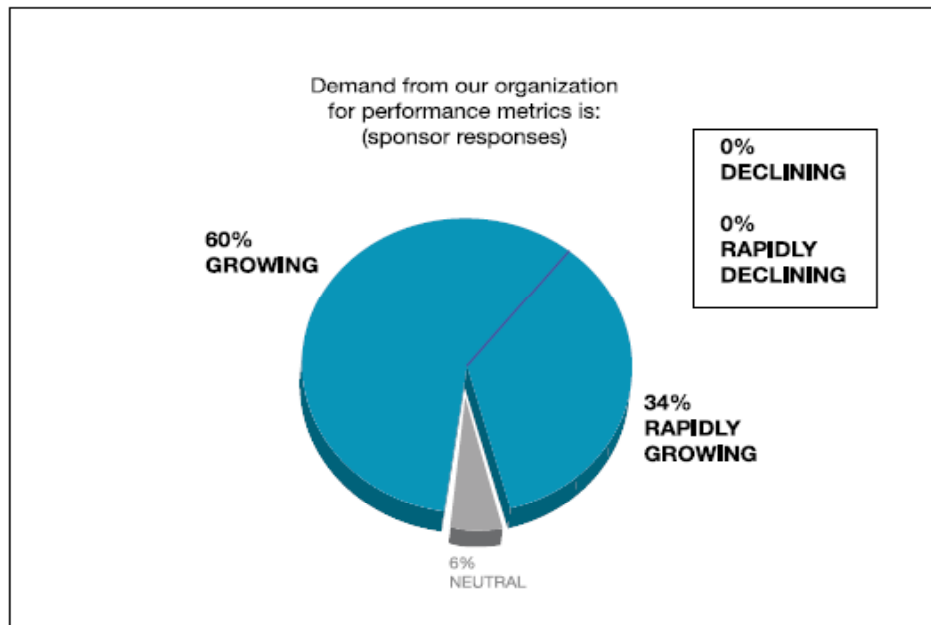
# Metrics Development Timeline



- Establish defined sets of standard performance metrics that facilitate the management of clinical trials
- Encourage the use of the standard metrics by sponsors and service providers to identify areas for improvement
- Facilitate the sharing of metric data among MCC member organizations (through a blinded database)
- Provide a common basis for constructive discussion between sponsor and service providers that will lead to a common understanding for the need to improve performance

# Demand for Performance Metrics Growing

**94%** of Sponsors reported that demand from their organizations for performance metrics was growing or rapidly growing (n=32)



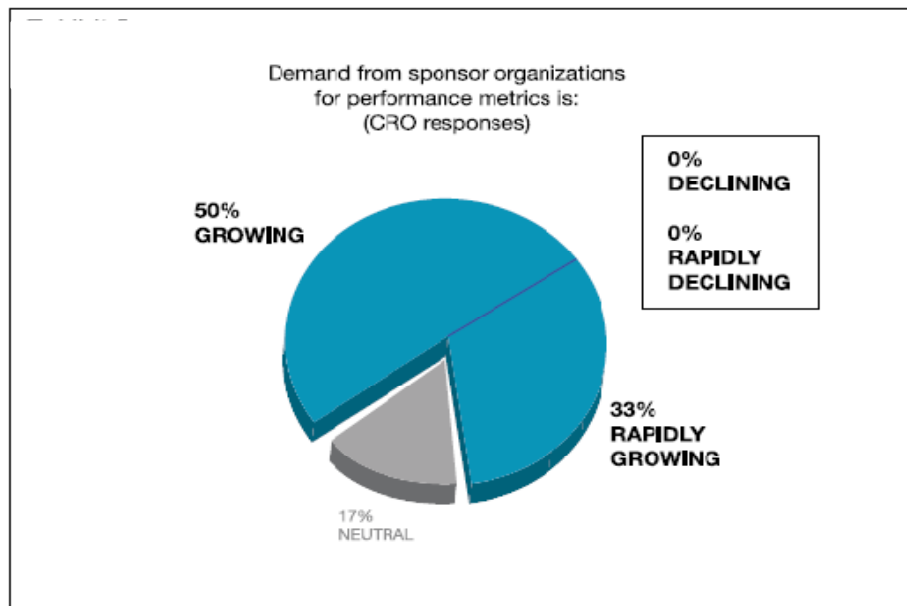
**9%** reported having well-defined/clearly understood metrics in place

**54%** reported they did **not** routinely use performance metrics to ***improve productivity*** with CROs

**62%** reported they did **not** routinely use performance metrics to help ***improve relationships*** with CROs

# Industry Players Not Utilizing Metrics to Potential

**83%** of CROs reported that the demand for performance metrics was growing (50%) or rapidly growing (33%) among Sponsor companies (n=14)

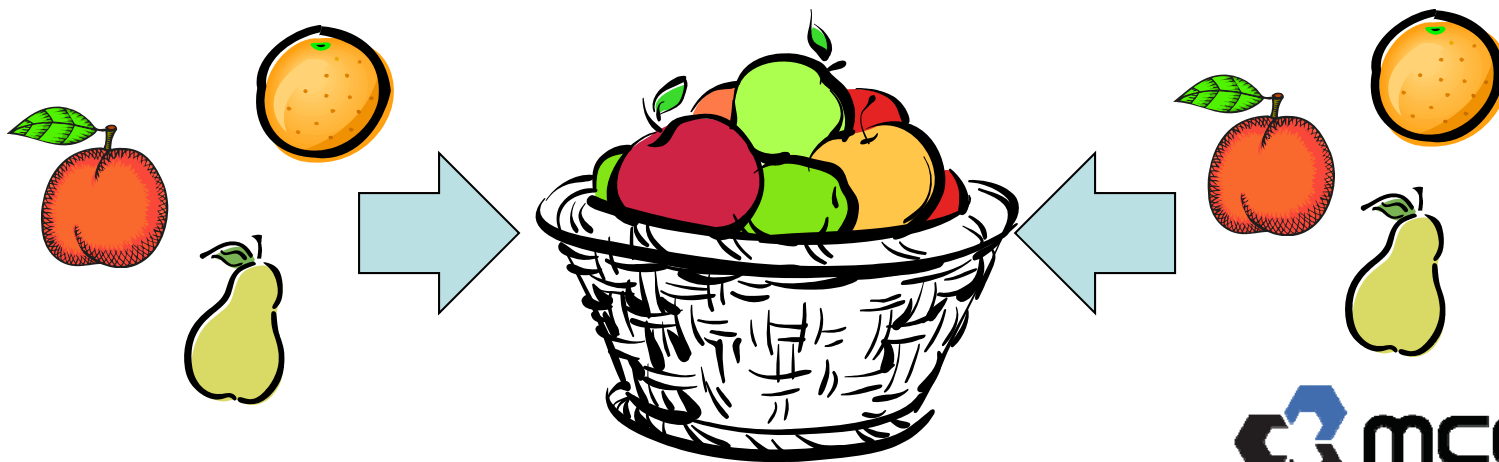
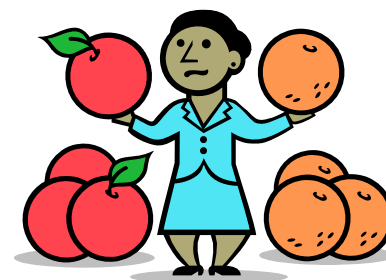


**0%** CROs reported that Sponsor companies request and review performance metrics to take effective action with them

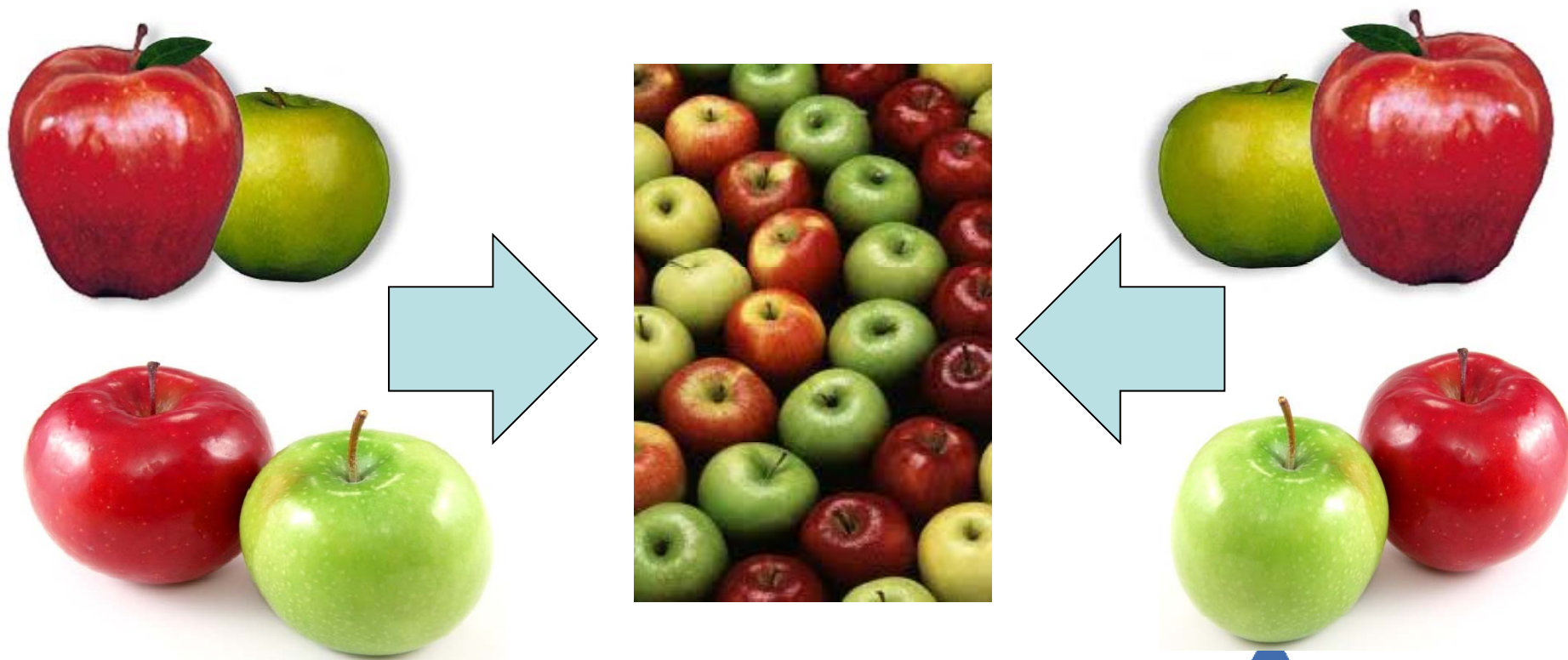


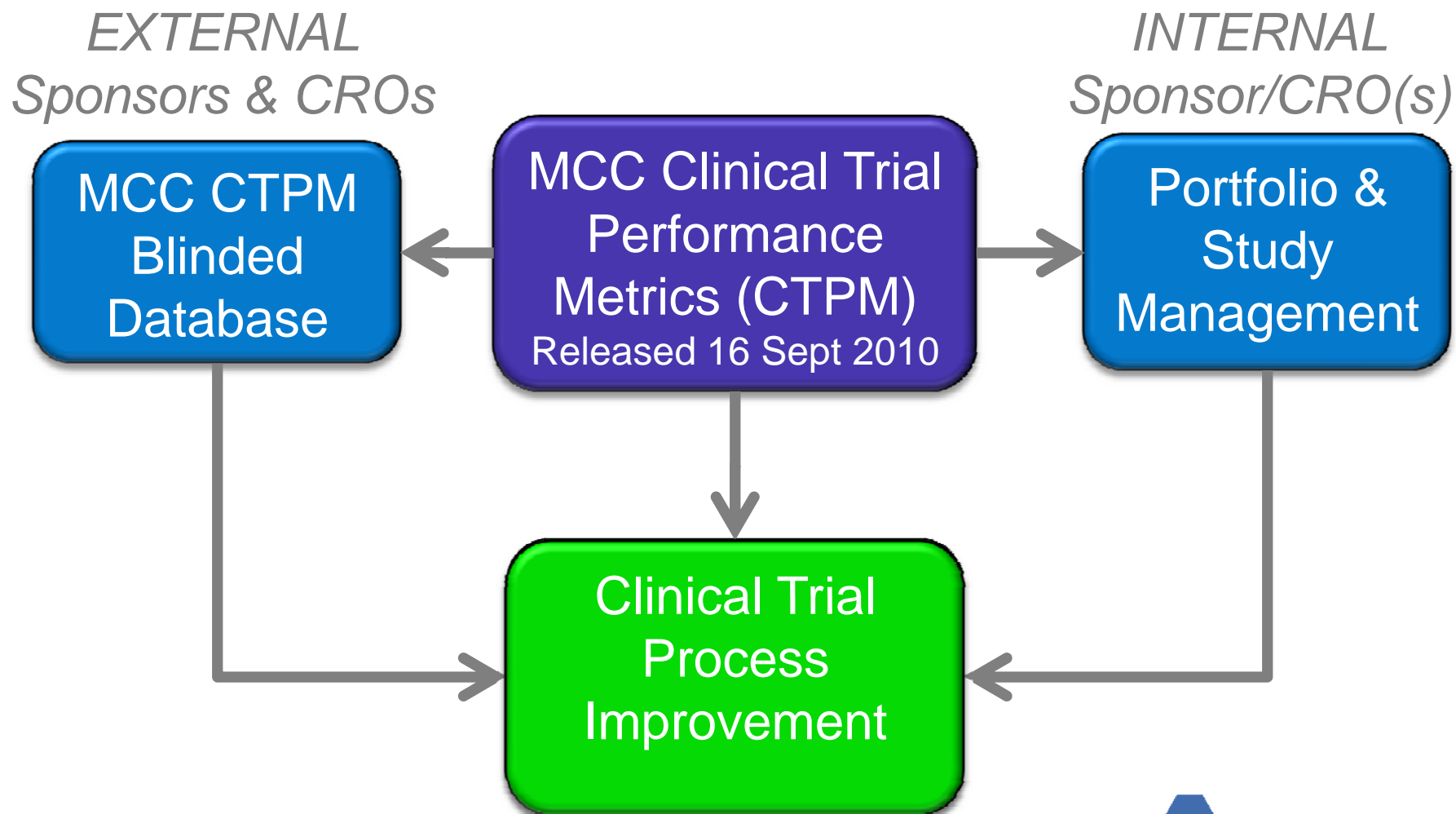
- Sponsors use different CROs
  - Managing metrics across CROs is a challenge

- CROs are faced with managing varying performance based metrics from Sponsors



Mutually beneficial standardized performance metrics can be achieved and fruitful for all parties







# *The collaborative approach to developing standardized metric definitions*





**CLINICAL TRIAL**  
metrics champion

# *MCC Clinical Trial Performance Metrics Initiative Timetable*

Phase 1:  
Define  
Metrics

Phase 2:  
Implement  
Metrics

Phase 3:  
Revise  
Metrics



## Phase 1: Define Metrics

MCC Metrics  
Work Groups  
4/08 – 3/09

Beta version  
4/09

Industry  
Feedback  
5/09 – 8/09

MCC Revisions  
& Enhancements  
9/09 – 8/10

Version 1.0  
9/10

- BioMetrics WG
- Business Operations WG
- Clinical Operations WG
- Drug Supply WG
- QA WG

- BioMetrics WG
- Business Operations WG
- Clinical Operations WG
- Drug Supply WG
- QA WG
- **Process Improvement WG**

- Measure performance of a specific task
  - ***Clinical trial performance metrics*** (not CRO metrics)
  - Not designated as Sponsor or CRO metric
- Key indicators of performance and allow for “additional for cause analysis”
- Clearly defined measurement criteria
- Add value – described in Business Driver
- “Soft” relationship metrics will be added in future versions

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

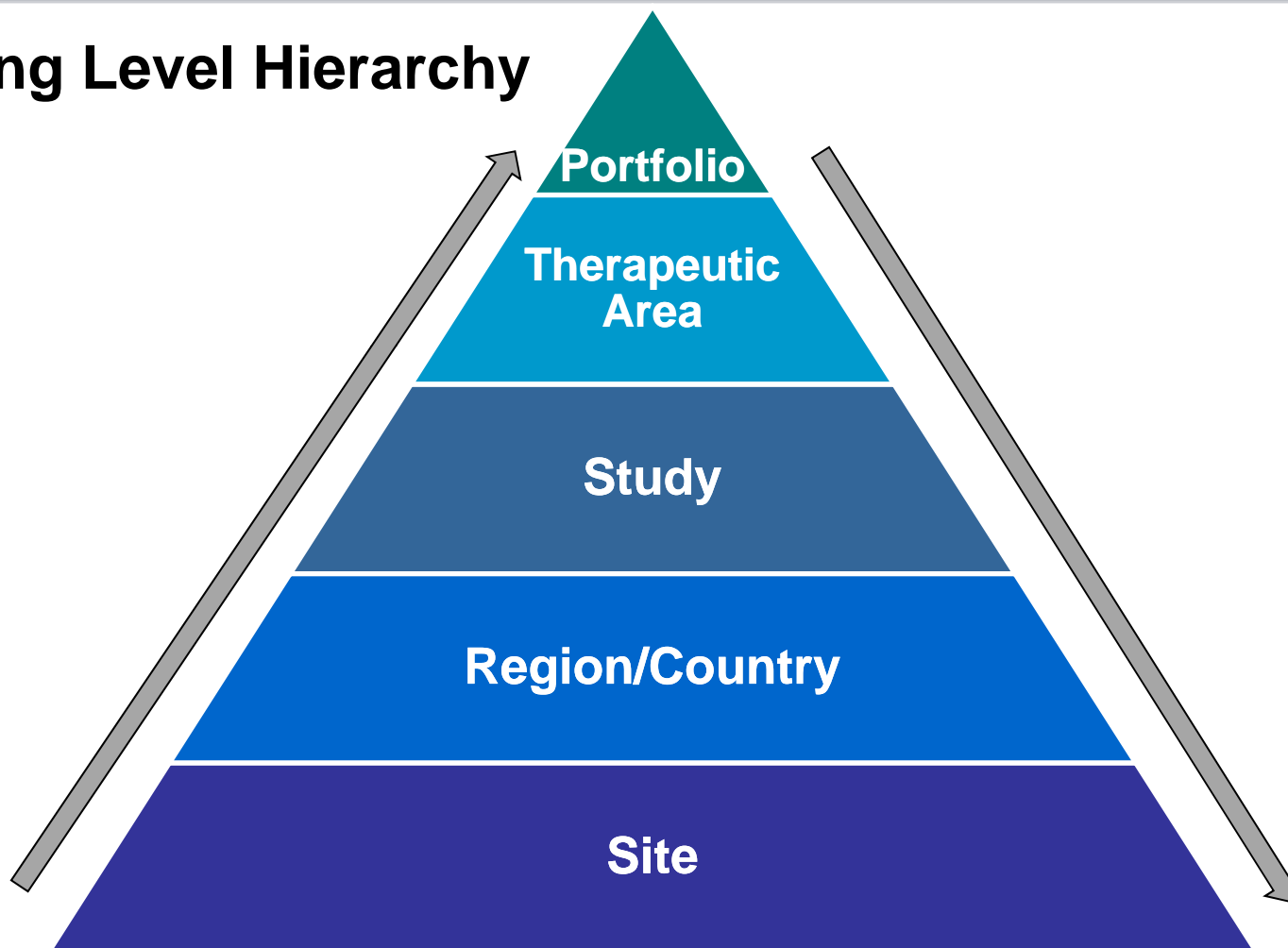
**Timeliness (T):** Measures whether a milestone was achieved on-time (i.e. within agreed upon turnaround time)

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

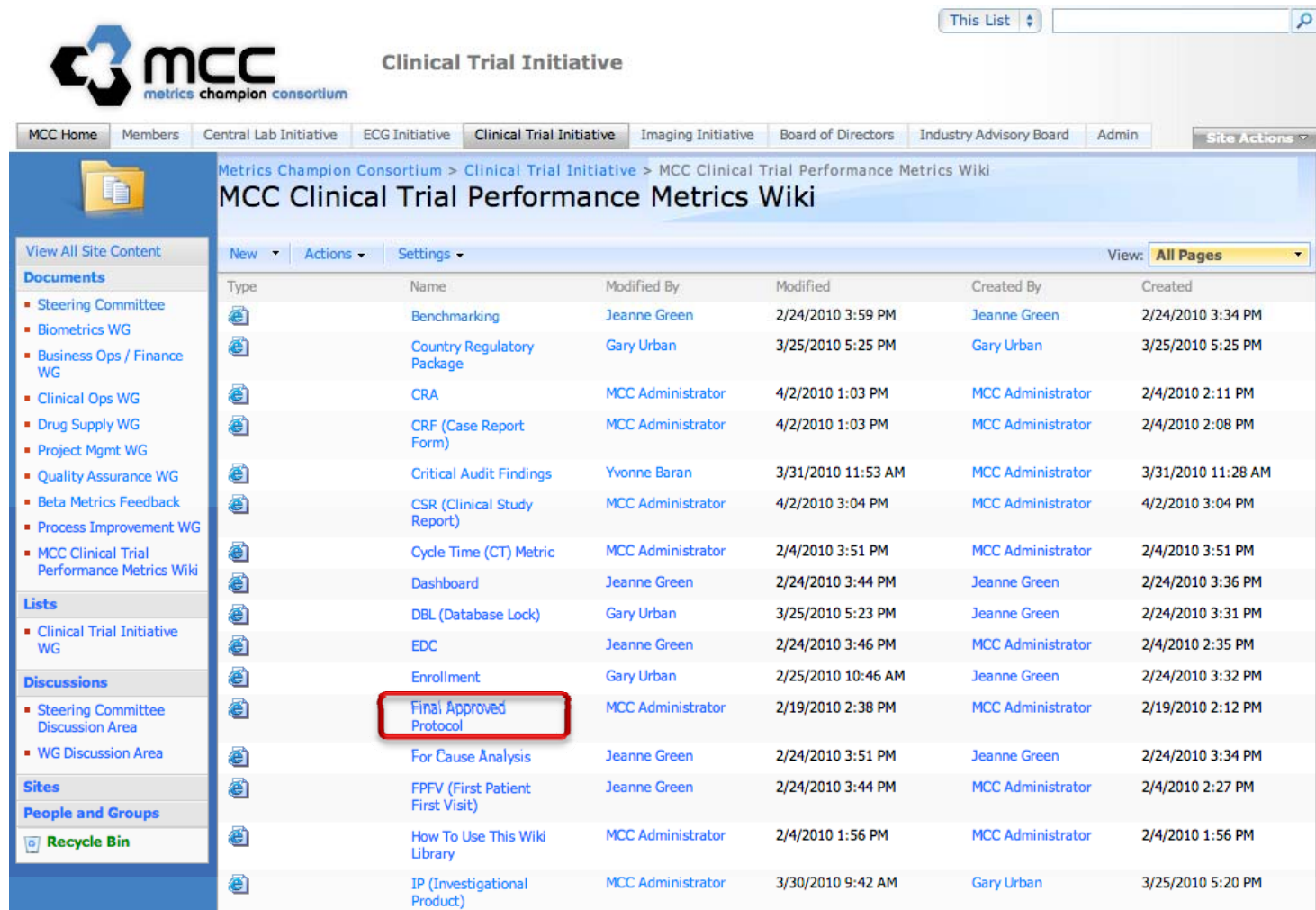
**Efficiency / Cost (E):** Measures the resources required to complete a task

- **Leading Indicator:** Metric can be used to identify opportunity to affect change to current study.
- **Lagging Indicator:** Metric can be used to identify opportunity to affect positive change to future studies only.

## Reporting Level Hierarchy



Metric #	Metric Type	Metric Title	Category	Metric Indicator	Part of Study
8	CT	Final Approved Protocol to Final Approved eCRF - EDC	CRF Design	LAGGING Indicator	Study Startup
		Definition (see Wiki for detailed definitions)	Formula / Example	Reporting Detail	
		Number of calendar days from <i>final approved protocol</i> to final approved eCRF.  <b>See MCC Wiki for definitions</b>	Formula: X-Y=# calendar days X = date eCRF final Y= date protocol final  Example: Final Protocol Date = 01Jan2008; Actual approval of eCRF is 26Jan 2008 [26 Jan -1 Jan] = 25 calendar days	Study / Therapeutic Area / Portfolio levels	
				Unit of Measure	
				Calendar days	
Business Driver(s) / Benefit Statement		Additional Analysis on a "for cause" basis		Reporting Frequency	Target
This task is critical in starting the remaining Data Management tasks. For example, once the eCRF is approved, edit checks can be created, tested etc. Therefore, this is really the starting point for Data Management to begin. The completion of the eCRF should also be completed before PPFV		Additional analysis on a "for cause" basis: Delays in the timeline could be due to the # of eCRF pages, complexity of the study, # of review rounds, pending protocol amendment, lack of agreement/ specificity on design, too many people to provide feedback, very burdensome review process, or lack of clinical trial development experience. Shorter ....		Once	15 calendar days
Companion Metrics		Need to develop e-CRF Quality metric			



Metrics Champion Consortium > Clinical Trial Initiative > MCC Clinical Trial Performance Metrics Wiki

MCC Clinical Trial Performance Metrics Wiki

View: All Pages

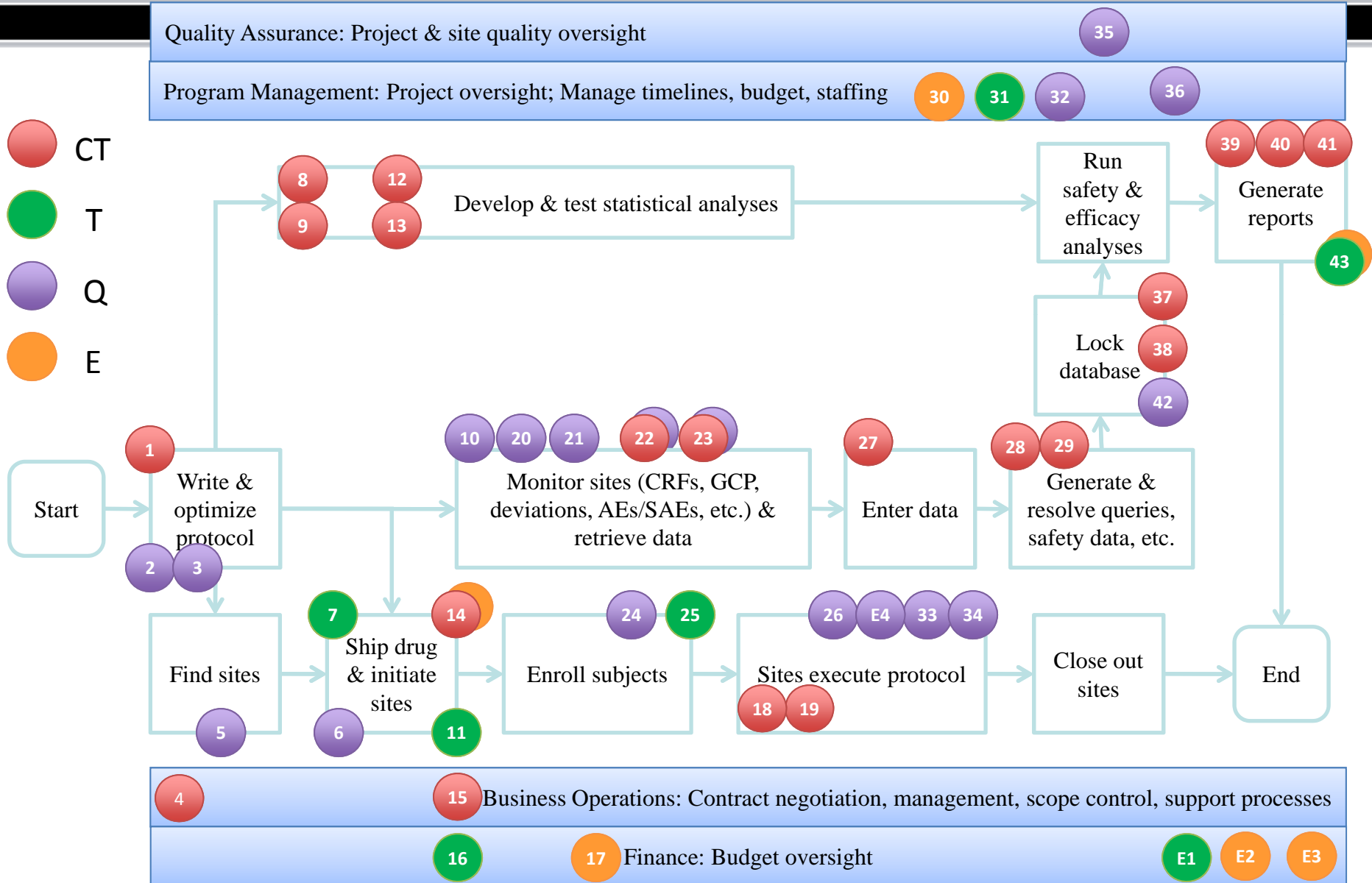
Type	Name	Modified By	Modified	Created By	Created
	Benchmarking	Jeanne Green	2/24/2010 3:59 PM	Jeanne Green	2/24/2010 3:34 PM
	Country Regulatory Package	Gary Urban	3/25/2010 5:25 PM	Gary Urban	3/25/2010 5:25 PM
	CRA	MCC Administrator	4/2/2010 1:03 PM	MCC Administrator	2/4/2010 2:11 PM
	CRF (Case Report 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
	<b>Final Approved Protocol</b>	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



# *MCC Clinical Trial Performance Metrics version 1.0*



# MCC Clinical Trial Performance Metrics v 1.0

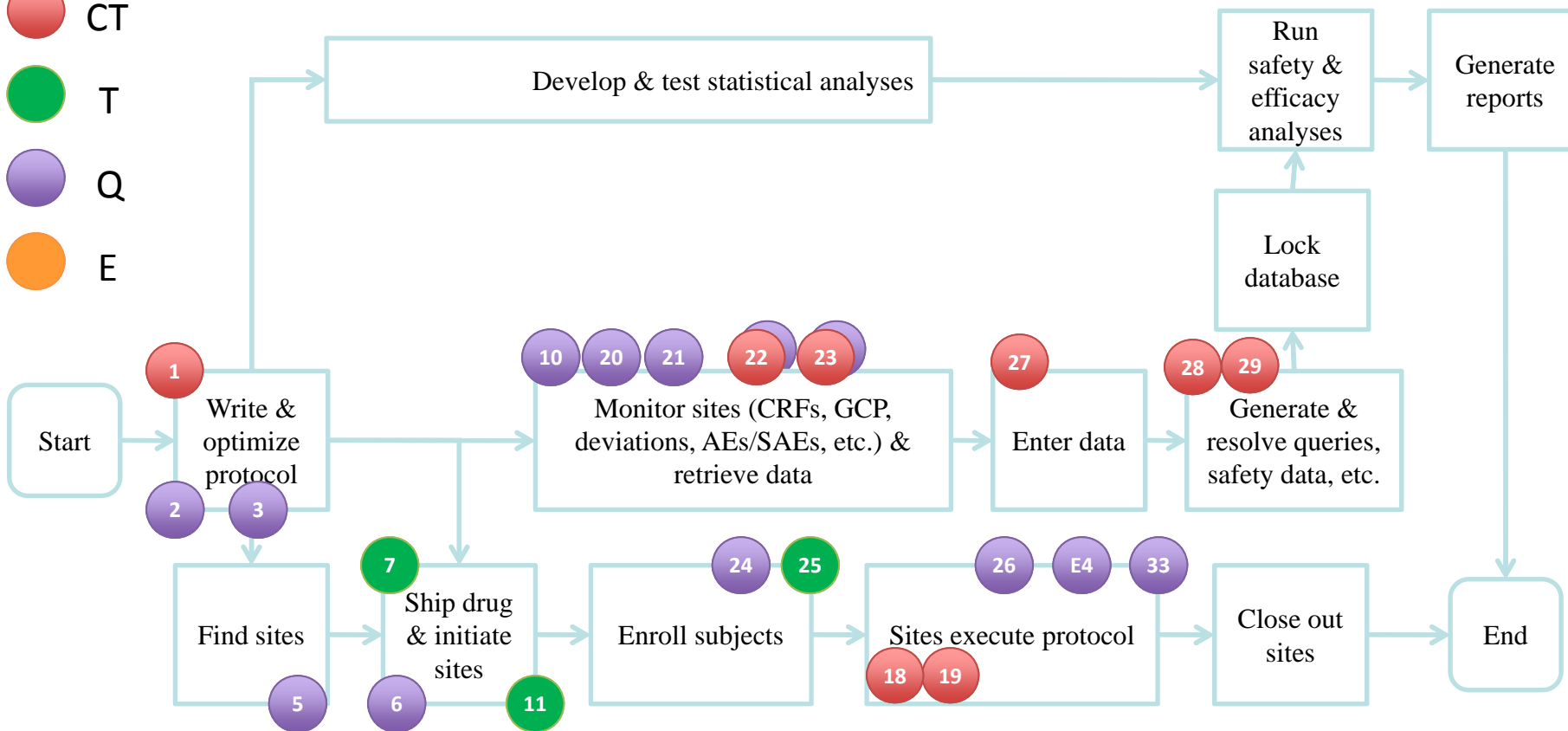


Quality Assurance: Project & site quality oversight

Program Management: Project oversight; Manage timelines, budget, staffing

30 31

- CT
- T
- Q
- E



Business Operations: Contract negotiation, management, scope control, support processes

Finance: Budget oversight

E2 E3



# MCC Clinical Trial Performance Metrics v 1.0

Metric #	Metric Type	Metric Title	Metric Indicator
1	CT	Protocol Feasibility	LEADING Indicator
2	Q	Protocol Versions	LEADING Indicator
3	Q	Protocol Quality Score	LEADING Indicator
4	CT	Contract execution timeliness for non functional outsourcing models	LAGGING Indicator
5	Q	Site Assessment	LEADING Indicator
6	Q	Regulatory Authority Package Approval Rate	LEADING Indicator
7	T	Protocol approval to first site activated	LEADING Indicator
8 - EDC	CT	Final Approved Protocol to Final Approved eCRF - EDC	LAGGING Indicator
9 - paper	CT	Final Approved Protocol to Final Approved CRF - paper	LAGGING Indicator
10	Q	Monitoring Plan Availability	LEADING Indicator
11	T	% Planned Sites Activated	LEADING Indicator
12 - EDC	CT	Final eCRF to Database "Go Live" - EDC	LAGGING Indicator

Metric #	Metric Type	Metric Title	Metric Indicator
13 - paper	CT	Final CRF to Database "Go Live" - paper	LAGGING Indicator
14	CT E	Site Activation to First Patient First Visit	LAGGING Indicator
15	CT	Timeliness of Change Order execution	LAGGING Indicator
16	T	Timeliness of Invoice payment	LAGGING Indicator
17	E	Budget and pricing accuracy	LAGGING Indicator
18 - EDC	CT	Patient Visit Complete to eCRF data entered - EDC	LEADING Indicator
19 - paper	CT	Patient Visit Complete to CRF data entered - Paper	LEADING Indicator
20	Q	Monitoring Visit Frequency	LEADING Indicator
21	Q	Monitoring Visit Report Completion	LEADING Indicator
22	CT Q	Documented Monitoring Visit Report Review	LEADING Indicator





# MCC Clinical Trial Performance Metrics v 1.0

Metric #	Metric Type	Metric Title	Metric Indicator
23	CT	Monitoring Follow-Up Letter Completion	LEADING Indicator
	Q		
24	Q	Site Productivity	LEADING Indicator
25	T	% subjects enrolled	LEADING Indicator
26	Q	Patient Retention	LEADING Indicator
27 - paper	CT	CRF Pages Received/scanned to Data Entry Complete - Paper	LEADING Indicator
28 - EDC	CT	Generation of Query to update of query response - EDC	LEADING Indicator
29 - paper	CT	Generation of Query to update of query response - paper	LEADING Indicator
30	E	Drug Supply Forecasting	LEADING Indicator
31	T	Variance of Drug Inventory & Resupply	LEADING Indicator
32	Q	Protocol Amendments	LAGGING Indicator
33	Q	Protocol Deviations	LEADING Indicator (if done Quarterly)

Metric #	Metric Type	Metric Title	Metric Indicator
34	Q	Sites Prematurely Terminated	LAGGING Indicator
35	Q	Audit Findings per Site	LAGGING Indicator
36	Q	Issue identification, management and criticality	LAGGING Indicator
37 - EDC	CT	LPLV to Database Lock - EDC	LAGGING Indicator
38 - paper	CT	LPLV to Database Lock - paper	LAGGING Indicator
39	CT	DBL (Database Lock) to final TLG/TFL (Tables, Listings and Graphs/Table Figure Listing)	LAGGING Indicator
40	CT	Final TLGs to First Draft CSR complete	LAGGING Indicator
41	CT	DBL (Data Base Lock) to Final CSR Complete	LAGGING Indicator
42 - paper	Q	Final Database Error Rate	LAGGING Indicator
43	T	Deviation of final TLGs delivered from final agreed target date.	LAGGING Indicator
	E		



## Exploratory Metrics

Metric #	Metric Type	Metric Title	Metric Indicator
E1	CT	Timeliness of Invoice generation following contractual milestones	LAGGING Indicator
E2	E	Determination of project progress versus planned (original contract value)	LEADING Indicator
E3	E	Determination of project progress versus planned (adjusted contract value)	LEADING Indicator
E4	Q	Site Quality Scores	LEADING Indicator



# MCC Members Can Access Metrics on the MCC Website

<http://www.metricschampion.org>

The screenshot shows the MCC website interface with several callouts:

- Member Tab:** Points to the 'Members' tab in the top navigation bar.
- Wiki Area:** Points to the 'MCC Clinical Trial PM Wiki' link in the left sidebar.
- Log onto MCC website:** Points to the 'Welcome MCC Administrator' dropdown menu in the top right corner.
- Metrics files:** Points to the 'CLINICAL TRIAL metrics champion Version 1.0' section, which includes a link to launch a session (spreadsheet).

The main content area features a message from the MCC Board of Directors regarding the official launch of the MCC Clinical Trial Performance Metrics version 1.0. It includes a registration link and details for a 90-minute session on Thursday, September 16, 2010, at 11:00 am Eastern Daylight Time. Below this, there are sections for 'MCC Performance Metrics' (listing Laboratory and ECG versions) and 'MCC Metrics Initiative Activities'.



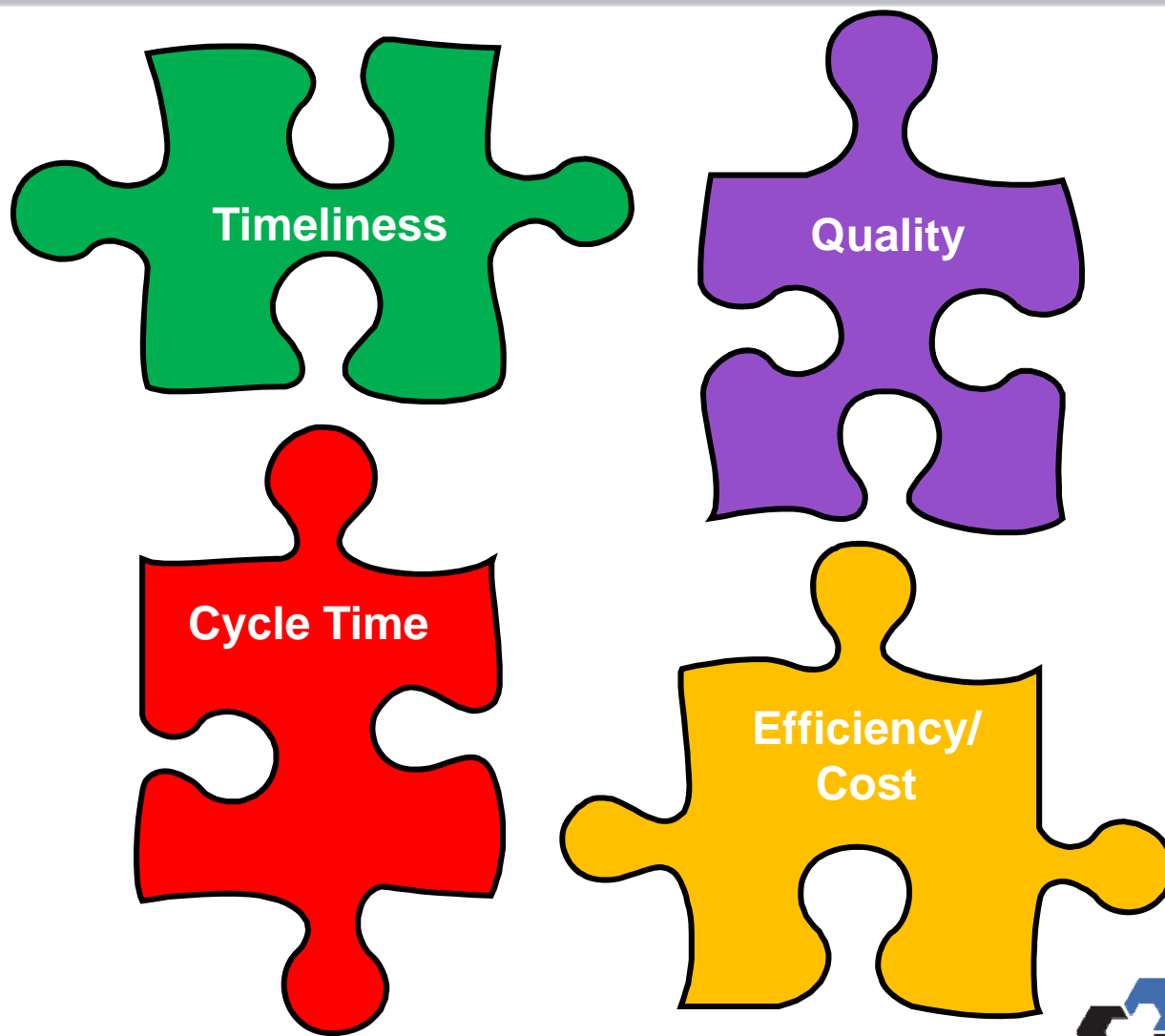


# *What are MCC Companion Metrics?*

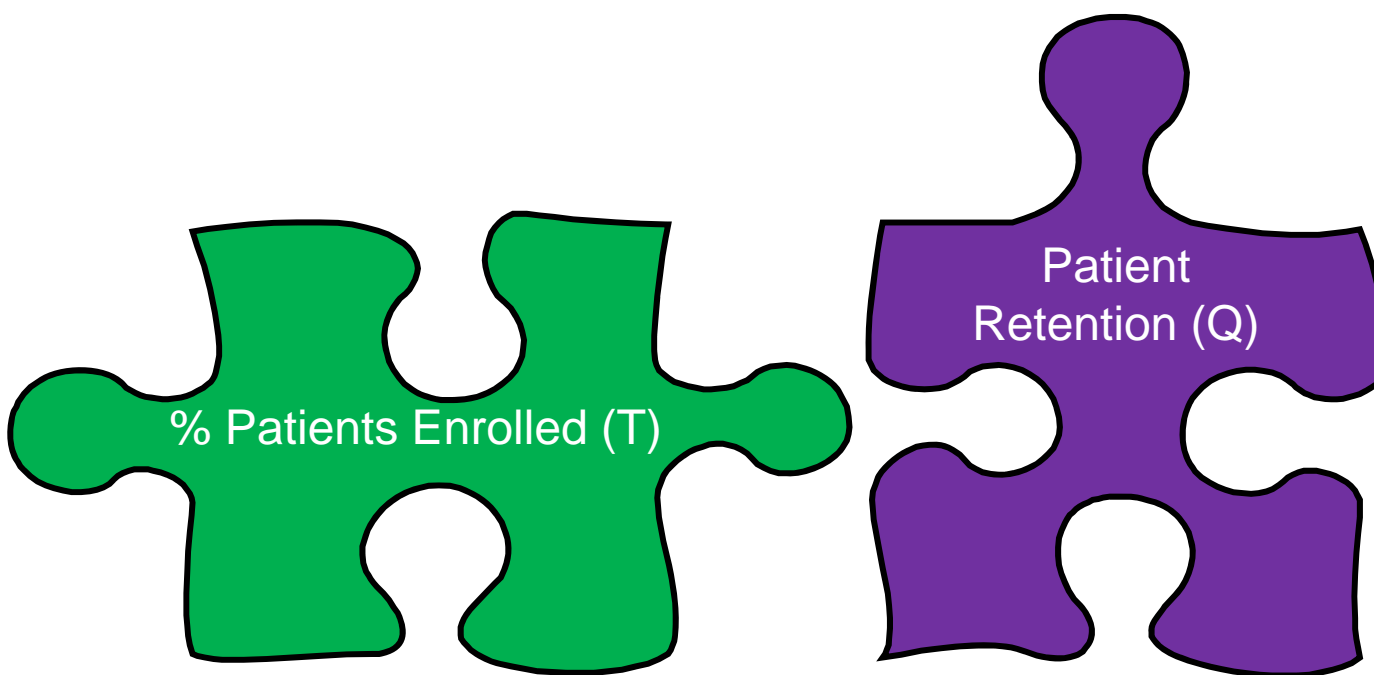


**Reducing the cycle time and cost of a task should be balanced with maintaining / improving quality**

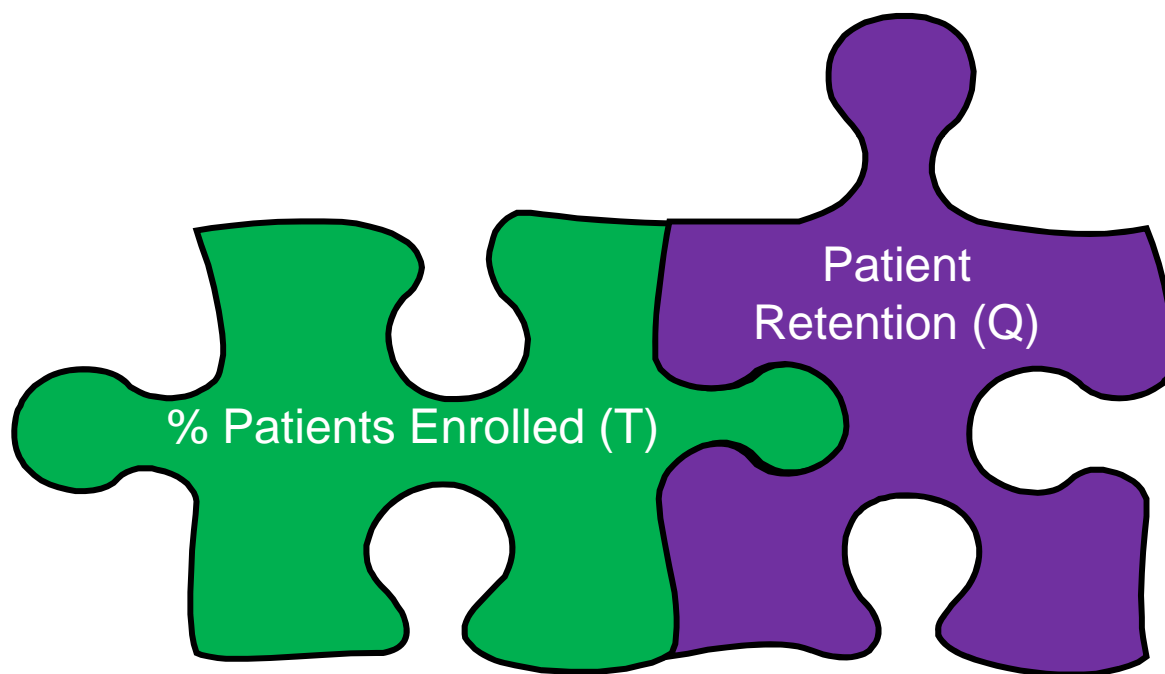




Alone each metric only tells part of the story ...



Reviewing these metrics together provides a more complete view of performance



<b>Metric #</b>	<b>Metric Title</b>	<b>Companion Metrics</b>
1	Protocol Feasibility	2, 3, 32, 33
2	Protocol Versions	1, 3
3	Protocol Quality Score	1, 2, 24, 25, 26, 32, 33



# *What are the MCC Process Improvement Quality Tools?*



## Process Improvement WG (launched Fall 2009)

Provides opportunity for MCC Members to work together to develop metrics and tools to drive process improvement

### ***Area of Concern:***

Time / Cost / Quality balance needed to avoid sub-optimization

### ***New Approach:***

- Created *How to use the metrics for process improvement* guidance paper
- Developed MCC companion metrics
- Created new quality metrics, including protocol writing, site assessment and site quality scoring tools

- 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 study start-up metrics:
  - Protocol Quality (MCC metric # 3)
  - Site Selection Quality (MCC metric # 5)
- Defined one new study conduct metric:
  - Site Quality (MCC Exploratory metric #4)

# *New MCC Quality Tools – Key Features*

- Provide Protocol Development and Site Selection teams with specialized quality scoring tools (self assessment)
  - Team completes quality survey to determine how the protocol or sites score against the appropriate quality criteria
  - If the quality score is below expectations, team should consider addressing the areas they scored poorly on in order to improve score

# New MCC Quality Tools – Key Features

- Provide Study Management teams with quality scoring tool to assess site performance across key areas:
  - Able to weight quality criteria based on study protocols
  - Use MCC performance metrics (including Lab, ECG & Imaging metrics)
  - Creates Quality score for each site (able to rollup to Country level)



- MCC member User Group forming to pilot the Quality Tools
  - Evaluate criteria included in each tool
  - Provide feedback about the prototype tools
  - Measure correlation of quality scores to related MCC companion metrics
- Interest in developing additional Quality Scoring Approach for CRFs and CSRs



# *Next Steps*



Phase 1:  
Define  
Metrics

**Phase 2: Implement Metrics**

Phase 3:  
Revise  
Metrics

## Within MCC Organizations

Now

- Select metrics for portfolio / study (Sponsor/CRO)
- Track metrics (Sponsors & CROs)
- Review metrics on a regular basis (Sponsor/CRO)
- Take remedial action where needed as identified thru metrics and discussions (Sponsor/CRO)

Now

Later

## MCC Activities:

- MCC Implementation WG monthly meetings (Sponsors & CROs)
  - ❖ Share case studies
  - ❖ Develop additional implementation support tools
  - ❖ Provide feedback on metrics and need for revisions (surveys)
- Process Improvement WG and Quality Tool User Groups (Sponsors & CROs)
- MCC Member Metrics Database WGs
- Submit data to MCC member metrics *blinded* database



# MCC Clinical Trial Performance Metrics Initiative Timetable

Phase 1:  
Define  
Metrics

Phase 2:  
Implement  
Metrics

## Phase 3: Revise Metrics

- MCC CTPM SC oversees revision process based on member feedback
- Exploratory metrics will be reviewed and added when member feedback is available
- New metrics may be added before Metric version 2.0 discussions
- Conduct review / update to version 2.0 after 2+years



## MCC Lab Metrics

- Release Version 2.0
- Input to Quality Tools

## MCC ECG Metrics

- Release Version 2.0
- Input to Quality Tools

## MCC Imaging Metrics

- Support Version 1.0 Implementation
- Input to Quality Tools

## MCC Clinical Trial Metrics

- Support Version 1.0 Implementation
- Pilot Quality Tools
- Continue Process Improvement WG

## MCC Member Blinded Database Project

- Develop database structure
- Pilot database

- MCC metrics support joint collaborative process improvement
- Common metrics language and definitions enable collaboration
- Metrics should drive desired behavior and minimize undesired short-sighted behavior
- Embed quality tools in the process to support first pass quality performance instead of only measuring it after the fact
- ***The most expensive study is the one you do twice***