



An Industry-wide Effort to Develop and Implement Standardized Clinical Trial Performance Metrics to Drive Process Improvement & Enhance Partnership Performance

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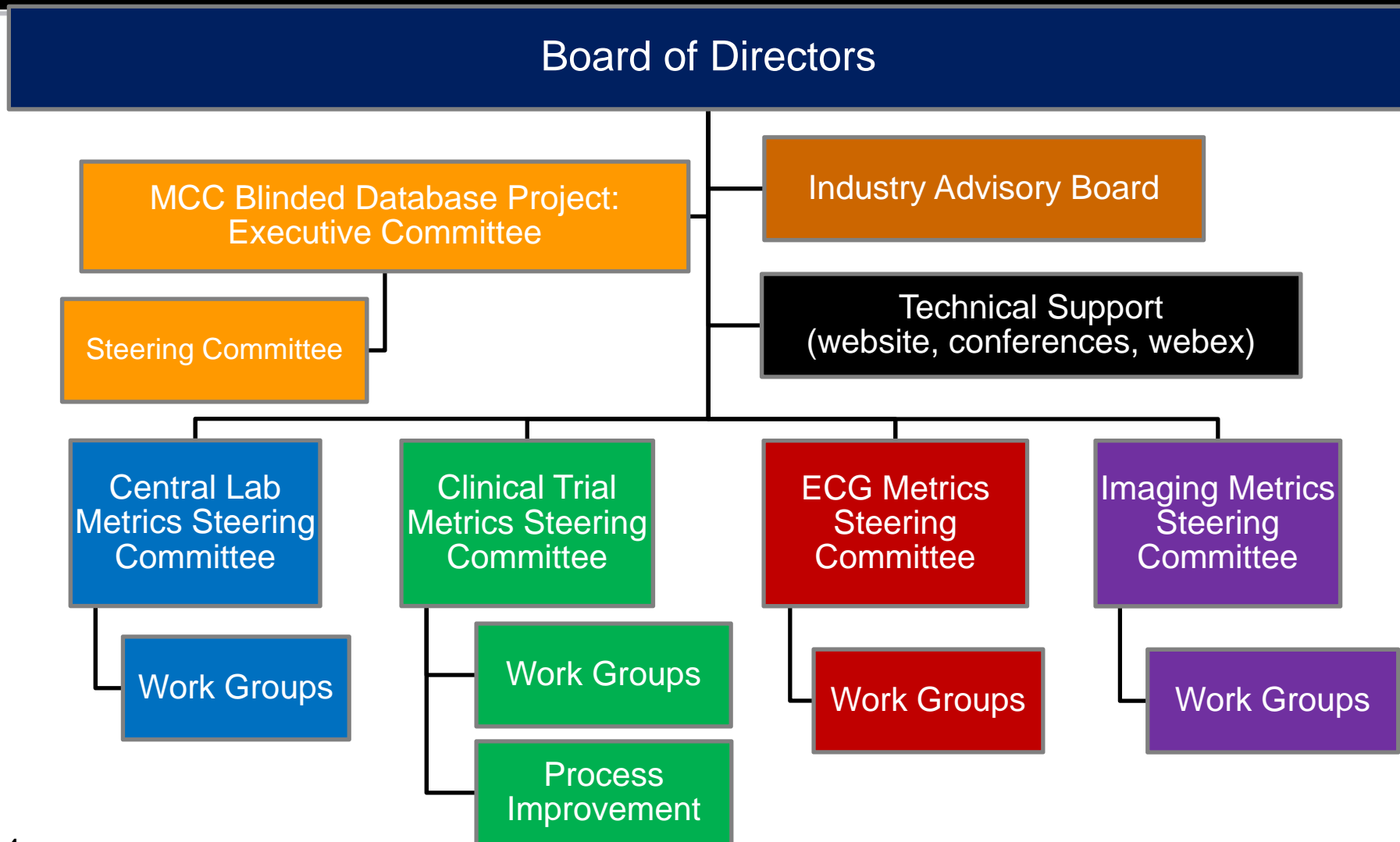
9th Annual Partnerships in Clinical Trials – Vienna, Austria

18 November 2010



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.

- 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





MCC Member Organizations

Abbott Laboratories

Acorda Therapeutics

Actelion Pharmaceuticals

AG Mednet

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

ERT

Esoterix Clinical Trial Services

Eurofins Medinet

ExecuPharm

Genentech

Genzyme

i3

iCardiac Technologies

ICON

Imaging Endpoints

INC Research

Incyte

Intrinsic Imaging

Ixico

Lilly

M2S

MacroGenics

Medidata Solutions

Medtronic

Merck

New England Research Institute

Novartis

Paragon Biomedical

Parexel / Perceptive Informatics

Pfizer

PharmaNet

PPD

PRA International

QD-Quality and Training Solutions

Quest Diagnostics

Quintiles

RadMD

Regeneron

Research Point

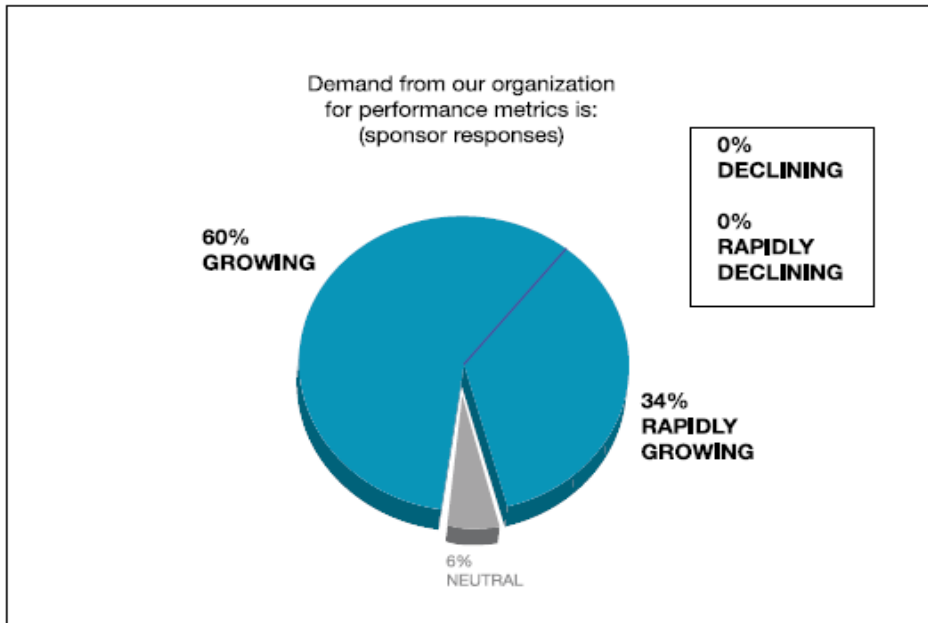
Roche

Synarc

Virtual Scopics

WorldCare Clinical

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



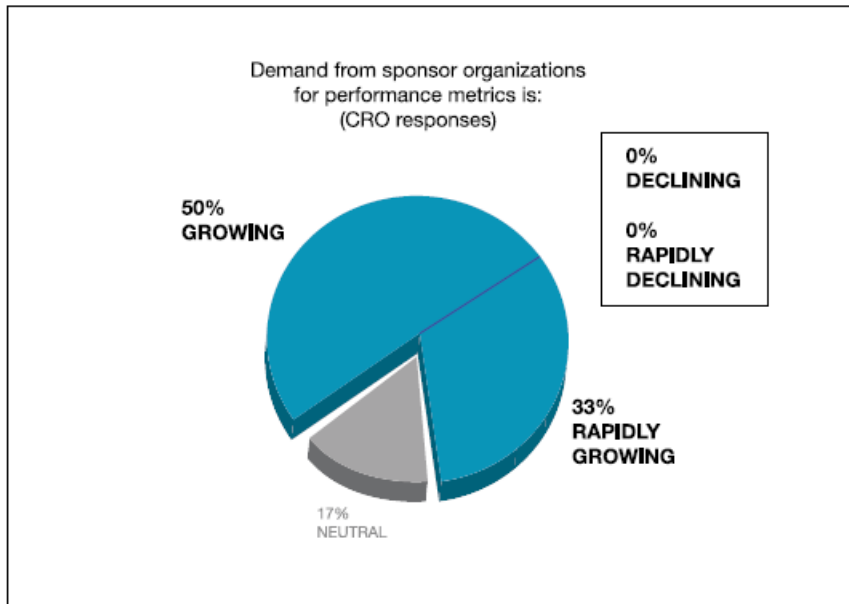
9% reported having well-defined/clearly understood metrics in place

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

Source: MCC Survey 2007

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

Source: MCC Survey 2007

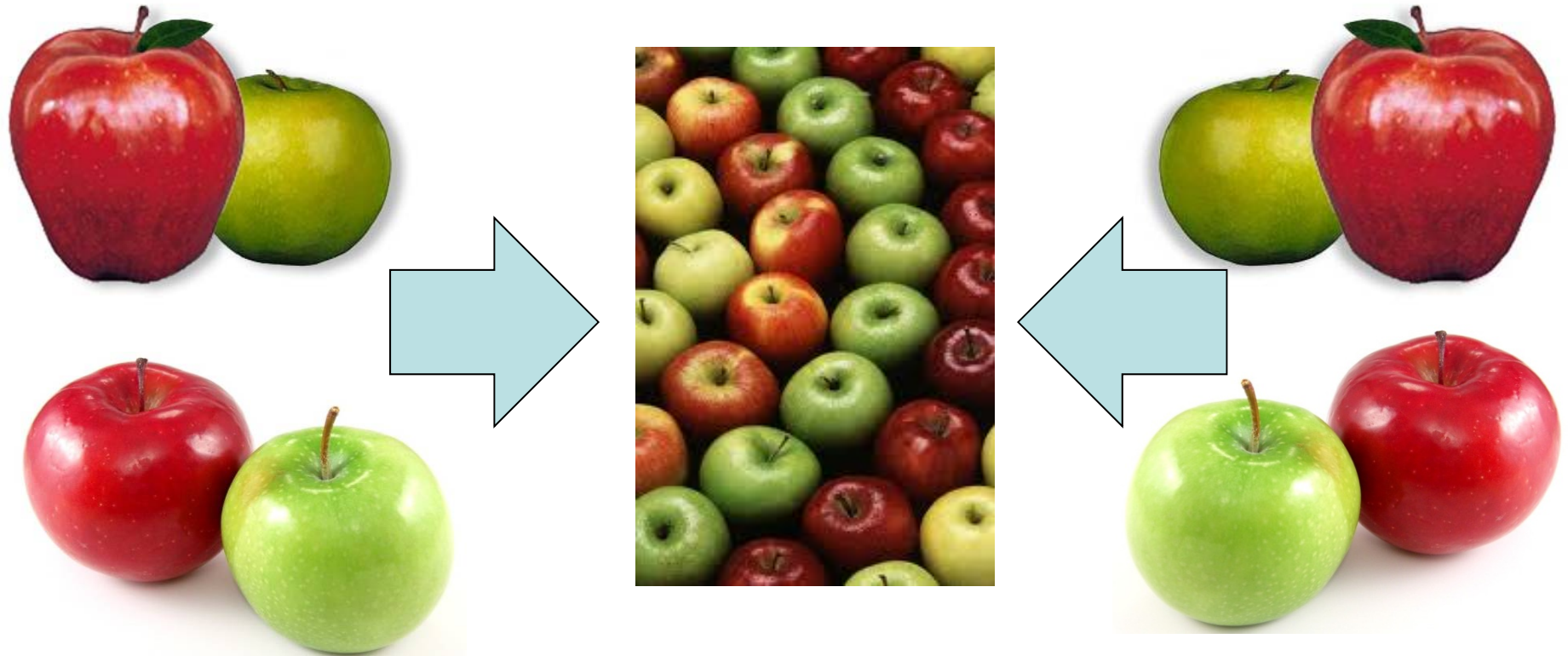


- Sponsors use different service providers
 - Managing metrics across portfolios across service providers is a challenge

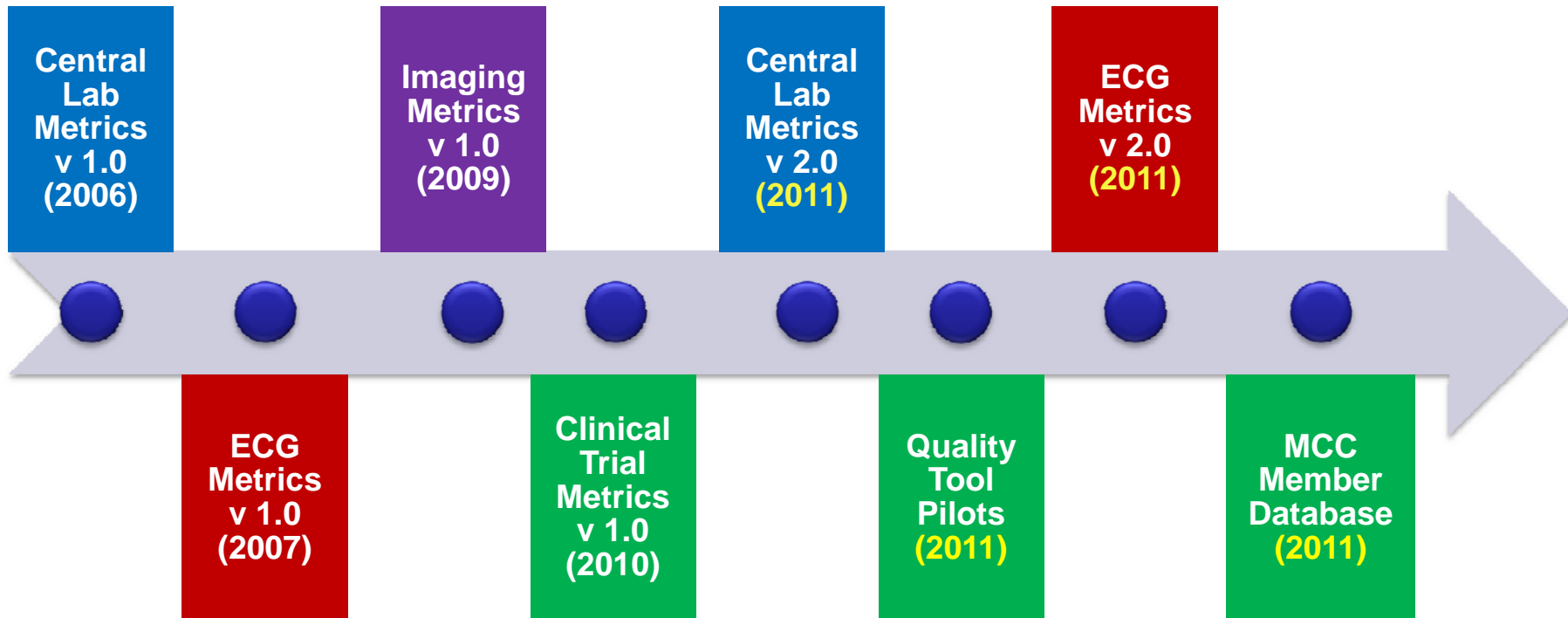
- Service providers are faced with managing varying performance based metrics from Sponsors



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



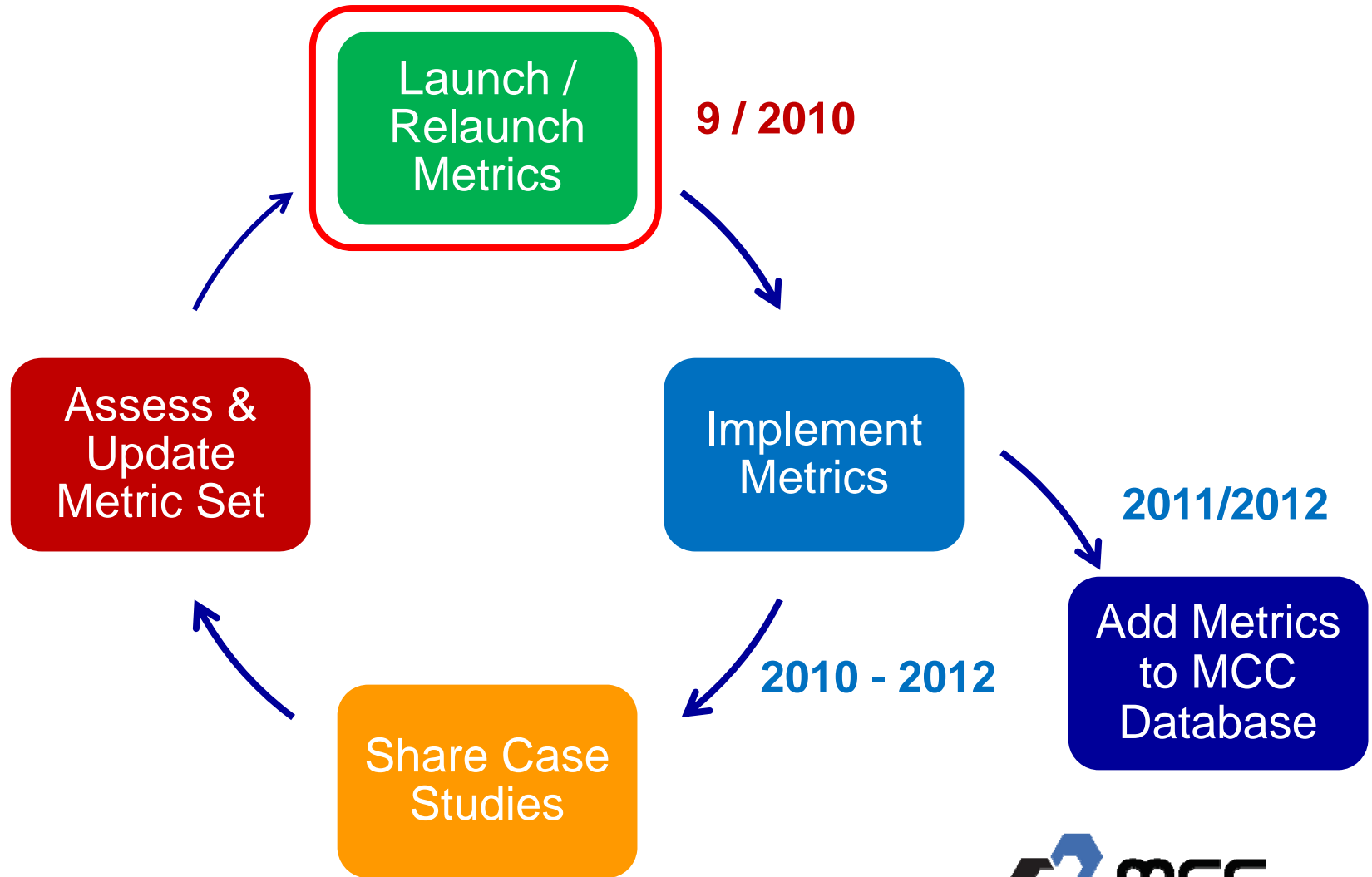
Metrics Development Timeline

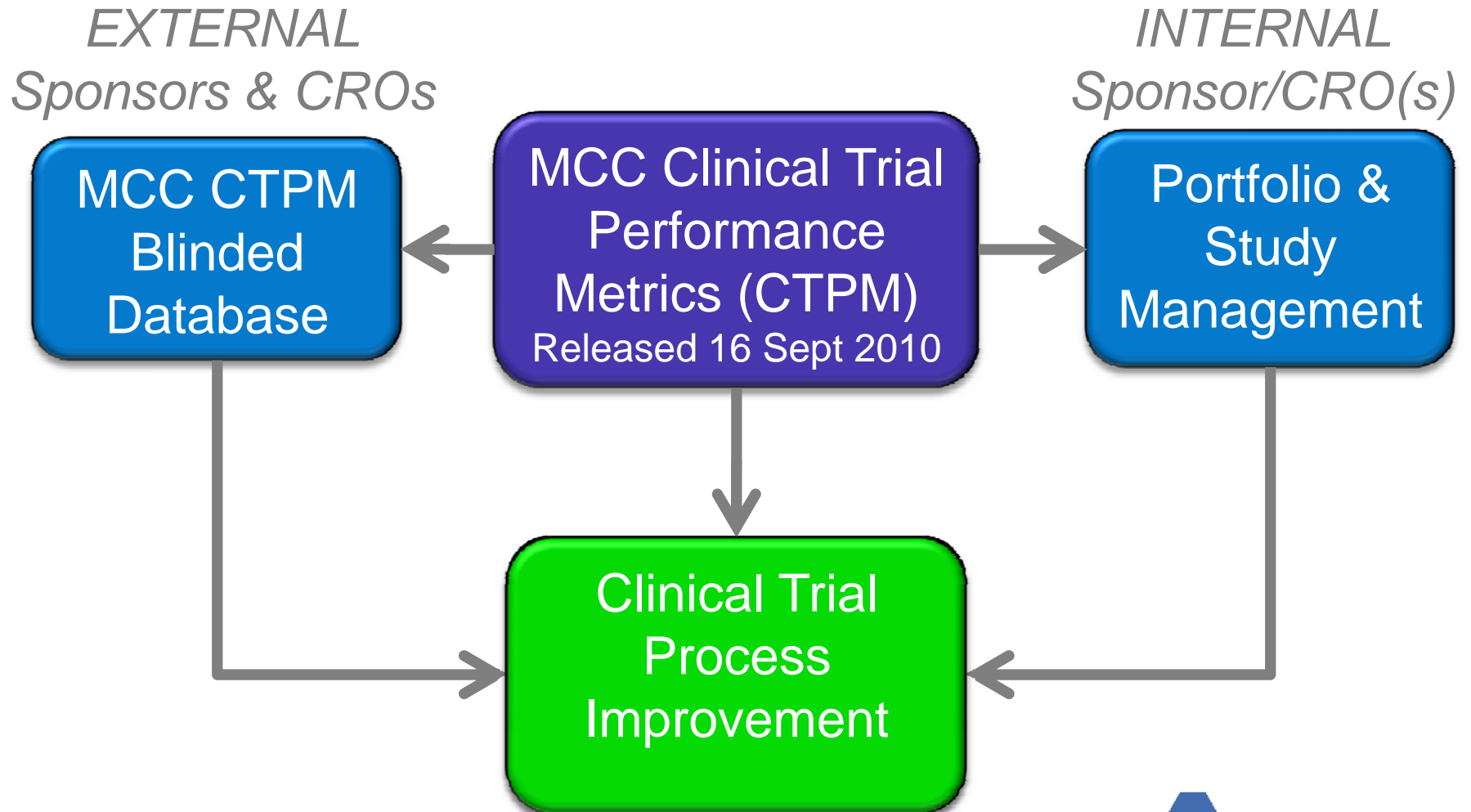




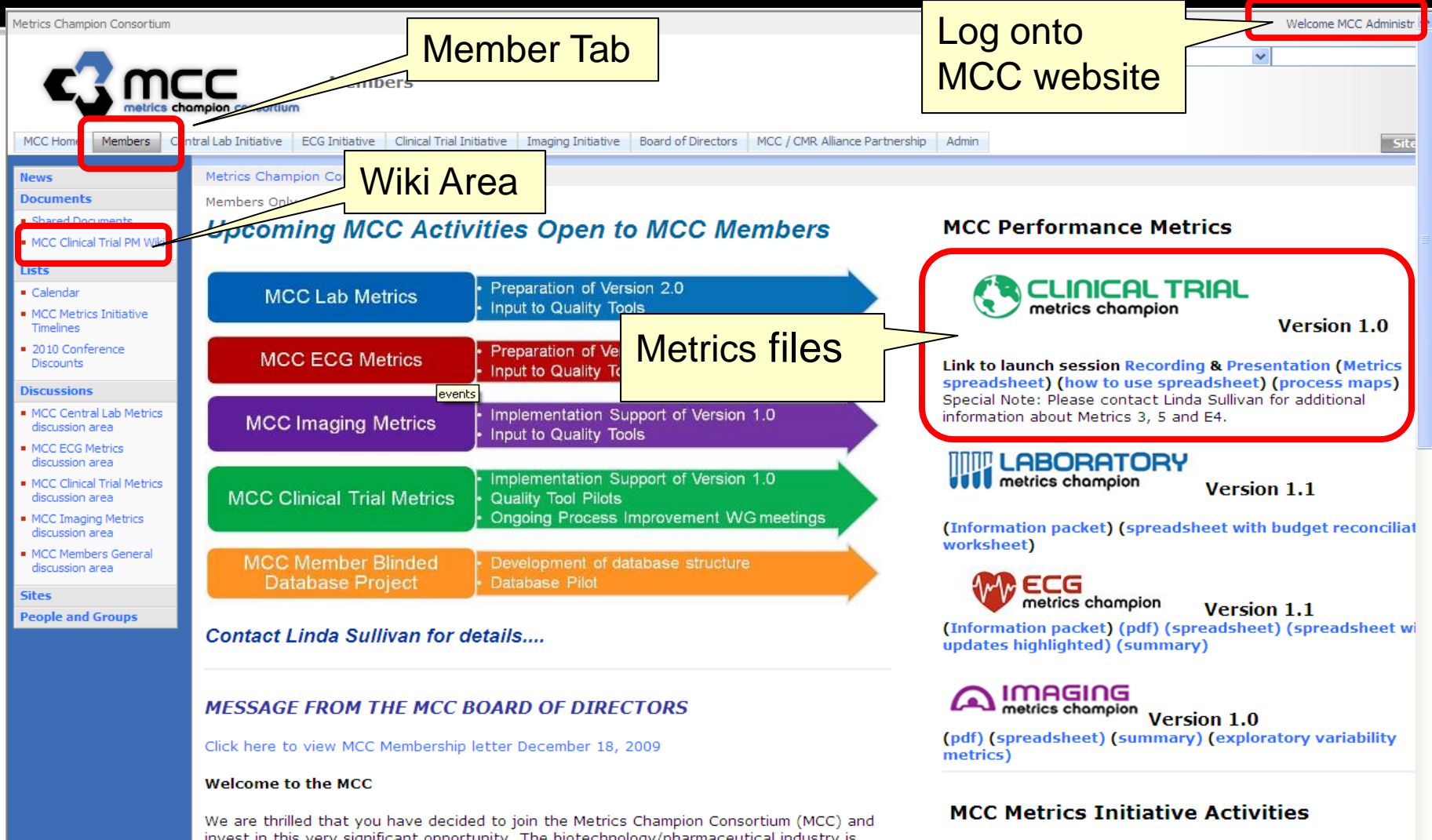
CLINICAL TRIAL
metrics champion

Clinical Trial Performance Metrics Initiative





MCC Members Can Access Metrics on the MCC Website



Member Tab (points to the 'Members' tab in the navigation bar)

Log onto MCC website (points to the 'Welcome MCC Administrator' dropdown menu)

Wiki Area (points to the 'MCC Clinical Trial PM Wiki' link in the left sidebar)

Metrics files (points to the 'MCC Lab Metrics', 'MCC ECG Metrics', and 'MCC Imaging Metrics' sections)

MCC Performance Metrics (points to the 'CLINICAL TRIAL metrics champion Version 1.0' section)

Upcoming MCC Activities Open to MCC Members

MCC Lab Metrics	Preparation of Version 2.0 Input to Quality Tools
MCC ECG Metrics	Preparation of Version 2.0 Input to Quality Tools
MCC Imaging Metrics	Implementation Support of Version 1.0 Input to Quality Tools
MCC Clinical Trial Metrics	Implementation Support of Version 1.0 Quality Tool Pilots Ongoing Process Improvement WG meetings
MCC Member Blinded Database Project	Development of database structure Database Pilot


MCC Performance Metrics


- CLINICAL TRIAL metrics champion Version 1.0**
Link to launch session Recording & Presentation (Metrics spreadsheet) (how to use spreadsheet) (process maps)
Special Note: Please contact Linda Sullivan for additional information about Metrics 3, 5 and E4.
- LABORATORY metrics champion Version 1.1**
(Information packet) (spreadsheet with budget reconciliation worksheet)
- ECG metrics champion Version 1.1**
(Information packet) (pdf) (spreadsheet) (spreadsheet with updates highlighted) (summary)
- IMAGING metrics champion Version 1.0**
(pdf) (spreadsheet) (summary) (exploratory variability metrics)



MCC Metrics Initiative Activities

<http://www.metricschampion.org>





Metrics Champion Consortium Welcome MCC Administrator | 



This List: MCC Clinical Trial PM  

Members

MCC Home
Members
Central Lab Initiative
ECG Initiative
Clinical Trial Initiative
Imaging Initiative
Board of Directors
MCC / CMR Alliance Partnership
Admin
Site Actions 

 **MCC Clinical Trial PM Wiki**

News

Documents

- Shared Documents
- MCC Clinical Trial PM Wiki

Lists

- Calendar
- MCC Metrics Initiative Timelines
- 2010 Conference Discounts





Discussions





















- MCC Central Lab Metrics discussion area
- MCC ECG Metrics discussion area
- MCC Clinical Trial Metrics discussion area
- MCC Imaging Metrics discussion area
- MCC Members General discussion area

Sites

People and Groups

MCC Clinical Trial PM Wiki

New 
Actions 
Settings 
View: **All Pages** 

Type	Name	Modified By	Modified	Created By	Created
	Baseline Contract Value	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	Benchmarking	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	Change Order (CO)	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	Change Order Threshold	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	Country Regulatory Package	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	CRA	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	CRF (Case Report Form)	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	Critical Audit Findings	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	CSR (Clinical Study Report)	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	Cycle Time (CT) Metric	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	Dashboard	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	DBL (Database Lock)	MCC Administrator	10/6/2010 9:38 AM	MCC Administrator	9/13/2010 4:02 PM
	Draft CSR (Clinical Study Report)	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	EDC	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	Enrollment	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	Final Approved Protocol	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	For Cause Analysis	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	FPFV (First Patient First Visit)	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	How To Use This Wiki Library	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM
	IP (Investigational Product)	MCC Administrator	9/13/2010 4:02 PM	MCC Administrator	9/13/2010 4:02 PM

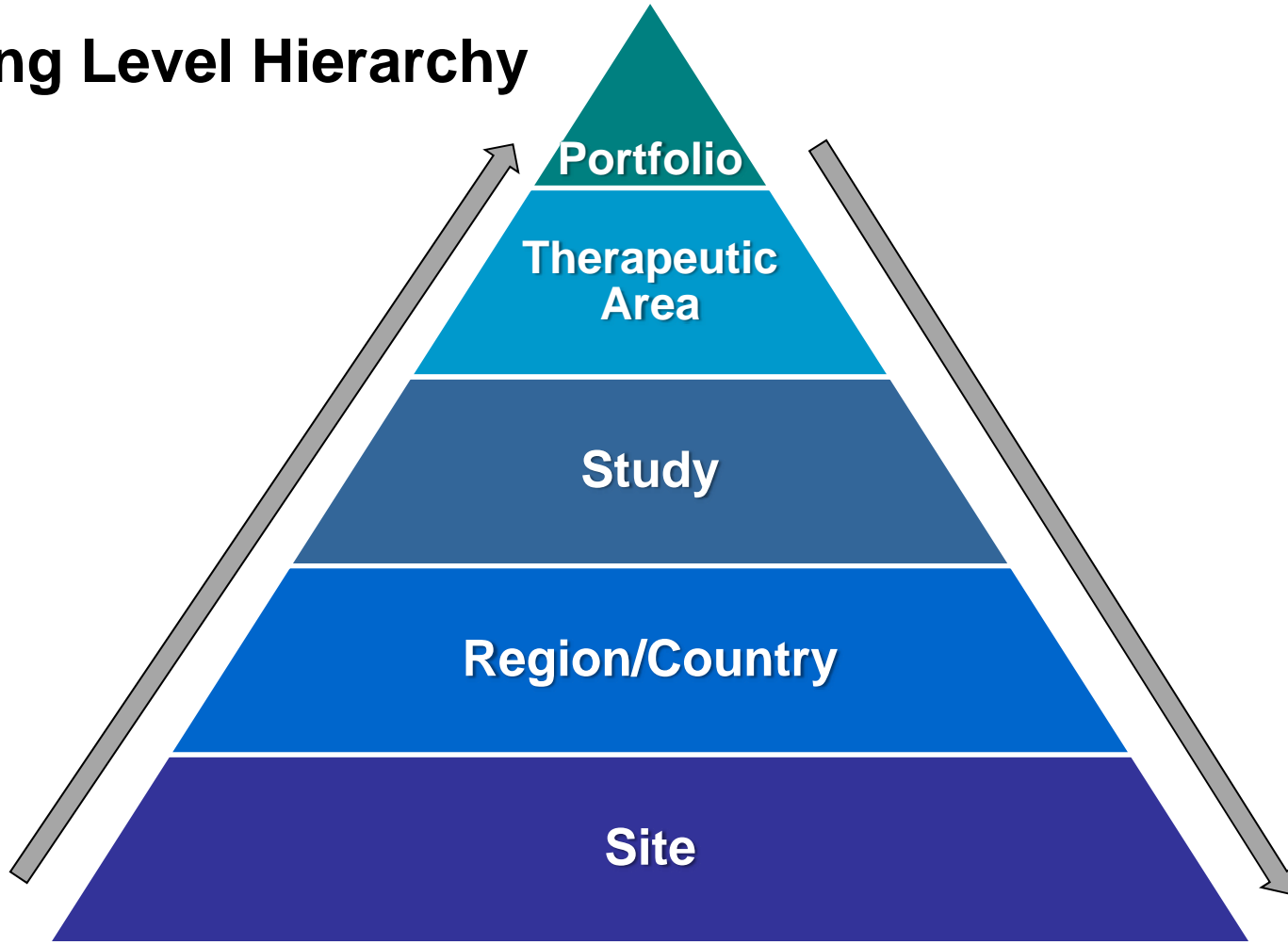
Metric #	Metric Type	Metric Title	Category	Metric Indicator	Part of Study
8	CT	Final Approved Protocol to Final Approved eCRF - EDC	CRF Design	LAGGING Indicator	Study Startup
		Definition (see Wiki for detailed definitions)	Formula / Example	Reporting Detail	
		Number of calendar days from <i>final approved protocol</i> to final approved eCRF. See MCC Wiki for definitions	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	New feature
				Calendar days	
		Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Threshold 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			

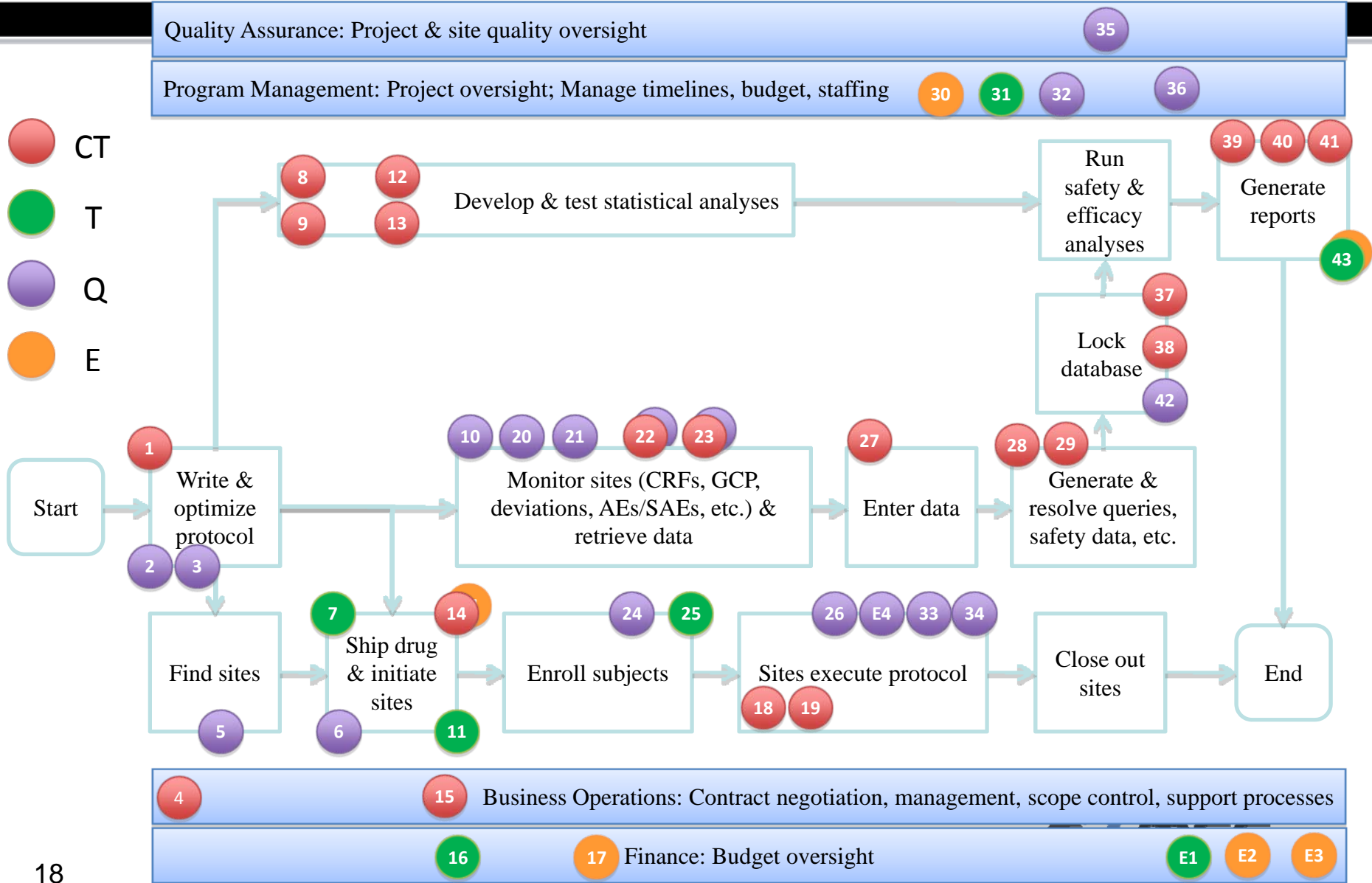
New feature

New feature

New feature

Reporting Level Hierarchy

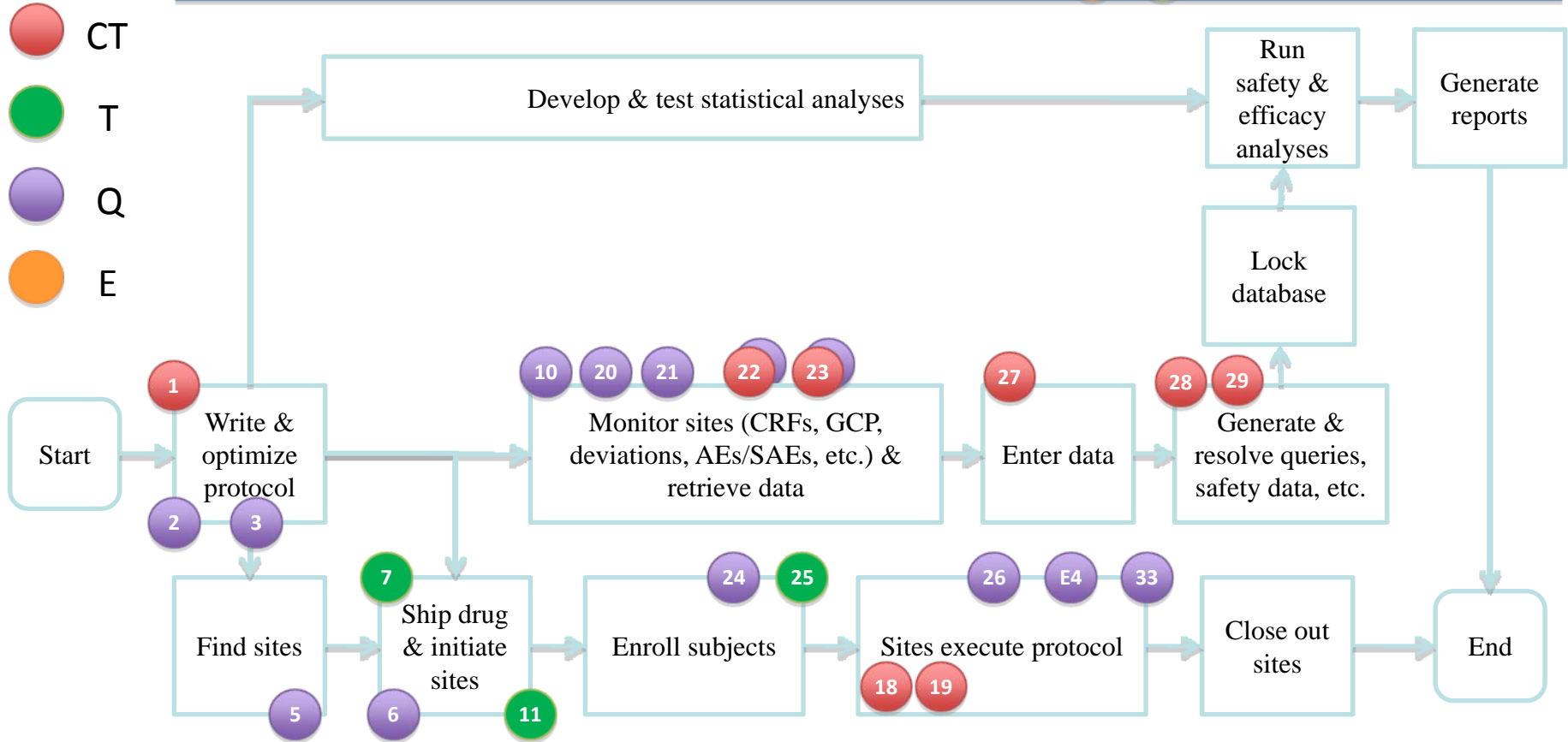




Quality Assurance: Project & site quality oversight

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

30 31



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

Finance: Budget oversight

E2 E3

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	Site Activation to First Patient First Visit	LAGGING Indicator
	E		
15	CT	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	Documented Monitoring Visit Report Review	LEADING Indicator
	Q		

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 Process Improvement Work Group – Quality Focus

Process Improvement WG (launched Fall 2009)

Provides opportunity for MCC Members (sponsors & CROs) to work together to develop metrics and tools to drive process improvement

Area of Concern:

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

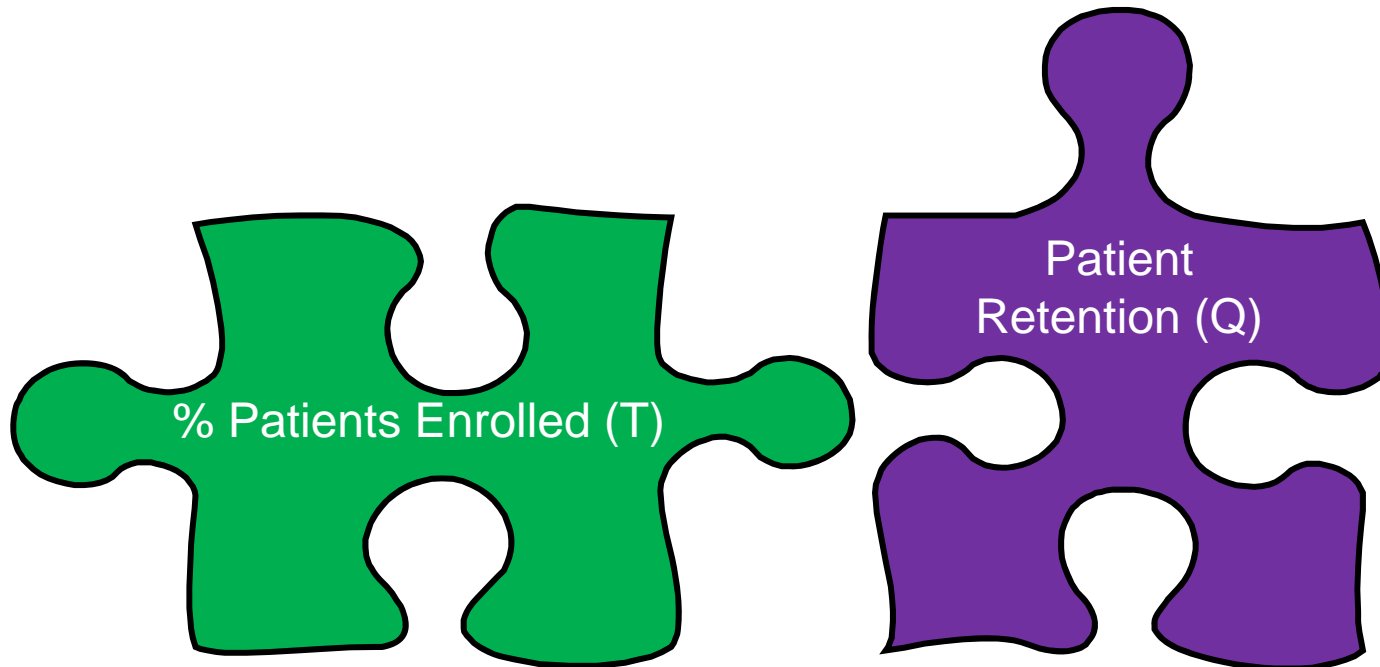
New Approach:

- 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

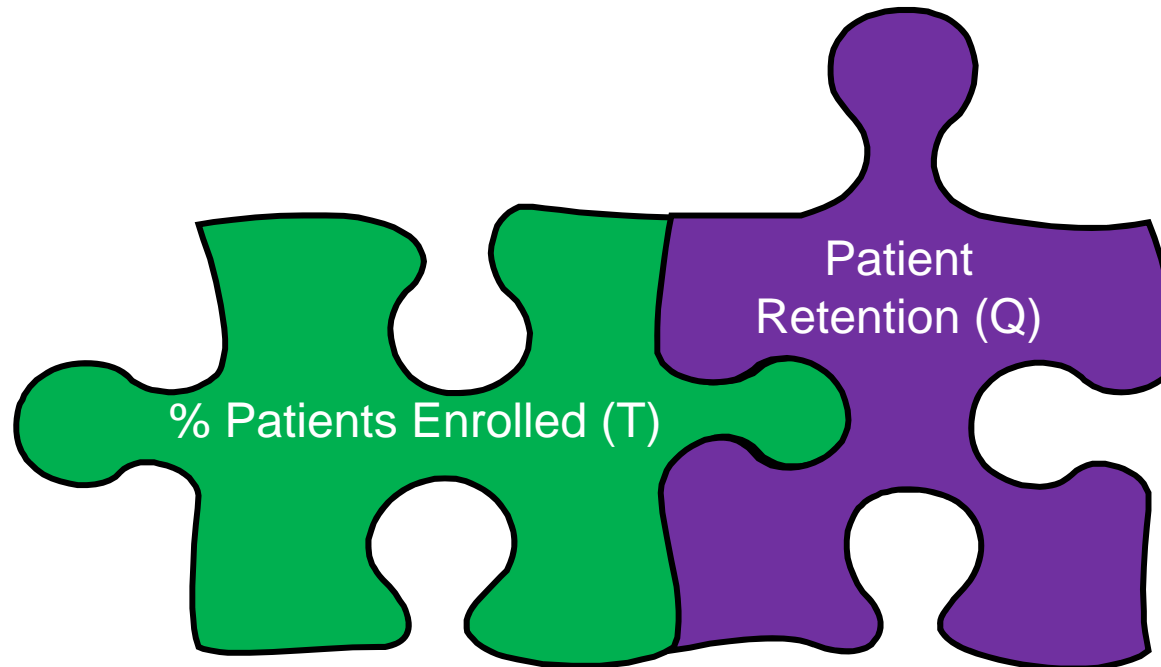
Reducing the cycle time and cost of a task should be balanced with maintaining / improving quality



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



Reviewing these metrics together provides a more complete view of performance



- Study start up process important to trial success

**High Quality
Protocol**

+

**Good Site
Selection**

=

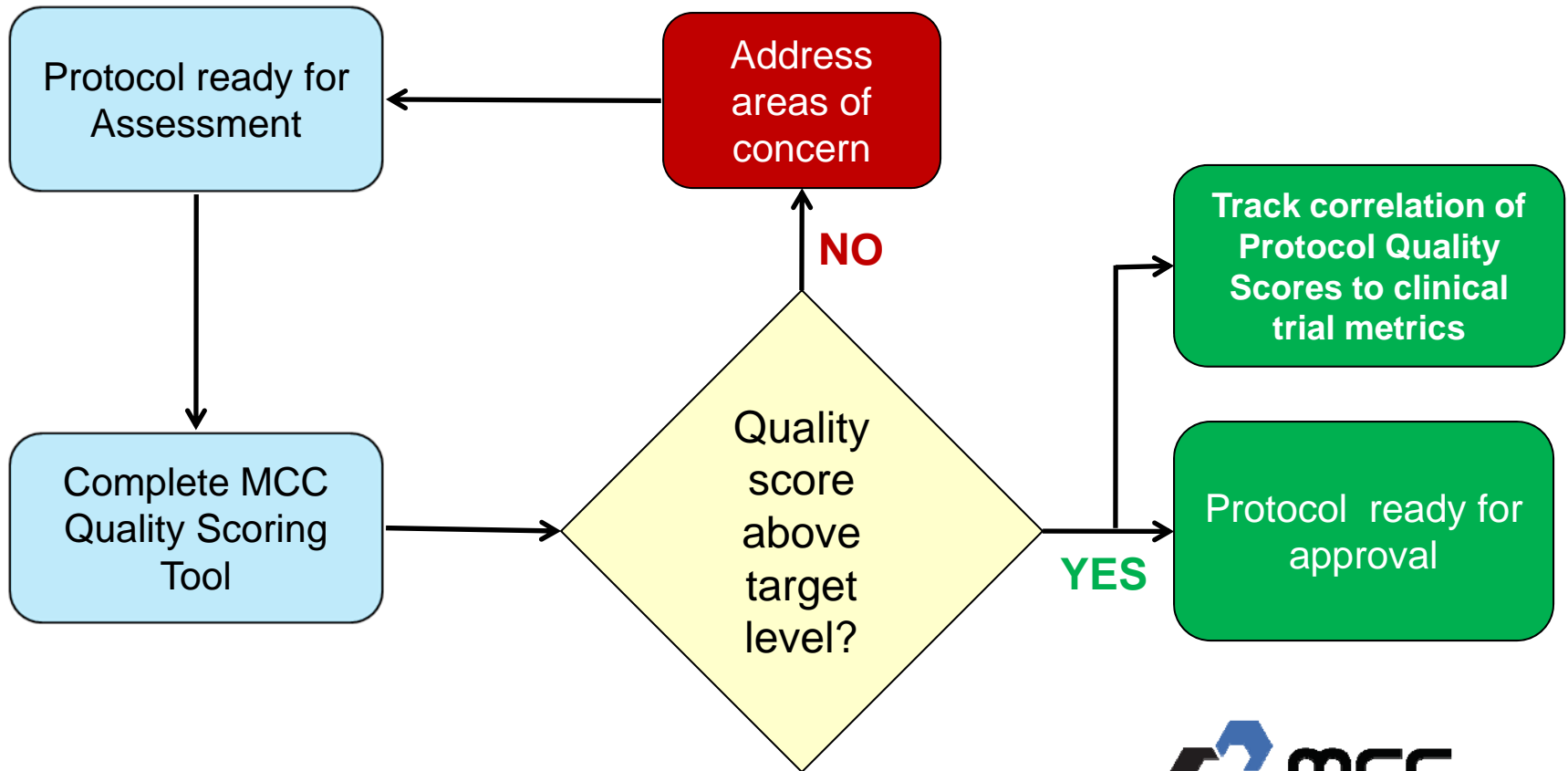
**High Chance of
Successful Trial**



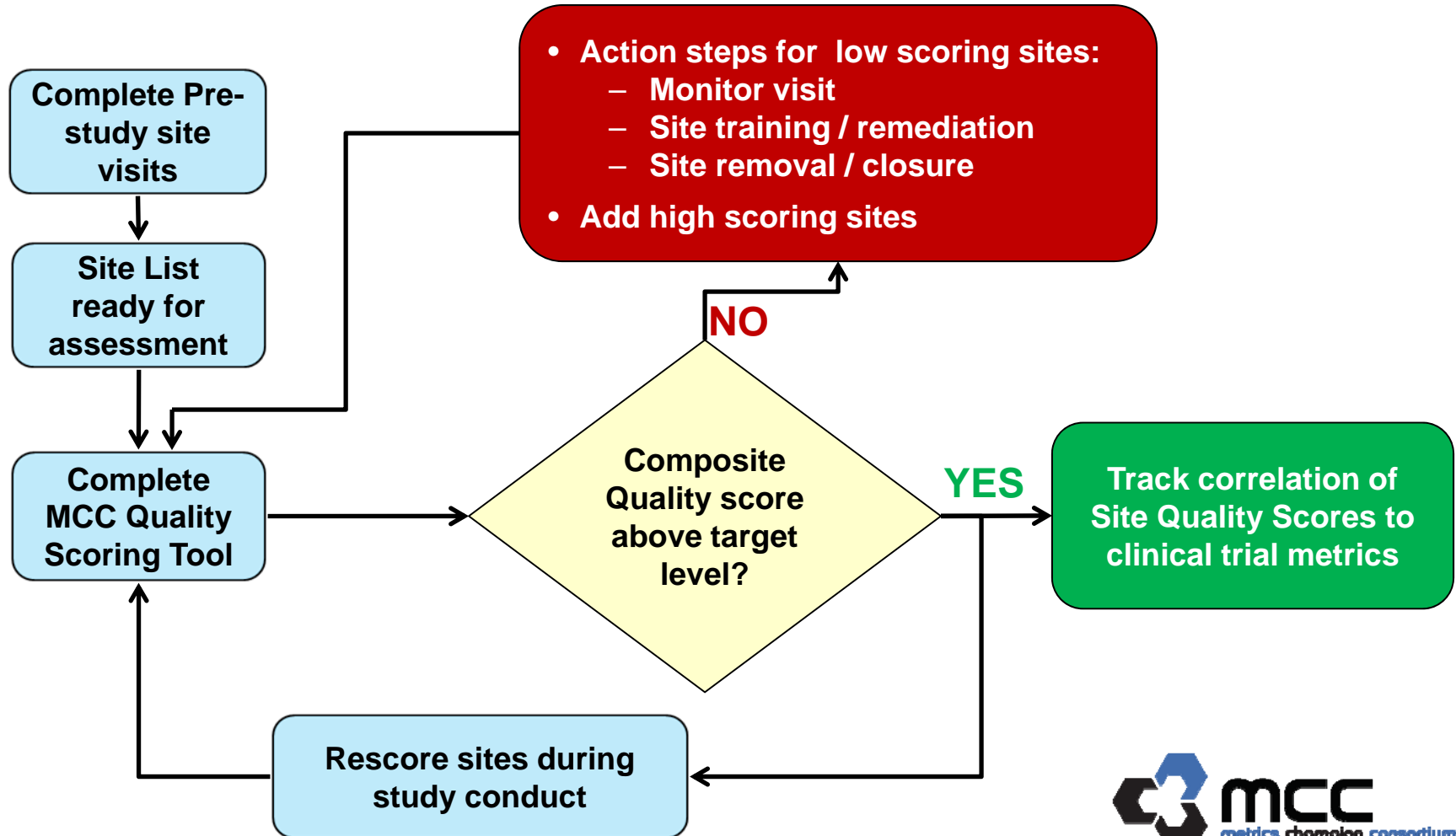
- Defined two new study start-up metrics:
 - Protocol Quality (MCC metric # 3)
 - Site Selection Quality (MCC metric # 5)
- Defined one new study conduct metric:
 - Site Quality (MCC Exploratory metric #4)

- 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

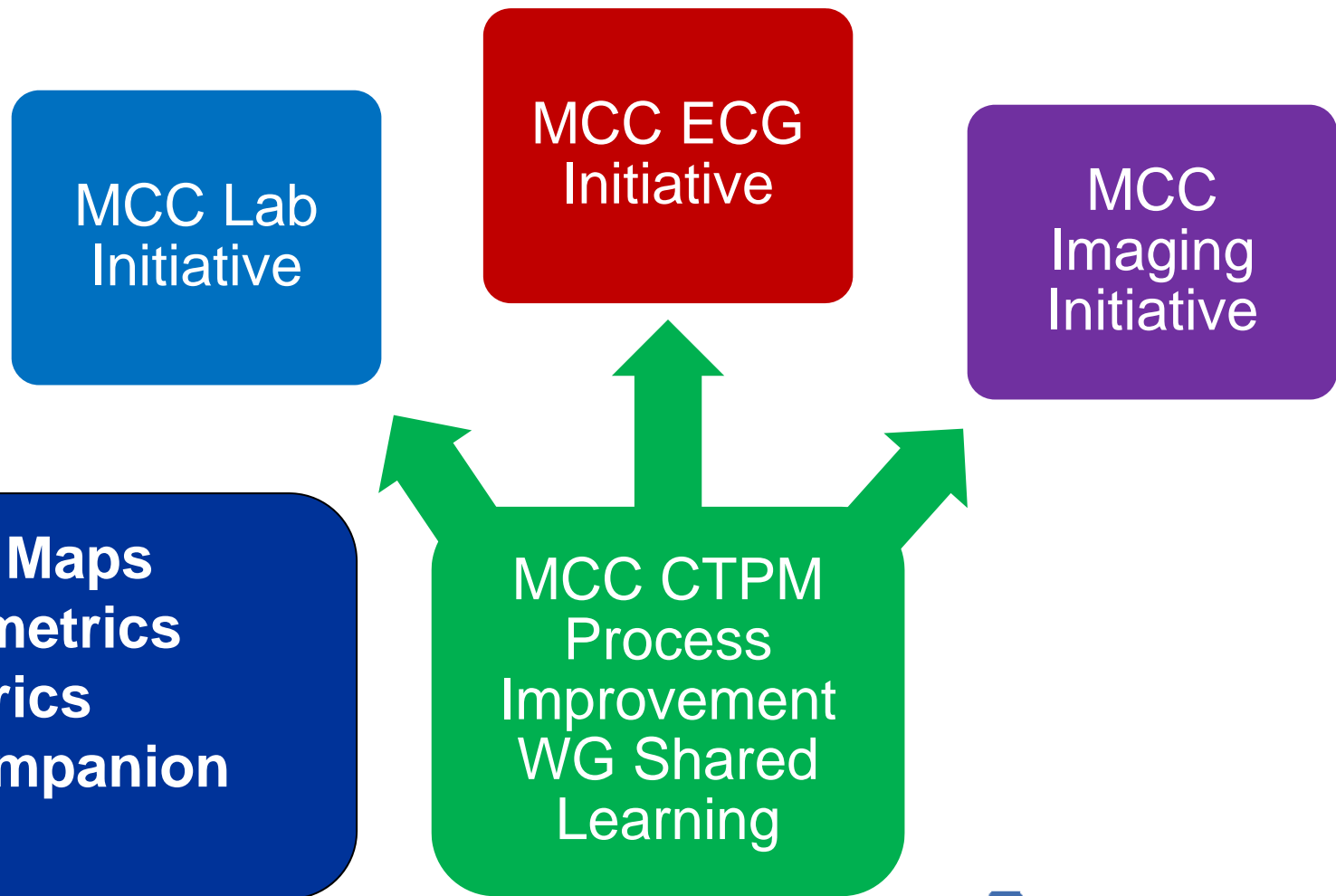
Protocol Development (self assessment)



Site Assessment/Site Quality Scoring Tool



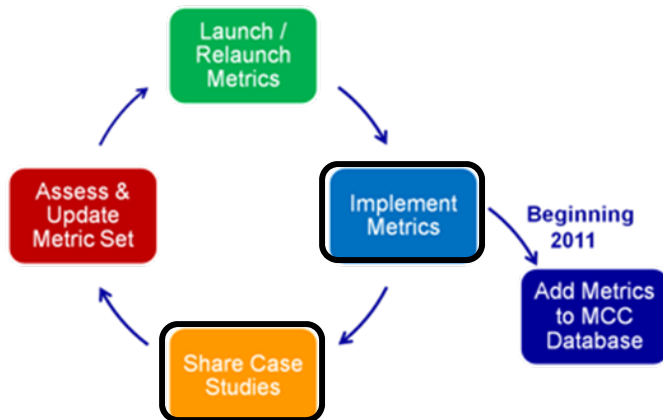
- Recruiting MCC members to pilot the Quality Tools
 - Evaluate criteria included in each prototype tool
 - Provide feedback about the prototype tools (excel)
 - Measure correlation of quality scores to related MCC companion metrics
- Interest in developing additional Quality Scoring Approach for Case Report Forms (CRFs) and Clinical Study Reports (CSRs)



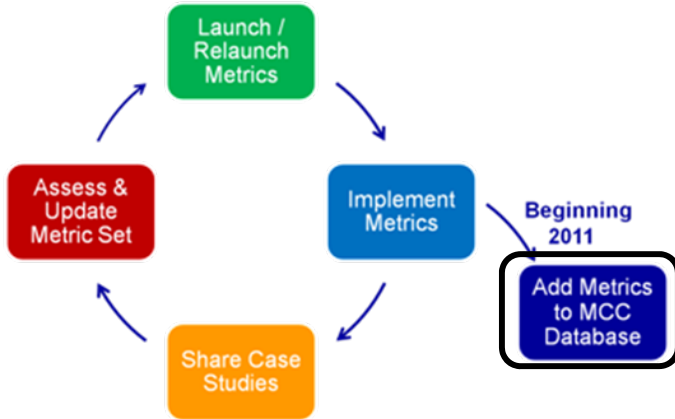
- **Process Maps**
- **Quality metrics**
- **Site metrics**
- **MCC Companion metrics**



Next Steps

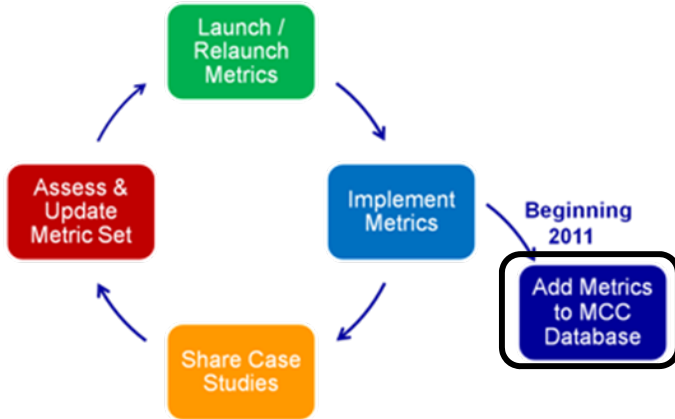


- Implementation WG (monthly) - support implementation and foster shared learning
- Process Improvement WG (1-2 meetings/month)
 - Lead quality scoring tool user group
 - Develop additional scoring tools
 - Guidance paper, articles, case studies
- Quality Scoring Tool User Group (TBD)
 - Online Surveys
 - Discussion groups
 - Correlation with MCC companion metrics



- MCC Executive and Steering Committees responsible for project oversight and ensuring project deliverables within the parameters of the strategic plan.

- Database Project Key Features:
 - compare company results to other members (blinded manner)
 - online metric analytic reporting tool
 - ability to “drill down & roll up” to different reporting levels



Database program requirements:

- MCC member organizations will have the option to participate in the database
- Must be MCC member to participate in database program
- Database will not available to non-MCC member organizations

Summary of MCC Activities

MCC Lab Metrics

- Preparation of Version 2.0
- Input to Quality Tools

MCC ECG Metrics

- Preparation of Version 2.0
- Input to Quality Tools

MCC Imaging Metrics

- Implementation Support of Version 1.0
- Input to Quality Tools

MCC Clinical Trial Metrics

- Implementation Support of Version 1.0
- Quality Tool Pilots
- Ongoing Process Improvement WG meetings

MCC Member Blinded Database Project

- Development of database structure
- Database Pilot



How can my company get involved?

For additional information about joining the MCC, visit

<http://www.metricschampion.org> or

contact Linda Sullivan (lsullivan@metricschampion.org)