



Utilizing metrics to drive quality management in clinical trials

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Metrics Champion Consortium Board of Directors



- MCC Mission, Goals & Organization
- MCC Clinical Trial Performance Metrics
- Interactive Session – What is Quality?
- MCC Quality Scoring Tools
- Conclusion

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

The mission of MCC is to develop, through a collaborative process, Performance Metrics within the Biotechnology and Pharmaceutical industry with the intent to **jointly** encourage performance improvement, effectiveness, efficiency, and appropriate levels of controls for both Sponsors and Service Providers in support of the clinical trial process

- 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) – *coming soon!*
- Provide opportunities for MCC members to share best practices through the MCC collaborative learning approach of regular online meetings, face-to-face workshops and web-based collaborative workspace areas.



MCC Member Organizations

Abbott Laboratories
Actelion Pharma
Acorda Therapeutics
AG Mednet
AstraZeneca*
BARC Global Central Lab
BioClinica
Biogen Idec
Biomedical Systems
CardiaBase
Cardio Analytics
Cardiocre
Cerexa
CHDI
Clinical Reference Laboratory
Clinsys Clinical Research
Cognizant
CoreLab Partners
Covance
Covidian
Customized Improvement Strategies

DecisionView
Duke Clinical Research Institute
ERT*
Esoterix Clinical Trial Services
Eurofins Medinet
ExecuPharm
GE Healthcare
Genentech
Genzyme
i3
iCardiac Technologies
ICON
Imaging Endpoints
INC Research
Incyte
Intrinsic Imaging
Ixico
Lilly*
M2S
Medidata GmbH
Medidata Solutions

Medtronic
Merck
New England Research Institute
Novartis
Paragon Biomedical
Parexel / Perceptive Informatics
Pfizer*
PharmaNet*
PPD*
PRA International
QD-Quality & Training Solutions
Quest Diagnostics
Quintiles*
RadMD
Regeneron
Roche*
Sunovion Pharmaceuticals
Synarc
Virtual Scopics
WorldCare Clinical

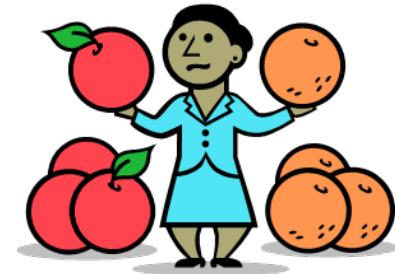
* MCC Board of Directors

Lack of Standardized Performance Metric Definitions Creates Challenges

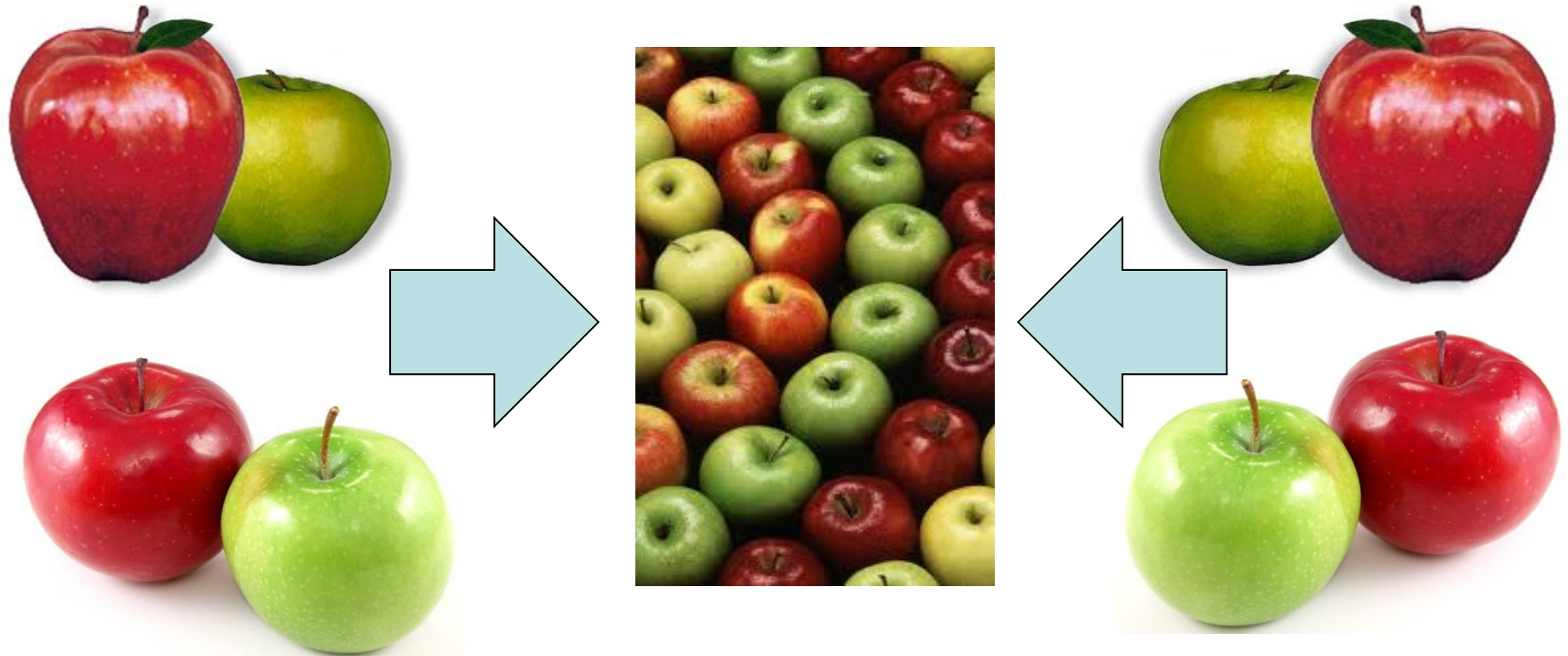


- Sponsors use different service providers
 - Managing metrics across portfolios across service providers is a challenge

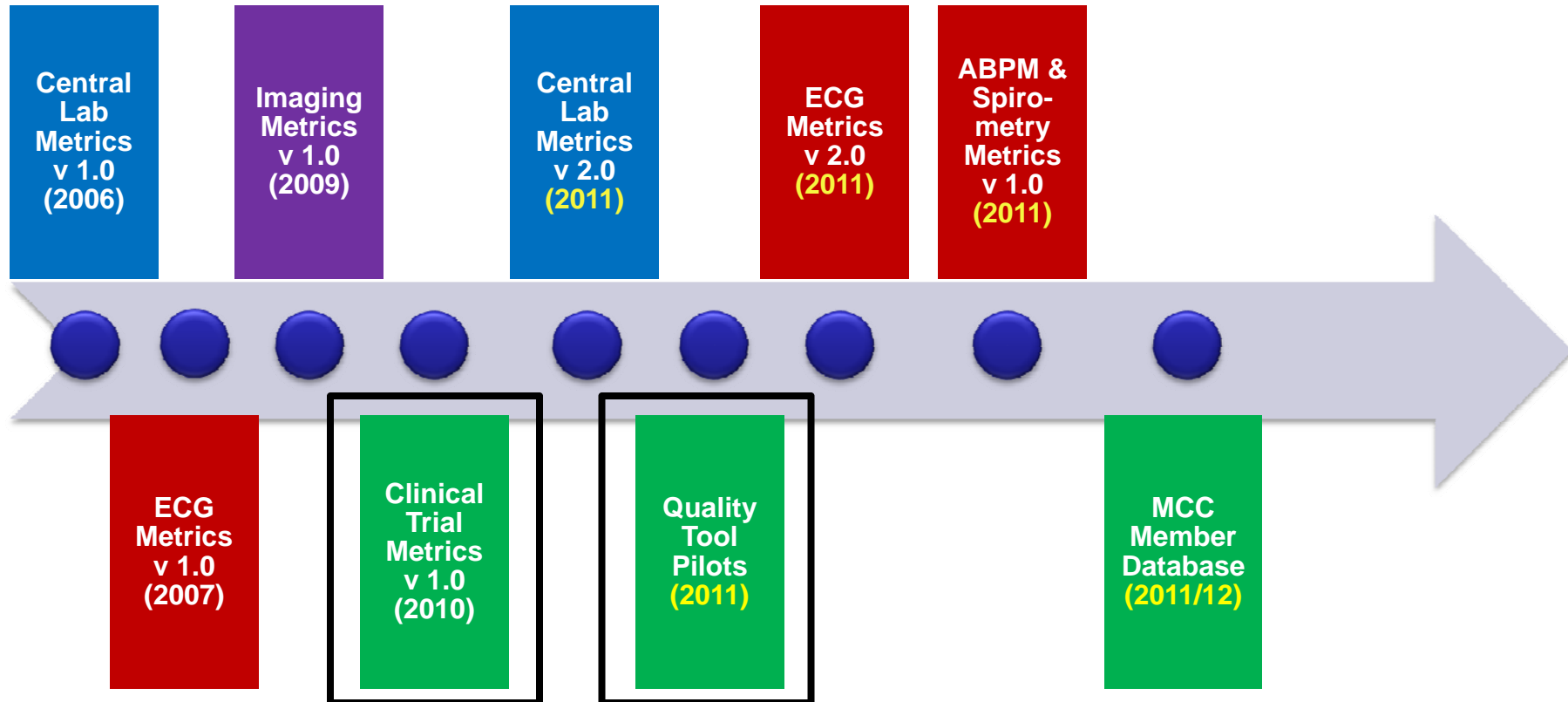
- Service providers are faced with managing varying performance based metrics from Sponsors



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



Metrics Development Timeline



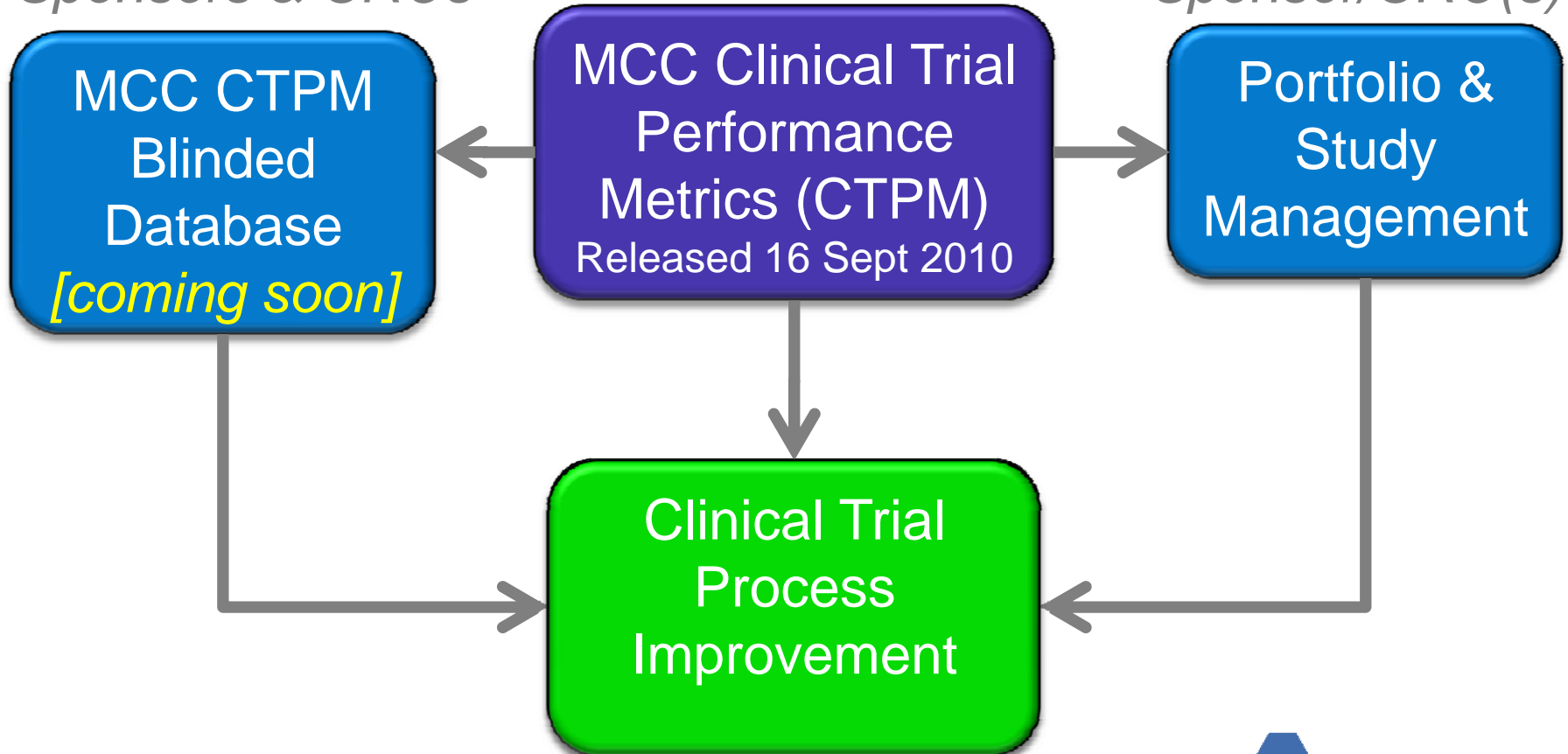


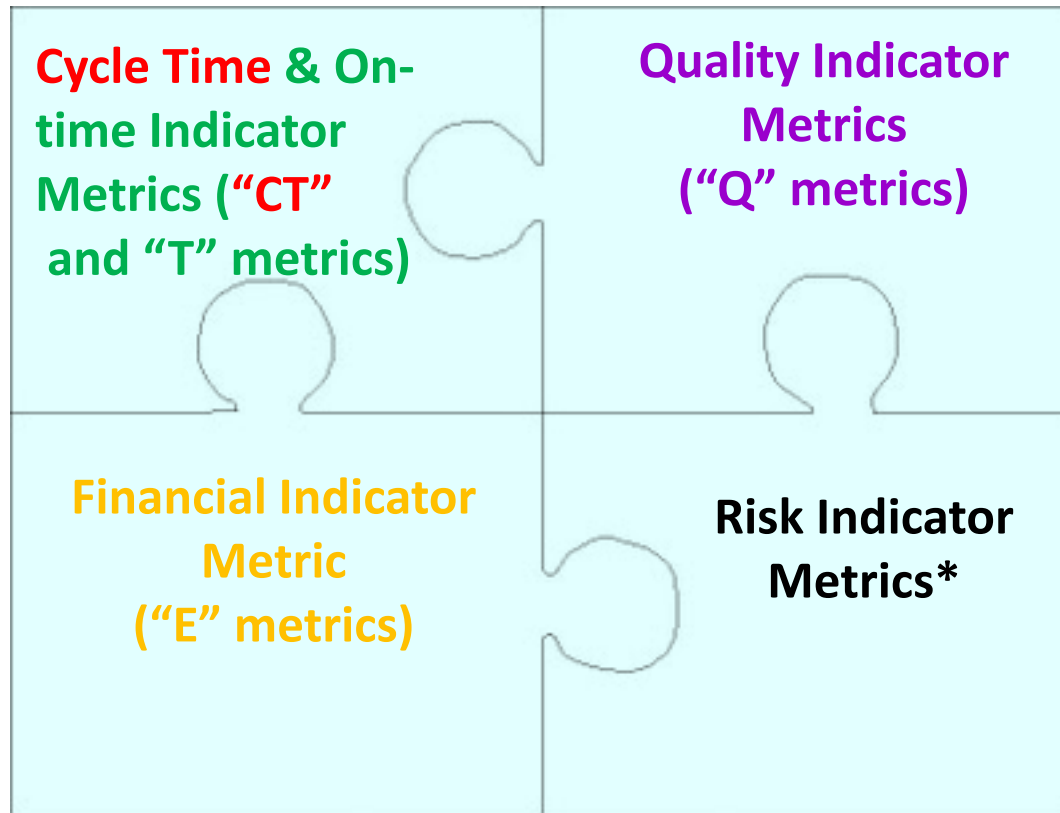
CLINICAL TRIAL
metrics champion

*Clinical Trial Performance Metrics
Initiative*

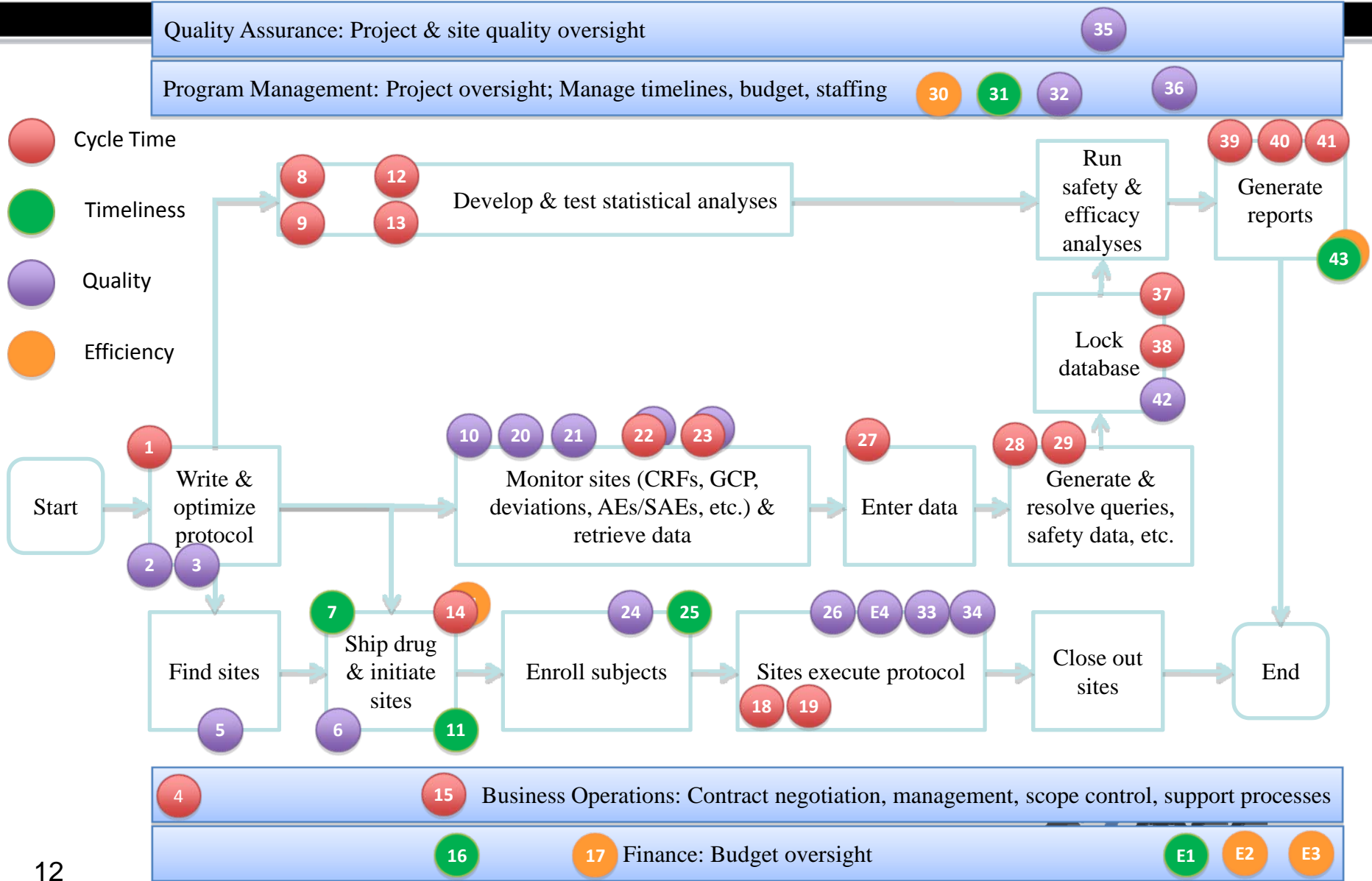
*EXTERNAL
Sponsors & CROs*

*INTERNAL
Sponsor/CRO(s)*





* Some MCC metrics can be used as Risk Indicator Metrics – this designation is determined by an organization.



Metric #	Metric Type	Metric Title	Metric Indicator
1	CT	Protocol Feasibility	LEADING Indicator
2	Q	Protocol Versions	LEADING Indicator
3	Q	Protocol Quality Tool	LEADING Indicator
4	CT	Contract execution timeliness for non functional outsourcing models	LAGGING Indicator
5	Q	Site Selection Quality Tool	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 Assessment Quality Tool	LEADING Indicator

Anatomy of a MCC Clinical Trial Performance Metric

Metric #	Metric Type	Metric Title	Category	Metric Indicator	Part of Study
	CT, T, Q or E		Business Operations, Clinical Operations, Data Management, etc.	LEADING or LAGGING Indicator	Study Startup, Conduct and Close-Out
Definition (see Wiki for detailed definitions)		Formula / Example		Reporting Detail	
		Formula: Example:		Site / Country / Study / Therapeutic Area / Portfolio levels	
				Unit of Measure	
				Calendar days, % etc.	
Business Driver(s) / Benefit Statement		Additional Analysis on a "for cause" basis		Reporting Frequency	Threshold Target
Statement about why this metric is important /the reason for utilizing metric. Who / what / why...		List of "drill down" metrics that should be reviewed when the metric is not within established target		Monthly, Quarterly, etc.	Threshold target or acceptable range. Exceeding target triggers additional analysis on a "for cause" basis
Companion Metrics		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			

This List



Clinical Trial Initiative

MCC Home
Members
Central Lab Initiative
ECG Initiative
Clinical Trial Initiative
Imaging Initiative
Board of Directors
Industry Advisory Board
Admin
Site Actions

View All Site Content

Documents

- Steering Committee
- Biometrics WG
- Business Ops / Finance WG
- Clinical Ops WG
- Drug Supply WG
- Project Mgmt WG
- Quality Assurance WG
- Beta Metrics Feedback
- Process Improvement WG
- MCC Clinical Trial Performance Metrics Wiki

Lists

- Clinical Trial Initiative WG

Discussions

- Steering Committee Discussion Area
- WG Discussion Area

Sites

People and Groups

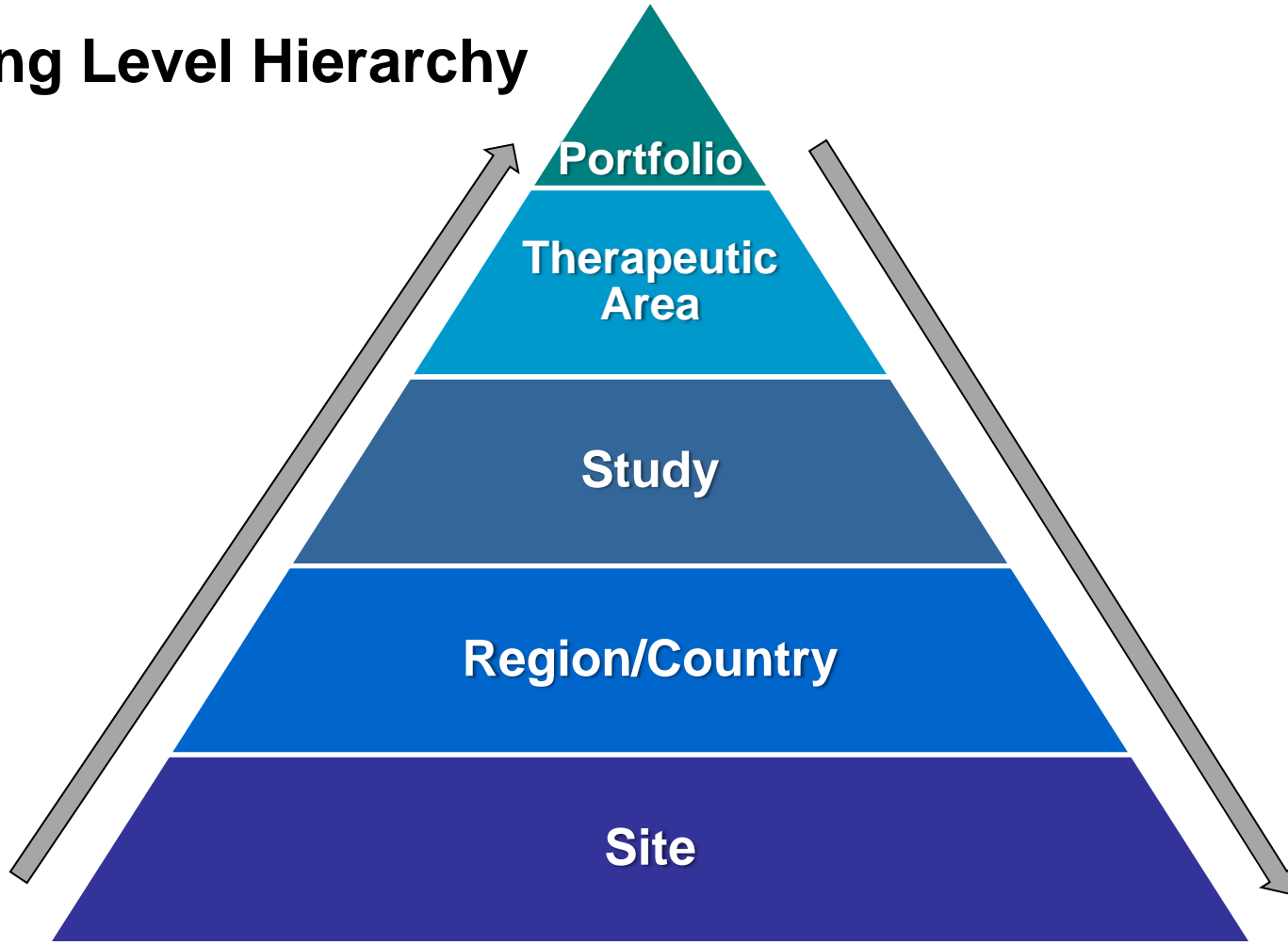
Metrics Champion Consortium > Clinical Trial Initiative > MCC Clinical Trial Performance Metrics Wiki

MCC Clinical Trial Performance Metrics Wiki

New ▾ Actions ▾ Settings ▾ 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
	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

Reporting Level Hierarchy



- MCC Committees are 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 will not available to non-MCC members

Expect to begin database pilot in late 2011

What is Quality?

A successful clinical trial is dependent on many factors:

- Robust, scientifically and ethically sound protocol
- Selection of high-performing, GCP compliant sites that contribute timely, accurate and complete data
- Keen oversight of quality execution throughout the life of the trial

Recent regulatory agency warning letters highlight deficiencies in GCP compliance and sponsor oversight, both which have the potential to compromise high-quality agency submissions.



The *quality* of something can be determined by comparing a set of inherent characteristics with a set of requirements.

- If those inherent characteristics meet all requirements, high or excellent quality is achieved.
- If those characteristics do not meet all requirements, a low or poor level of quality is achieved

ISO: 9000



Group Discussion



1. How does your organization define **quality** in clinical trial execution?
2. How does your organization assess / measure quality?
3. Does your organization and your clinical trial partners define quality in a similar manner?



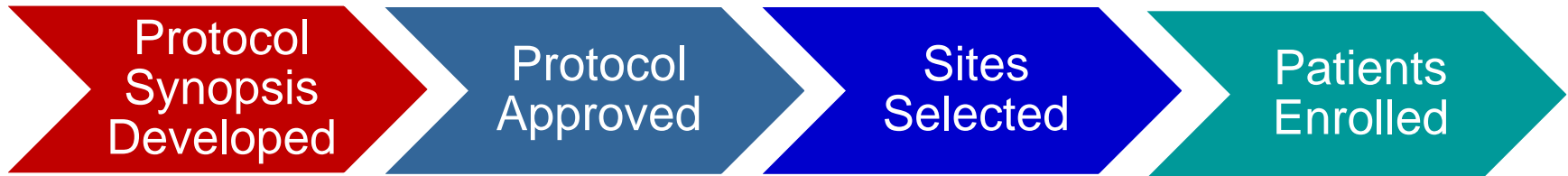
MCC Quality Tools



Beginning in Q4 2009, a group of Sponsor and CRO Process Improvement & QM specialists began working together to:

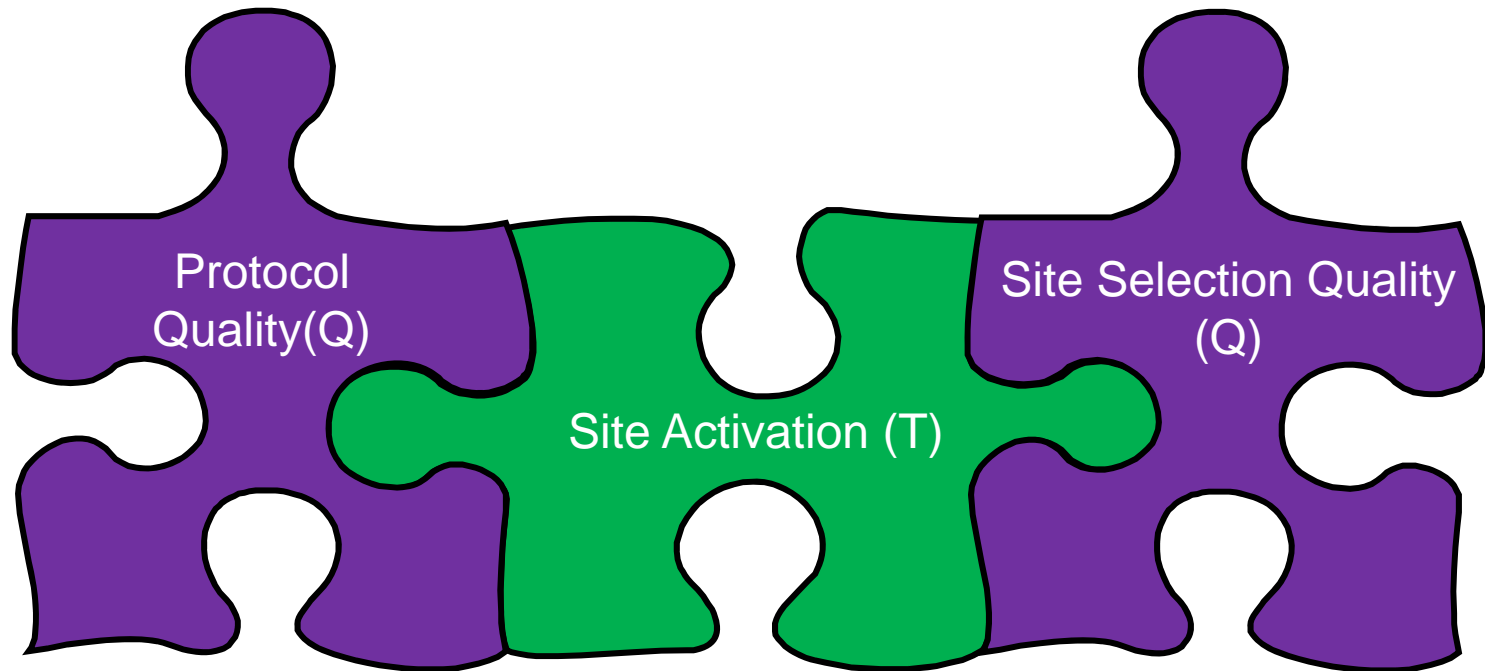
- Encourage the use of the metrics for process improvement
- Help MCC members avoid pitfalls such as sub-optimization
- Develop new approaches to assessing Quality

MCC Process Improvement WG expressed frustrations that many organizations focus on whether clinical trials are being executing in a **timely** manner ...



... but do not measure how **well** tasks are being completed.

MCC Companion Metrics show the interrelationship of clinical trial tasks



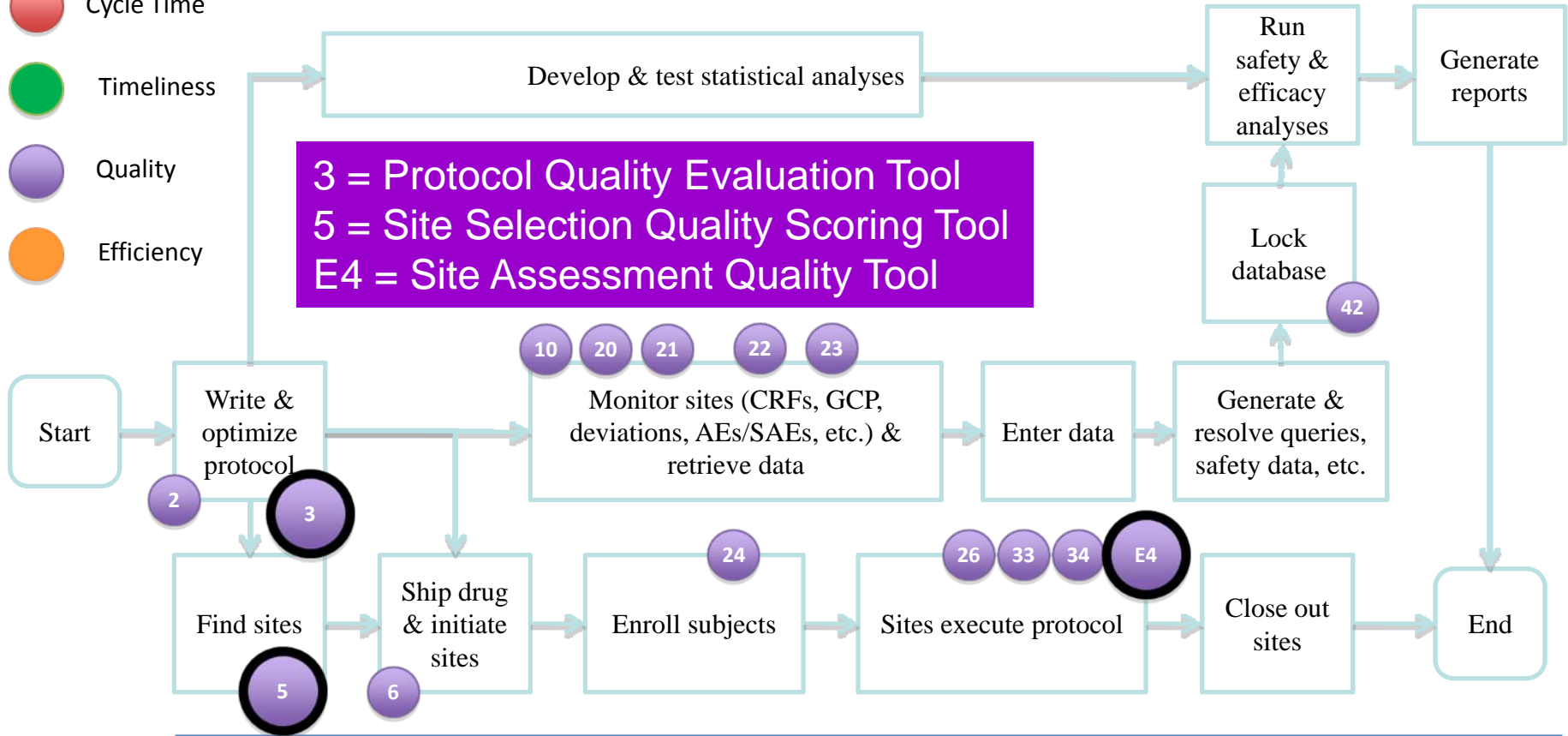
.... developing a quality protocol and selecting the right sites has a direct impact on site activation

Quality Assurance: Project & site quality oversight 35

Program Management: Project oversight; Manage timelines, budget, staffing 32 36

- Cycle Time
- Timeliness
- Quality
- Efficiency

3 = Protocol Quality Evaluation Tool
 5 = Site Selection Quality Scoring Tool
 E4 = Site Assessment Quality Tool



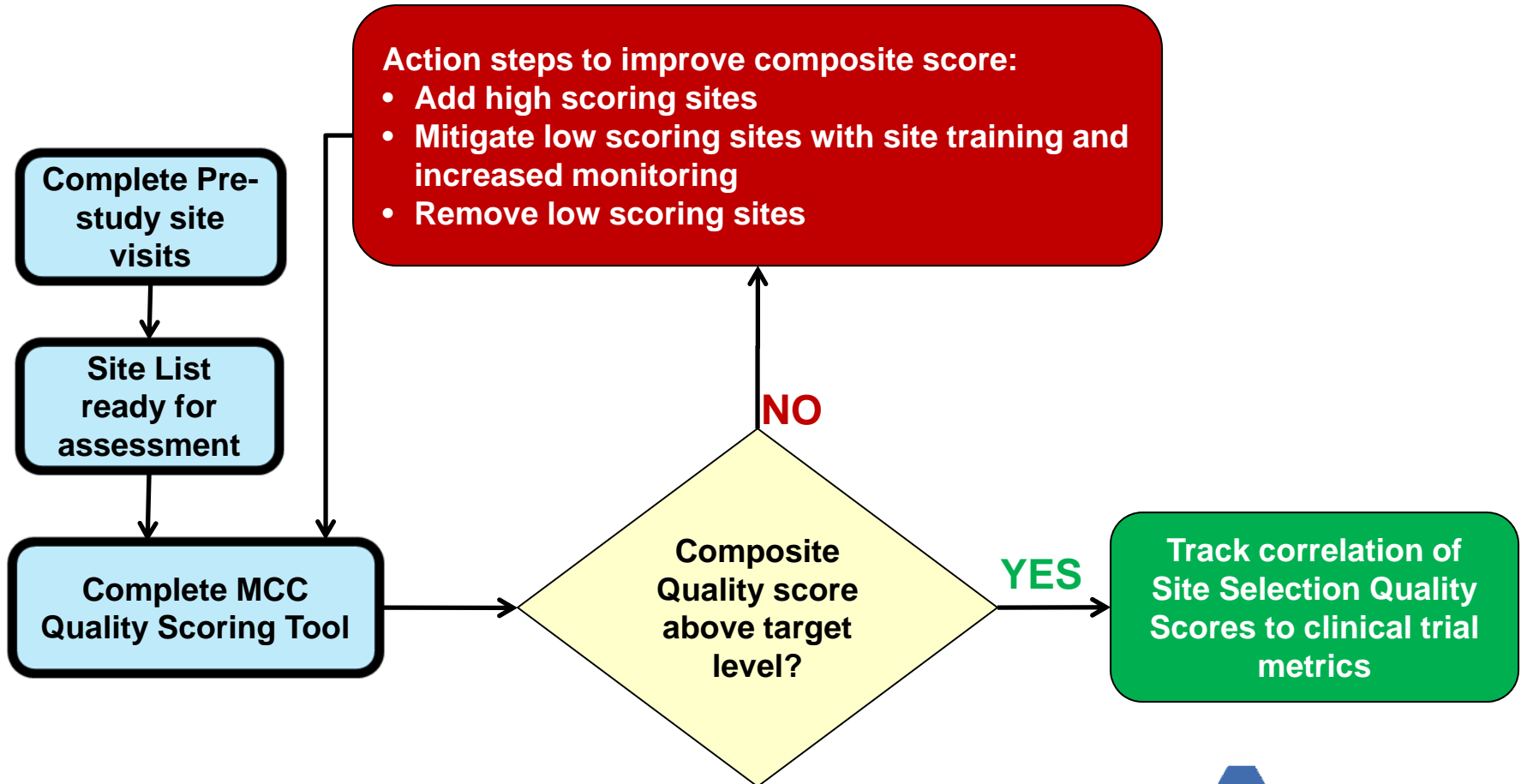
Business Operations: Contract negotiation, management, scope control, support processes

Finance: Budget oversight

Each **MCC Quality Scoring Tool** contains a set of requirements against which organizations can compare study start-up activities in order to determine a quality score and look for quality improvement opportunities.

The quality scores shows how well your processes outline site attributes that correlate to performance.

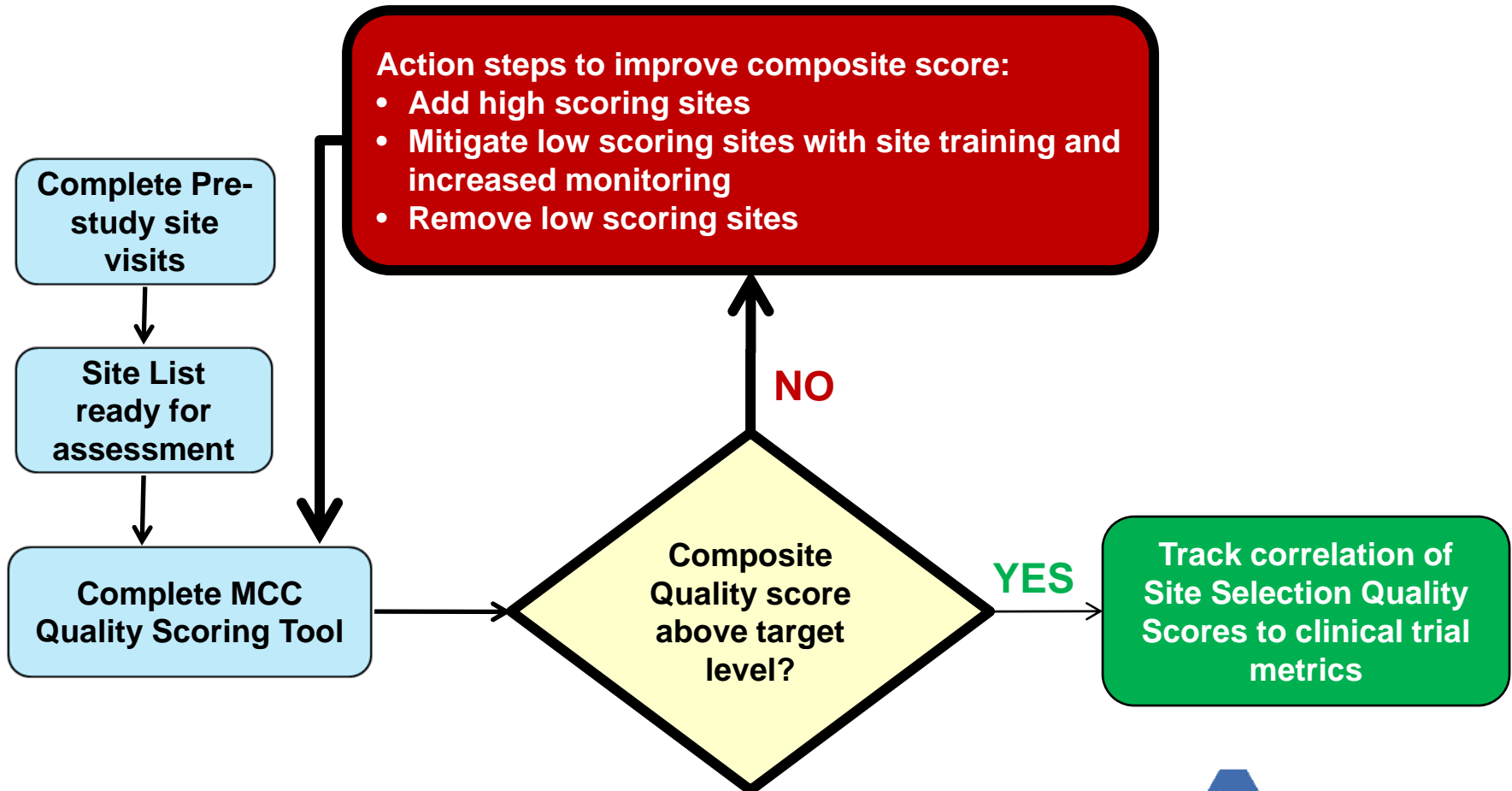
Site Selection Quality Scoring Tool



- Each site is rated on a standard set of eight site quality criteria
- Criteria are weighted as to relevance per protocol
- Each site score is automatically calculated from responses to these quality criteria

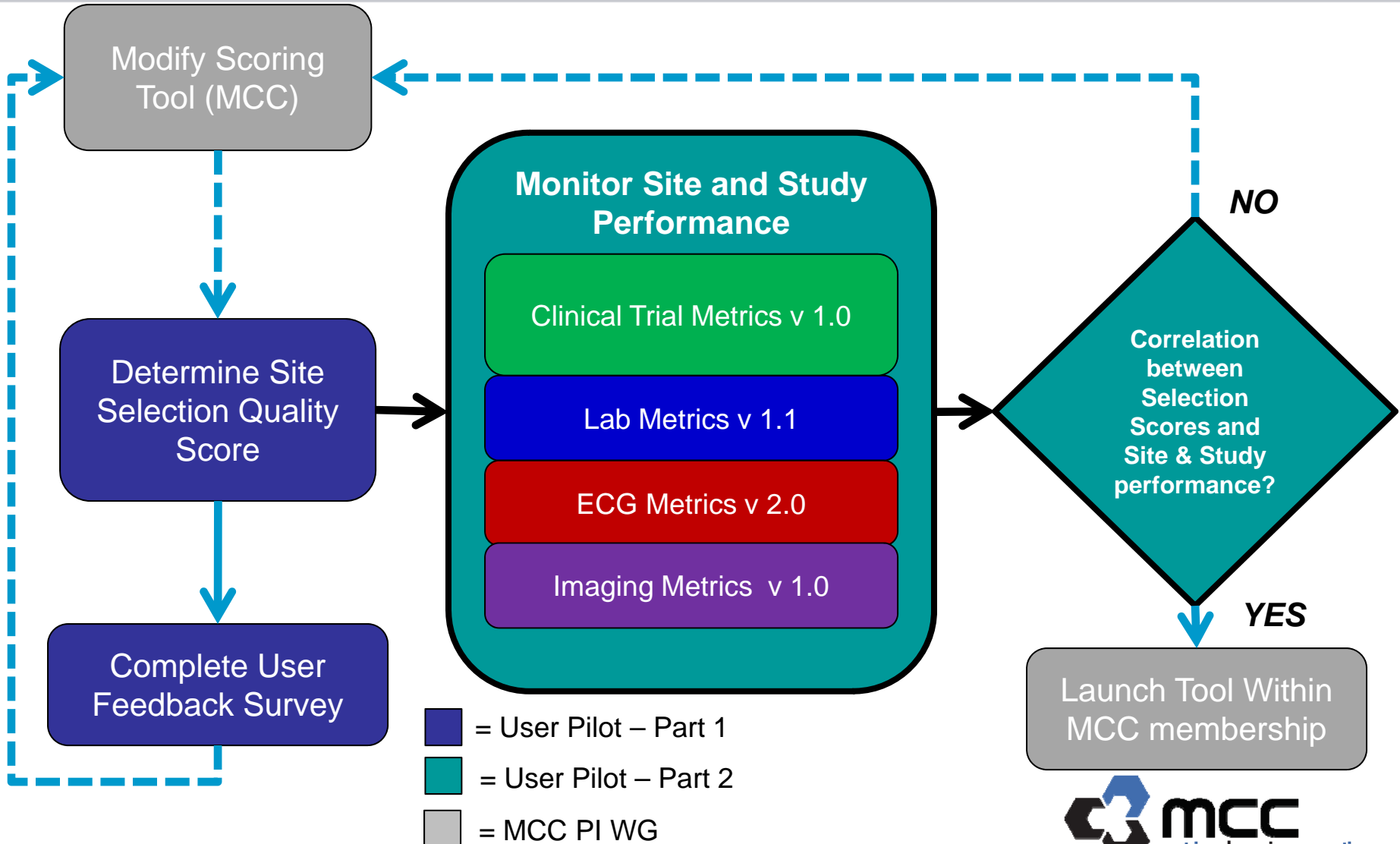
- Sites can be marked as included or excluded in final site selection list
- A total score is derived for individual countries for all sites scored as well as selected sites only
- Final result should be used as a guide in determining final site selection list

Site Selection Quality Scoring Tool

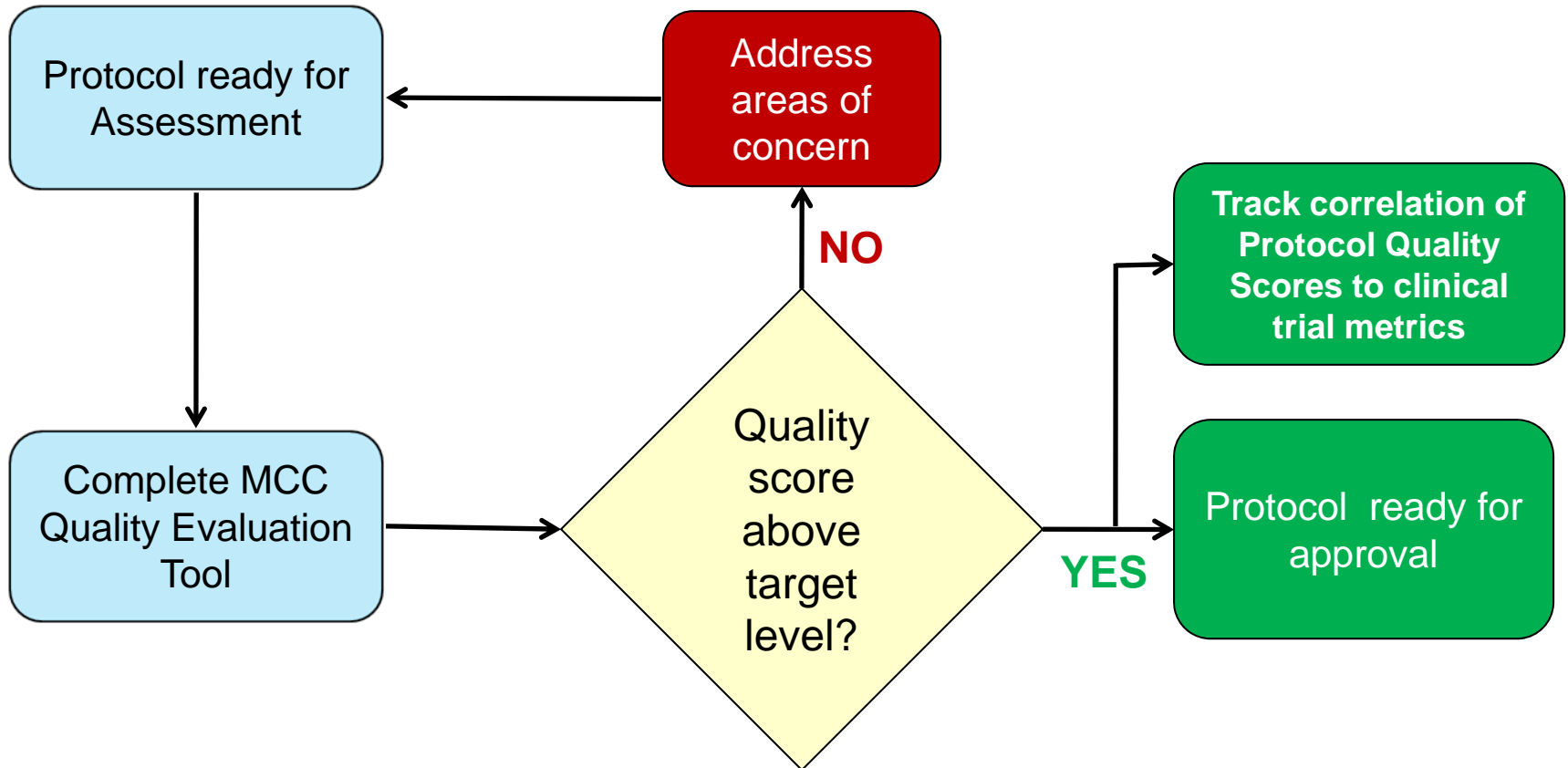


- Goal is to establish a reasonable threshold which all sites surpass as a measure of quality
- Focus should not just be on the score - but rather using the tool to assist in rational discussion amongst the team evaluating and selecting sites
- The act of measuring should modify behavior and highlight sites at risk for poor performance:
 - Does a site lack skills and need specific training?
 - Are there enough high quality sites selected in country X?

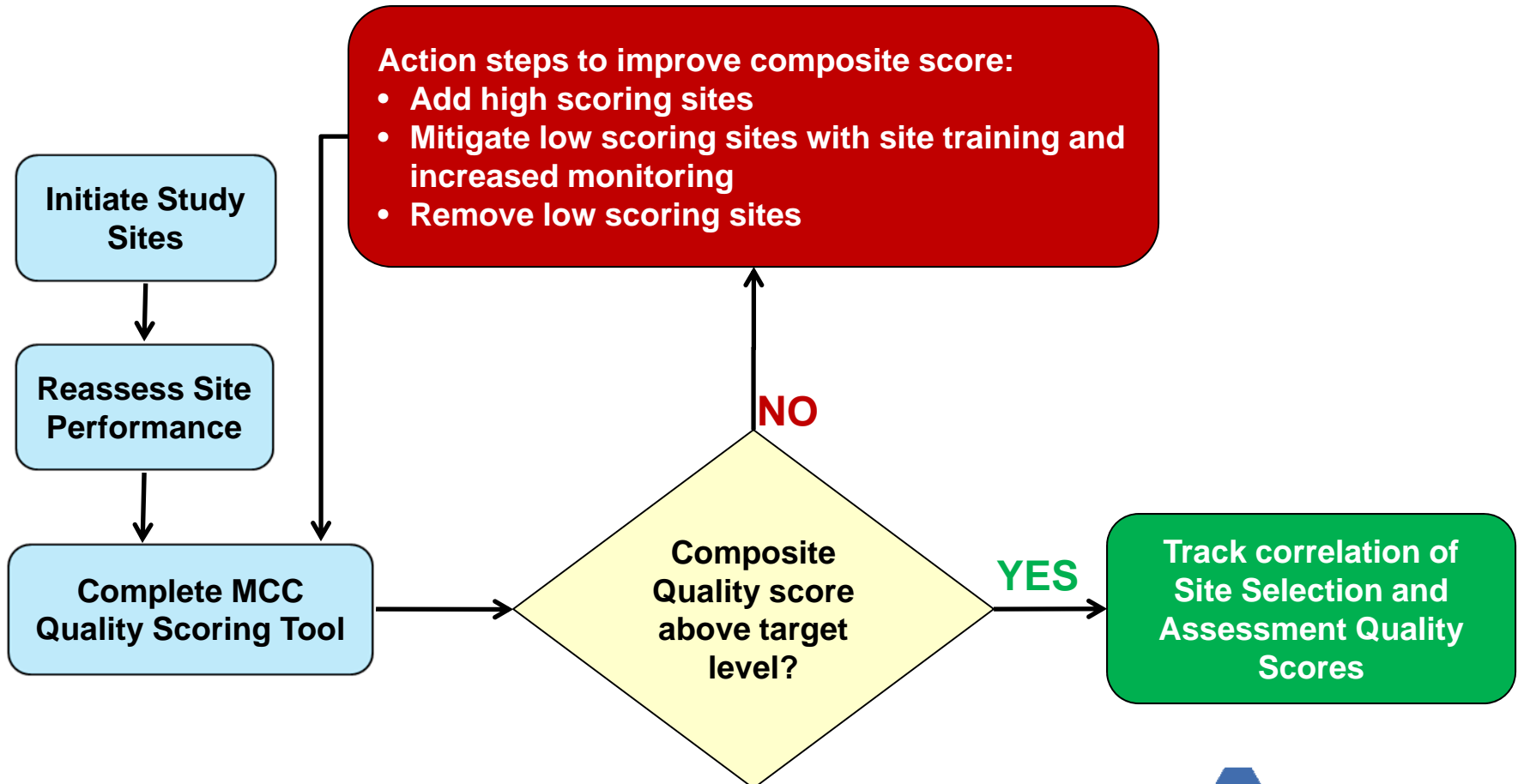
By maximizing the overall score for selected sites, organizations maximize your chances of on-time enrollment and successful completion of a trial!



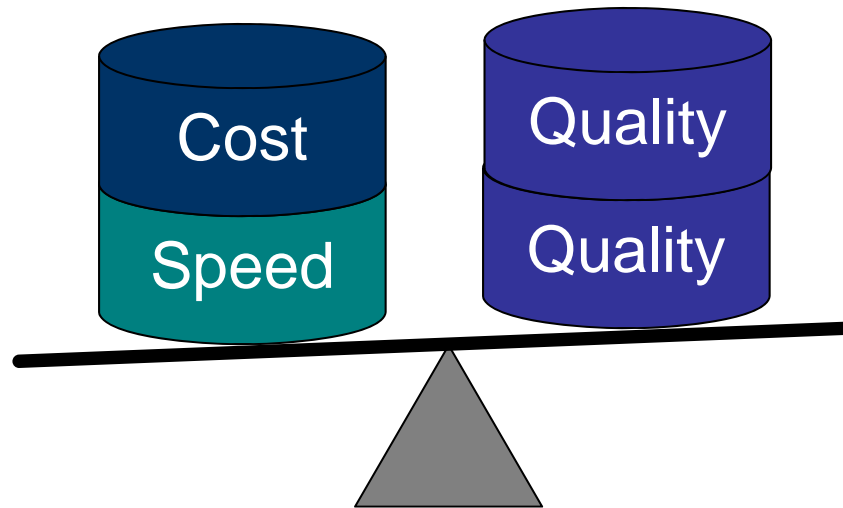
Protocol Quality Evaluation Tool (self assessment)



Site Assessment Quality Scoring Tool



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



MCC Performance Metrics and Quality Tools provide sponsors and service providers with the ability to achieve the right balance

Please visit
<http://www.metricschampion.org>
for additional information.