Workshop B4 –
MCC Clinical Trial Performance Metrics:

An Industry-wide Effort to Develop and Implement Standardized Performance Metrics to Drive Time, Cost and Quality & Enhance Partnership Performance … UPDATE!

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IIR Partnerships in Clinical Trials ◆ April 12, 2010 ◆ Orlando, FL

Agenda

Part I: Overview of the Metrics Champion Consortium (MCC) Clinical Trial Performance Metrics Initiative

BREAK

Part II: Clinical Trial Performance Metrics: Workgroup Breakout Session

Part III: Incorporating Performance Metrics into CRO contracts

Part IV: Clinical Trial Performance Metrics: Feedback/Discussion Session

Part V: Q&A Panel Discussion

Part I: Overview of the MCC Clinical Trial Performance Metrics Initiative

Building Partnerships Around Standardized 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 aimed at improving the efficiency and effectiveness of managing and tracking resources needed to successfully run clinical trials.

Demand for Performance Metrics Growing

94% of Sponsors reported that demand from their organizations for performance metrics was growing or rapidly growing

Exhibit 1

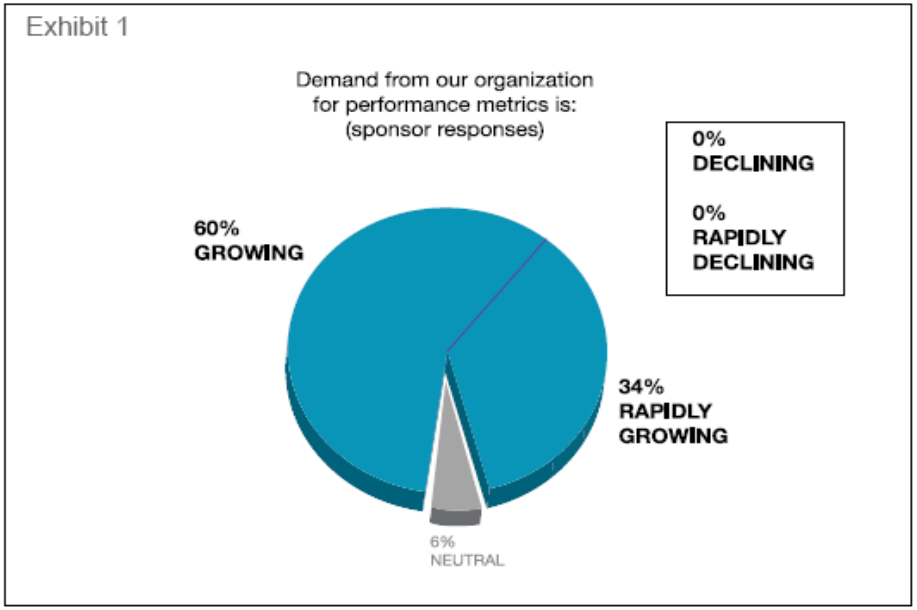
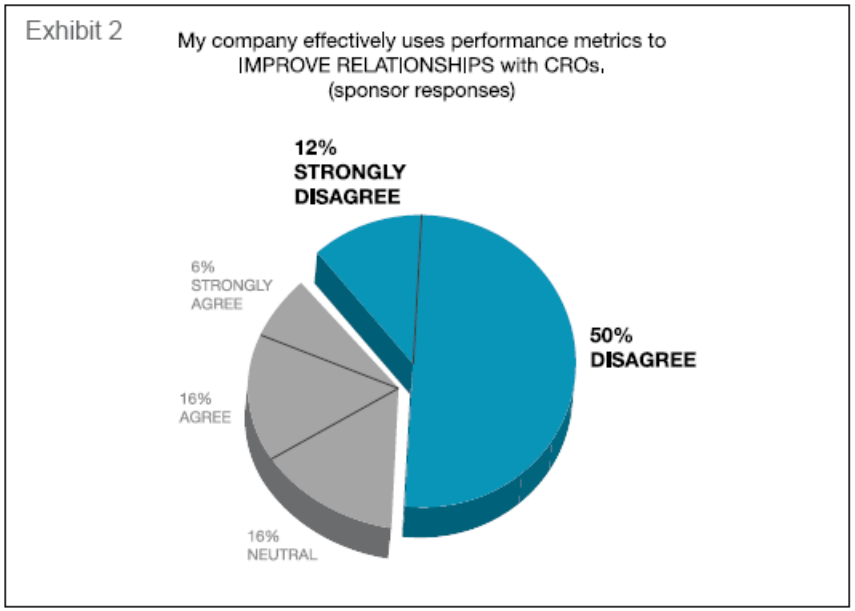


Exhibit 2



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

Source: MCC Survey 2007

Industry Players Not Utilizing Metrics to Potential

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

Exhibit 3

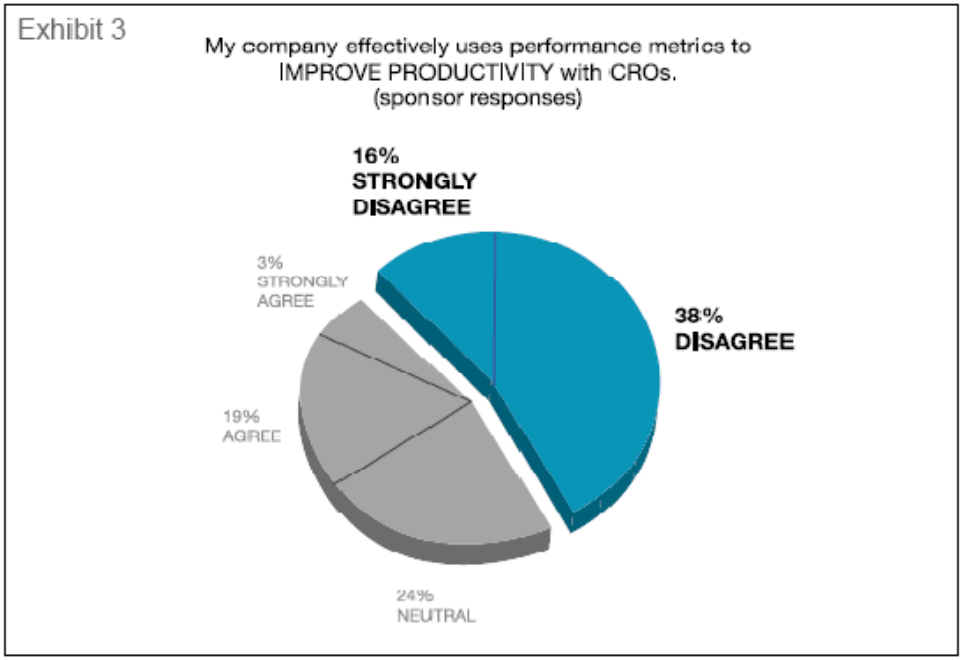
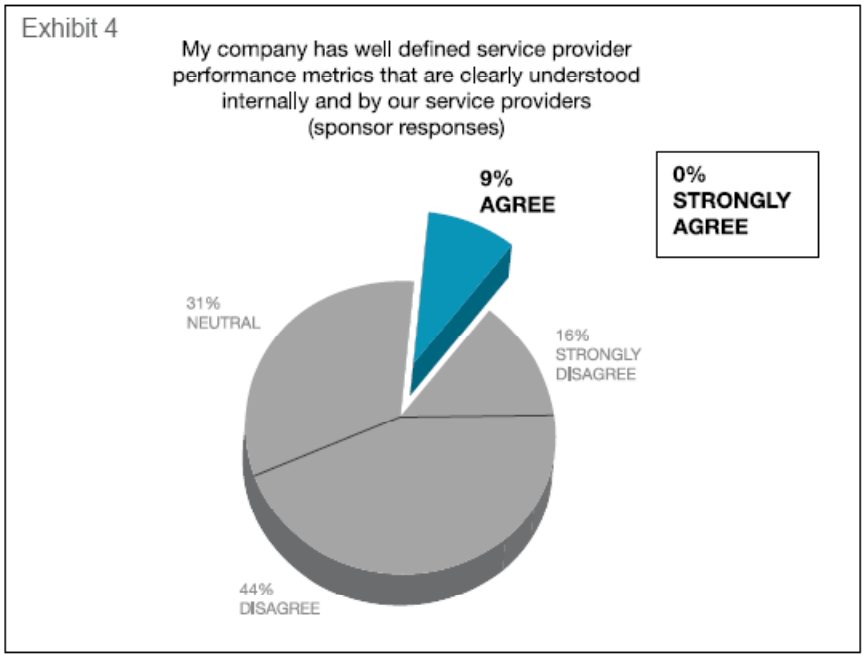


Exhibit 4



9% of Sponsors reported having well-defined, clearly understood performance metrics currently in place

Source: MCC Survey 2007

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

Exhibit 5

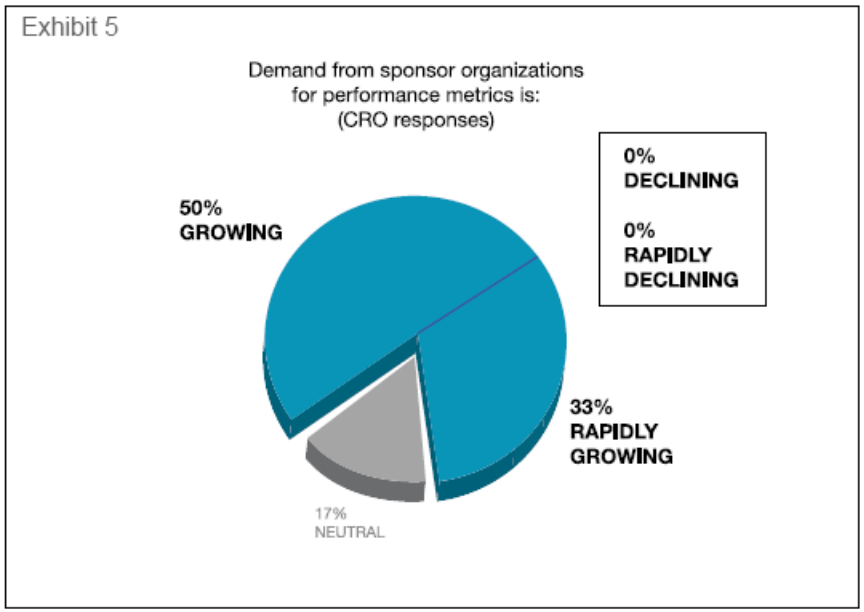
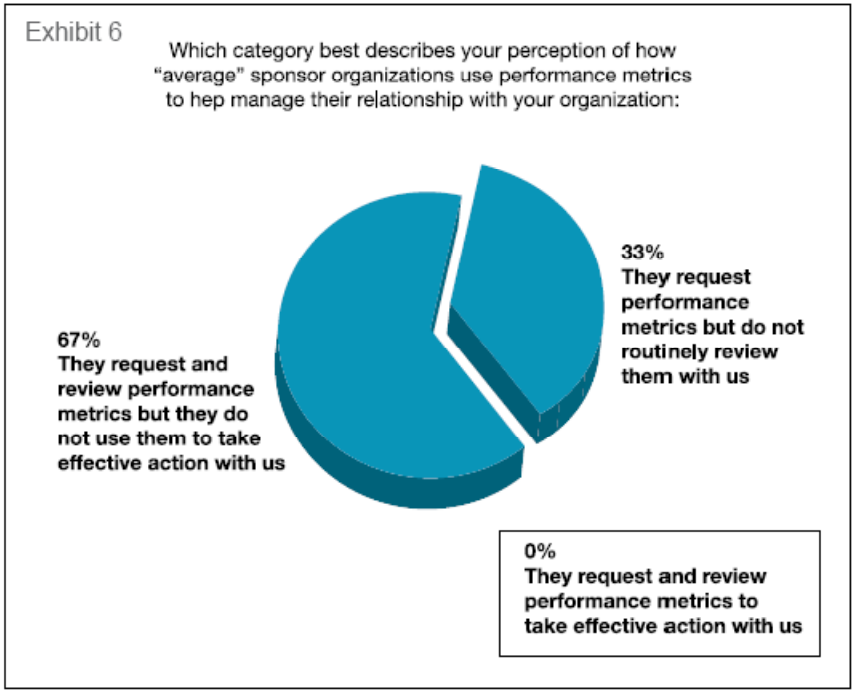


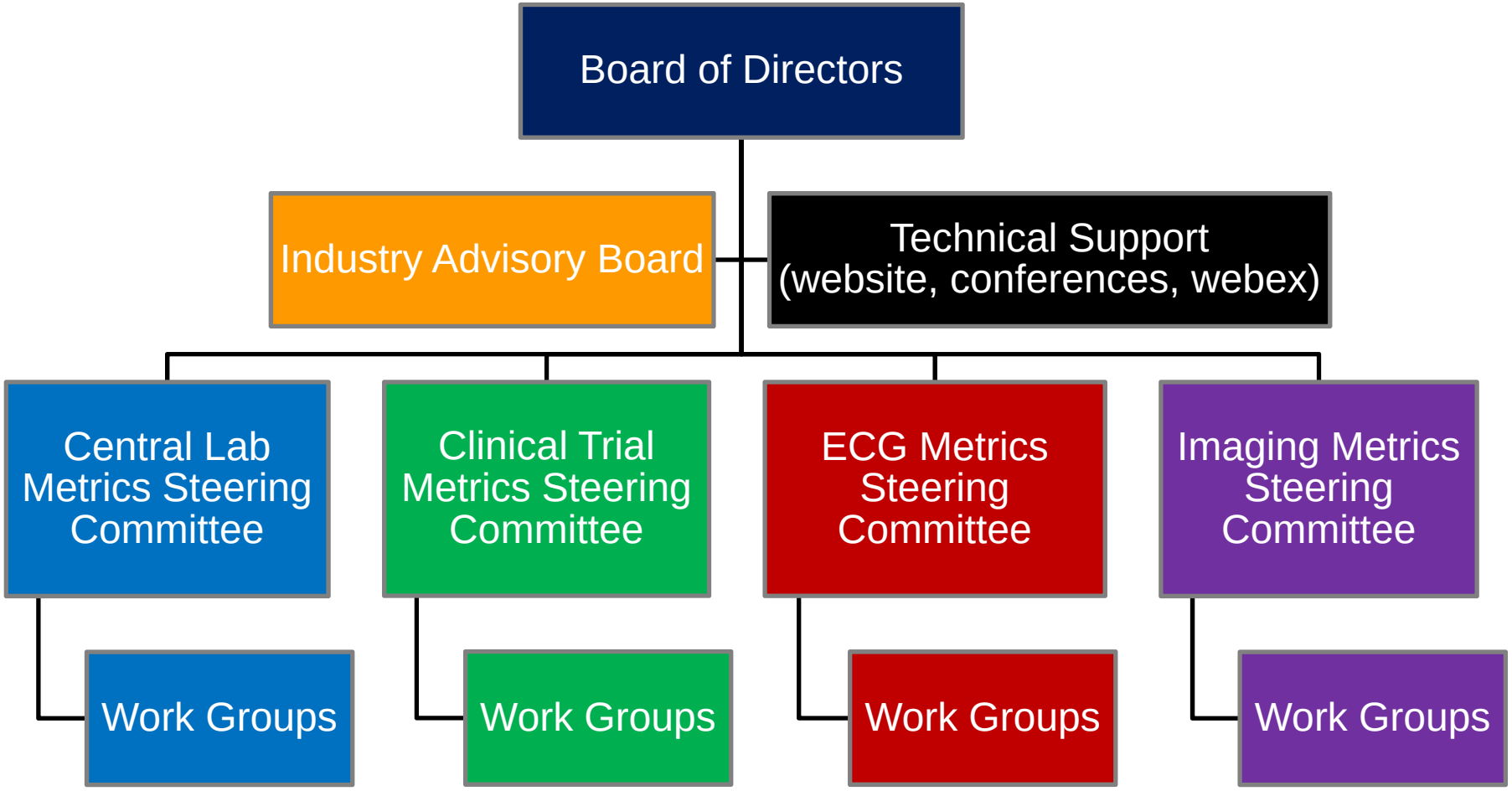
Exhibit 6



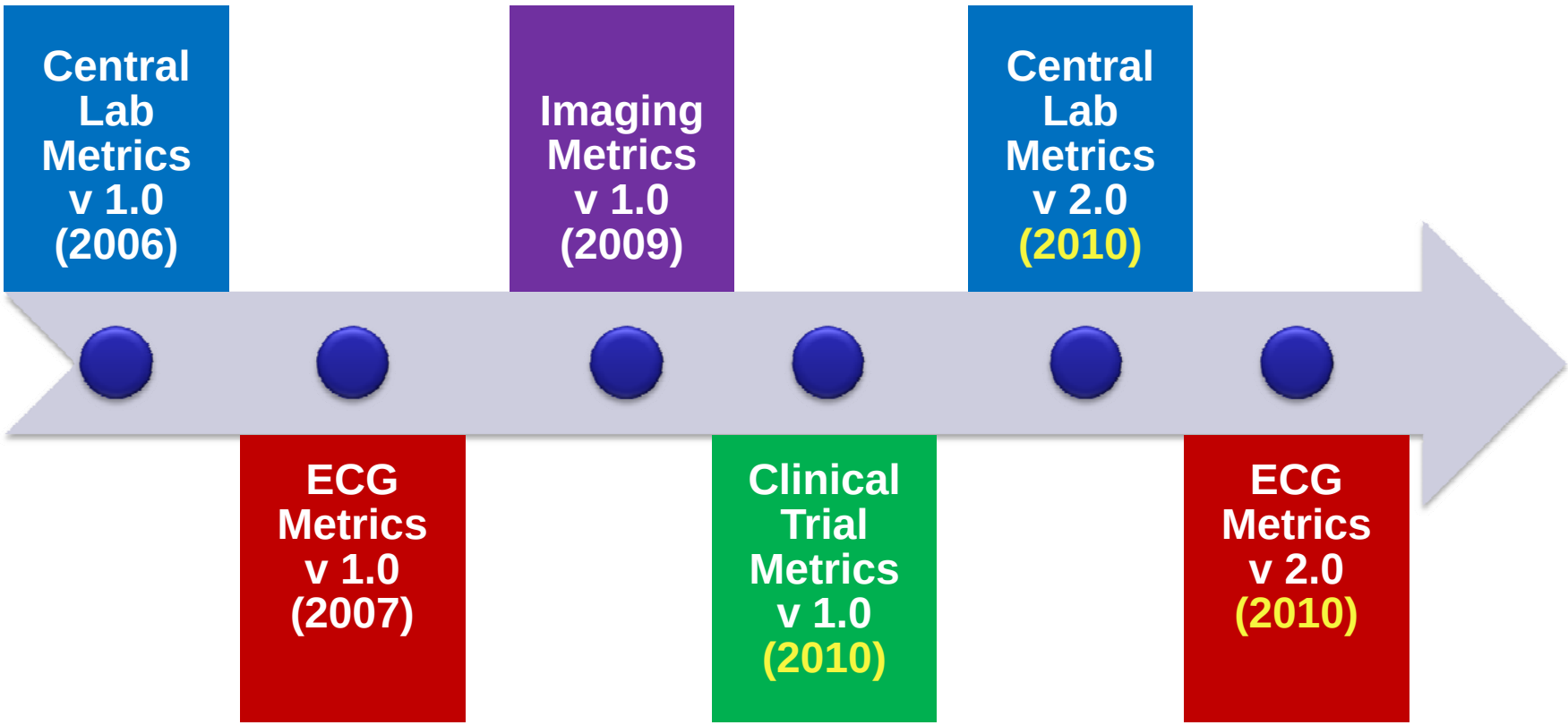
0% CROs reported that Sponsor companies request and review performance metrics to take effective action with them

Source: MCC Survey 2007

Organizational Structure



Metrics Development Timeline



MCC Clinical Trial Performance Metrics

Metrics Development Timeline

Metrics Development Oversight

Clinical Trial Metrics Steering Committee (2008-2010)

- Cory Gutterman / Abbott
- Ed Cannon / AstraZeneca
- Jennifer Holmes & Holly Hankins / Eli Lilly
- Colleen McCoy / Genentech
- Keith Dorricott / i3
- Pam Howard / ICON Clinical Research
- Kathe Balinski / Mederex
- Magaly Woolard / Merck
- April Davis / Perceptive Informatics
- Lorraine Waring / Pfizer
- Bryan Haas / PPD

Metrics Development Process

Proposed Metric - Qualities

- Well defined
- Be measurable
- Be high level – but allow for further analysis
- Leading Indicator - Lagging Indicator
- Provide a benefit to Sponsor and Service Provider
- Add Value
- Relationship metrics will be added in future version

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

MCC Clinical Trial Performance Metrics v 1.0

Metric #	Metric Type	Metric Title	Category	Metric Indicator	Part of Study

Definition	Formula / Example	Reporting Detail
		Unit of Measure

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target

Companion Metrics	

Example: MCC Clinical Trial Performance Metrics v 1.0

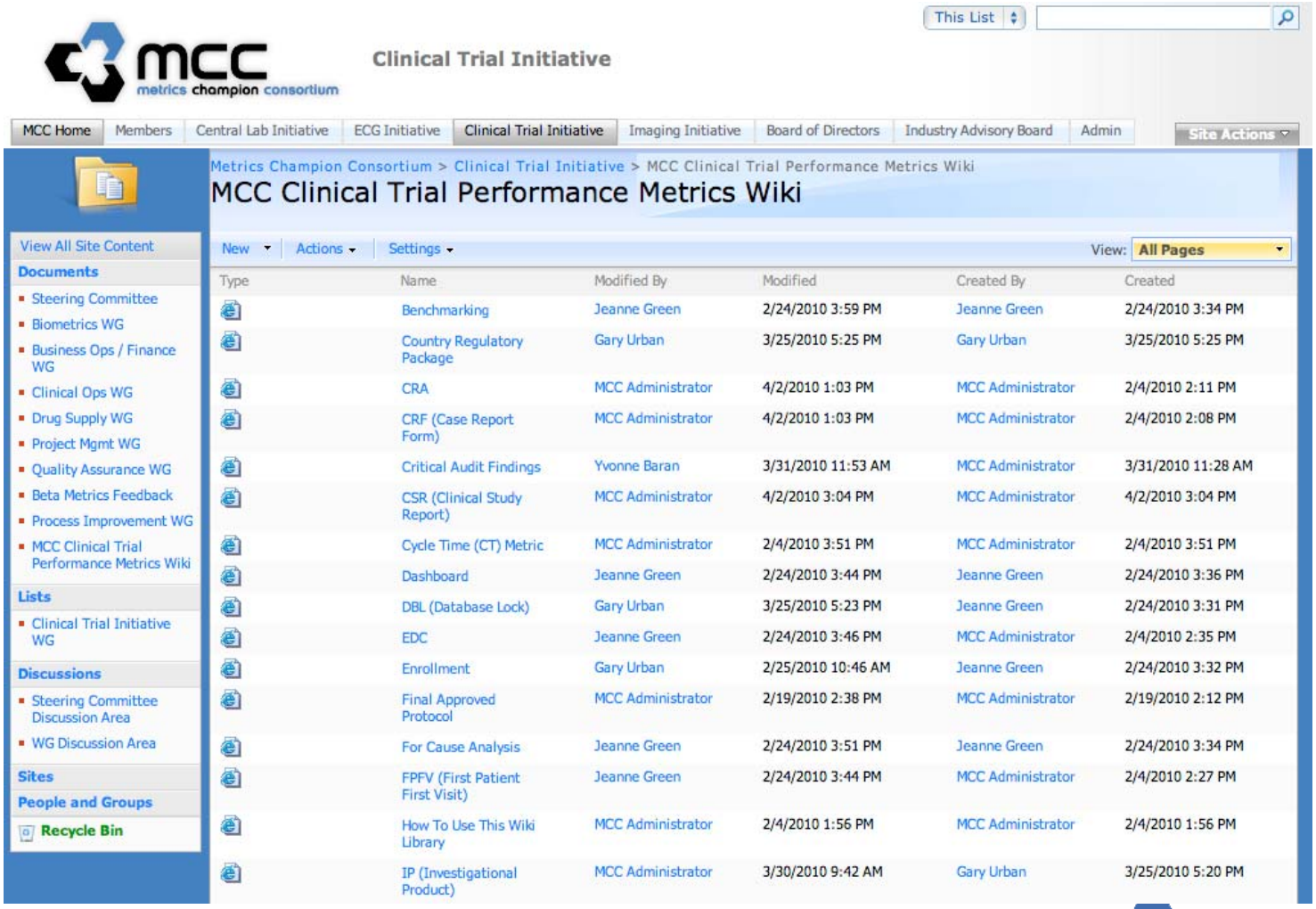
Metric #	Metric Type	Metric Title	Category	Metric Indicator	Part of Study
7	CT	Protocol approval to first site activated	Site Selection and Activation	LEADING Indicator	Study Startup

Definition (see Wiki for detailed definitions)	Formula / Example	Reporting Detail
Number of calendar days from the date the final approved protocol is released to the Project Team to the date of first site activated (trial level, country level) **See MCC Wiki for definitions**	Formula: Duration to first site activated = X - Y, where X is Date of First Site Activated; and Y is Date of Protocol Approval Example: Protocol Approved April 13 and First Site Activated August 1; [Aug 1 -- Apr 13] = 109 calendar days	By trial level By country **Unit of Measure** Calendar days

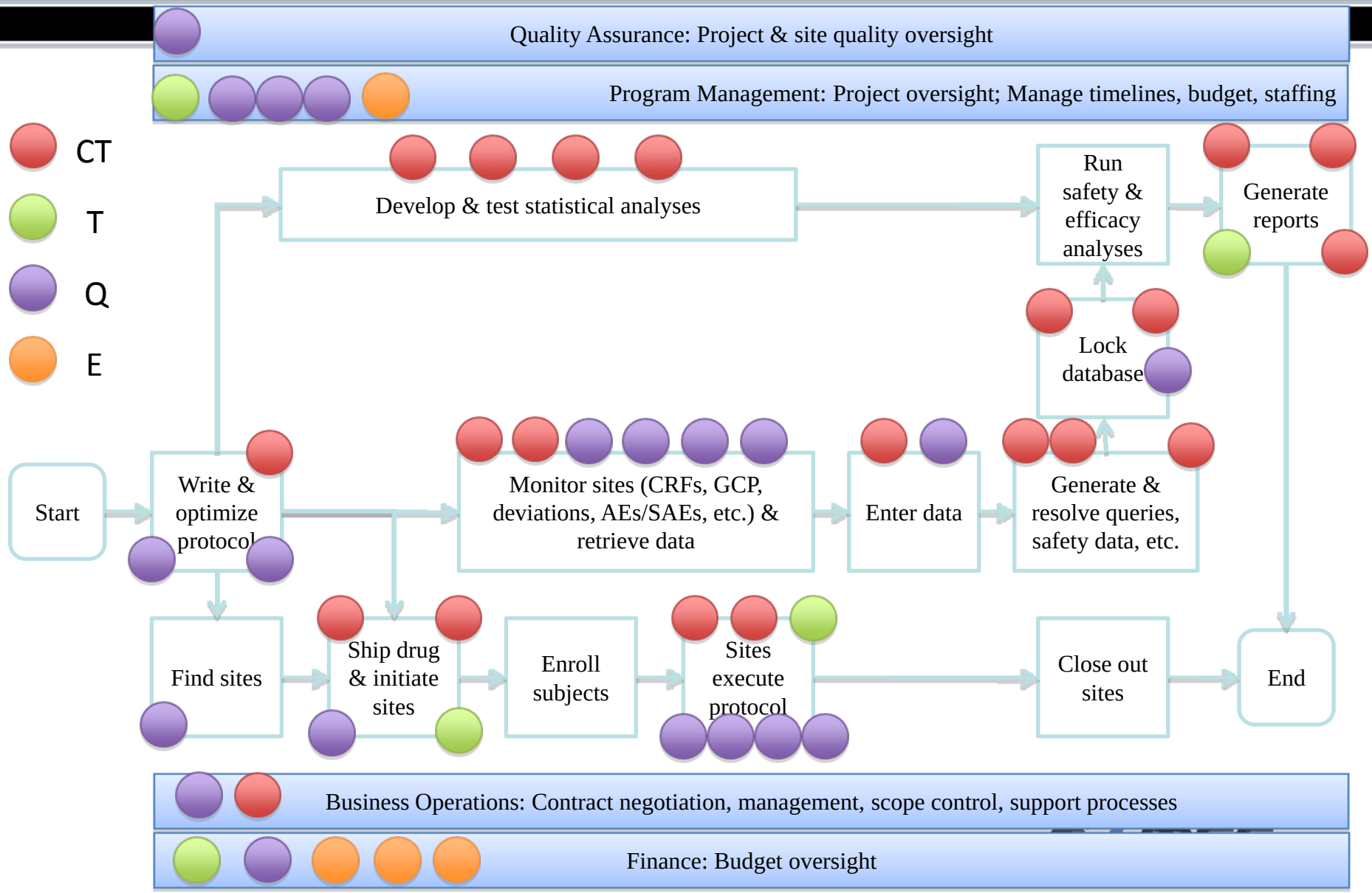
Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Leading indicator for protocol issues, site performance, CRO performance, regulatory approvals, etc. Increased understanding of geographical differences in site activation. The adherence to plan for site activation is a leading indicator for site activation performance. Key project management indicator of adherence to project plan.	Analysis of reasons for delay include: - timelines for ethics approvals/ signed site agreement and regulatory approval - monitoring resource availability - protocol amendments	Bi monthly during site selection phase	+/ - 14 calendar days per contract, by geography (Green) Within 14 – 28 calendar days per contract by geography (Yellow) > 28 calendar days per contract by geography (Red)

Companion Metrics	Metric # 5 - Site Assessment Quality Score, Metric #6

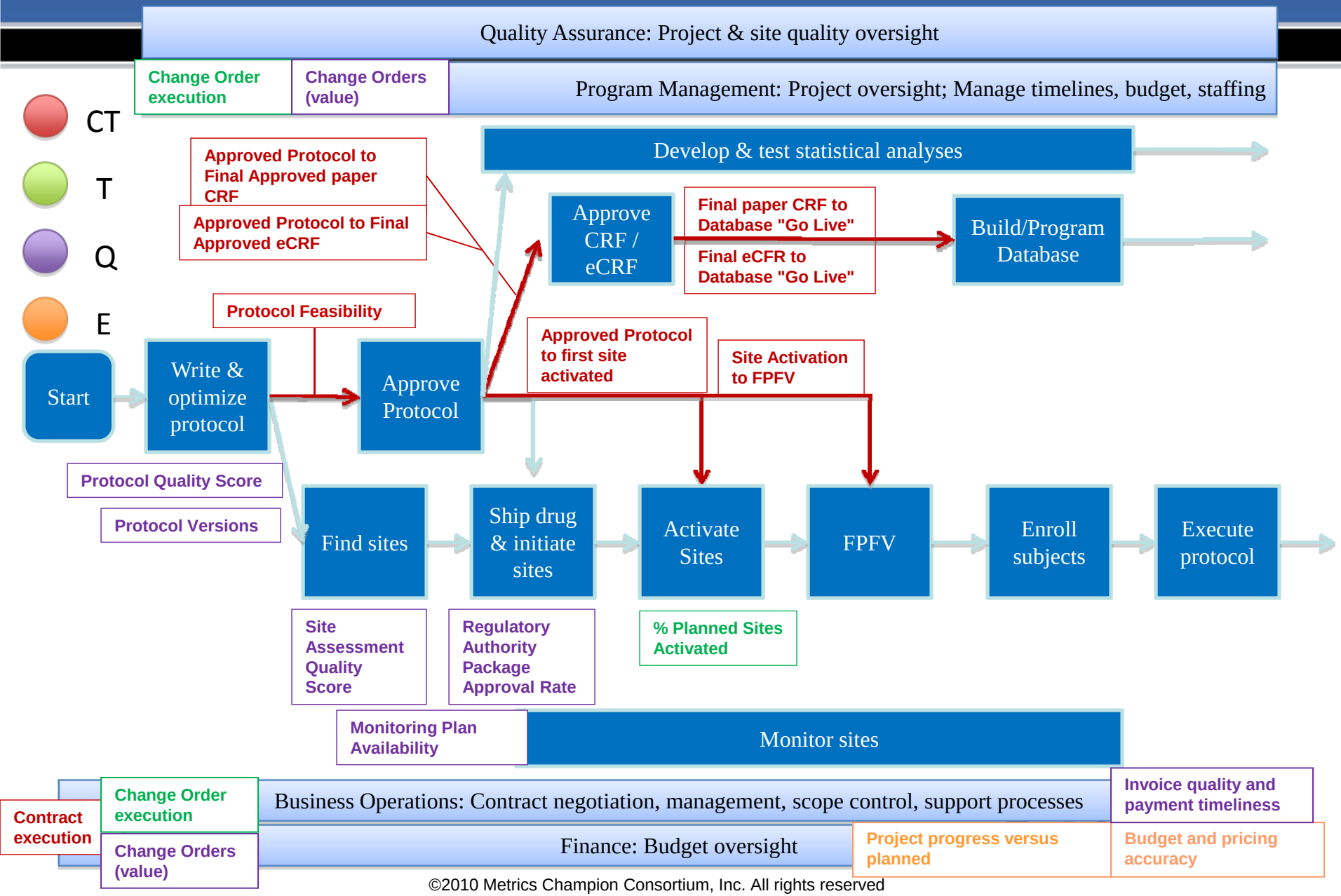
MCC Clinical Trial Performance Metrics Wiki



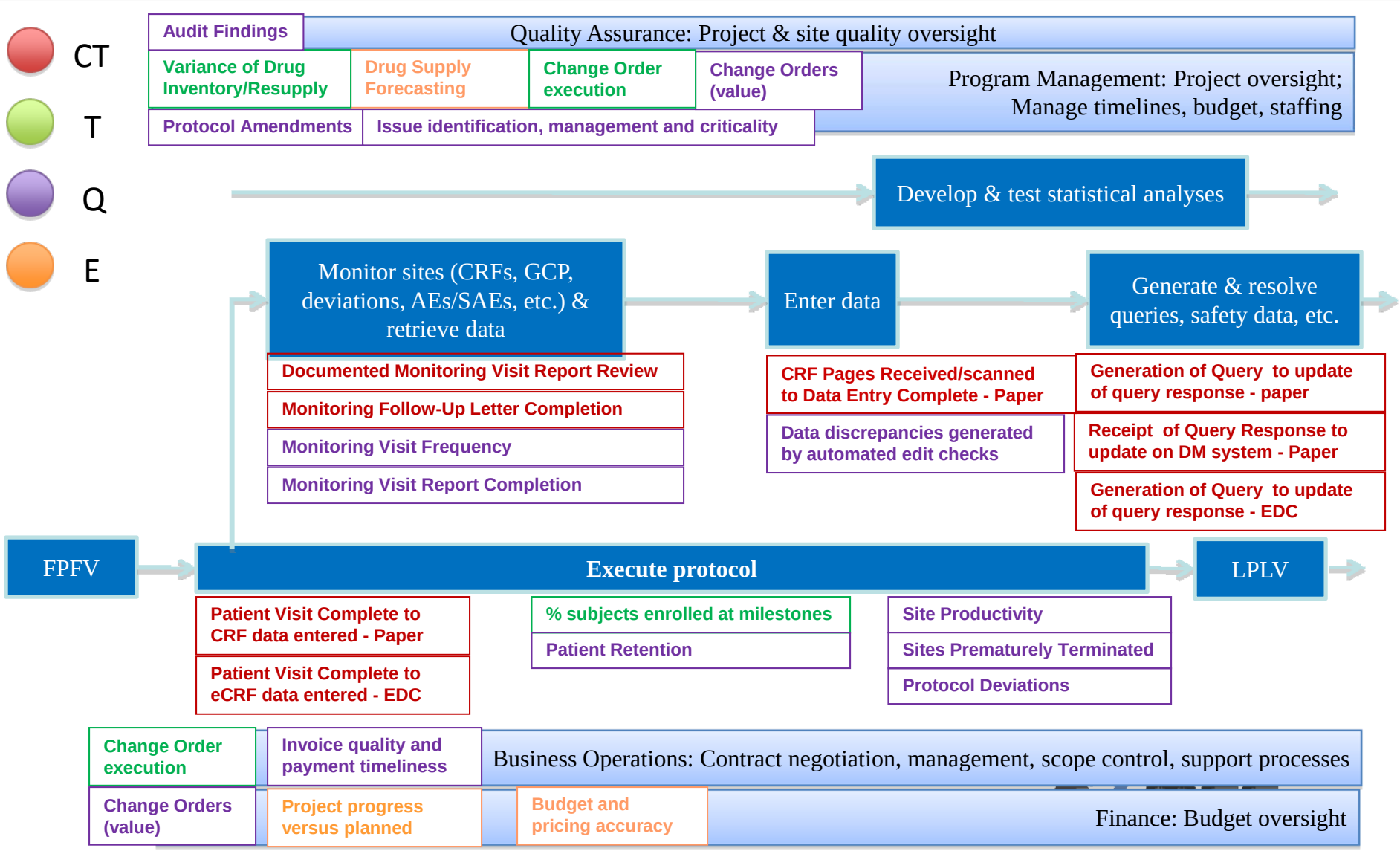
MCC Clinical Trial Performance Metrics v 1.0



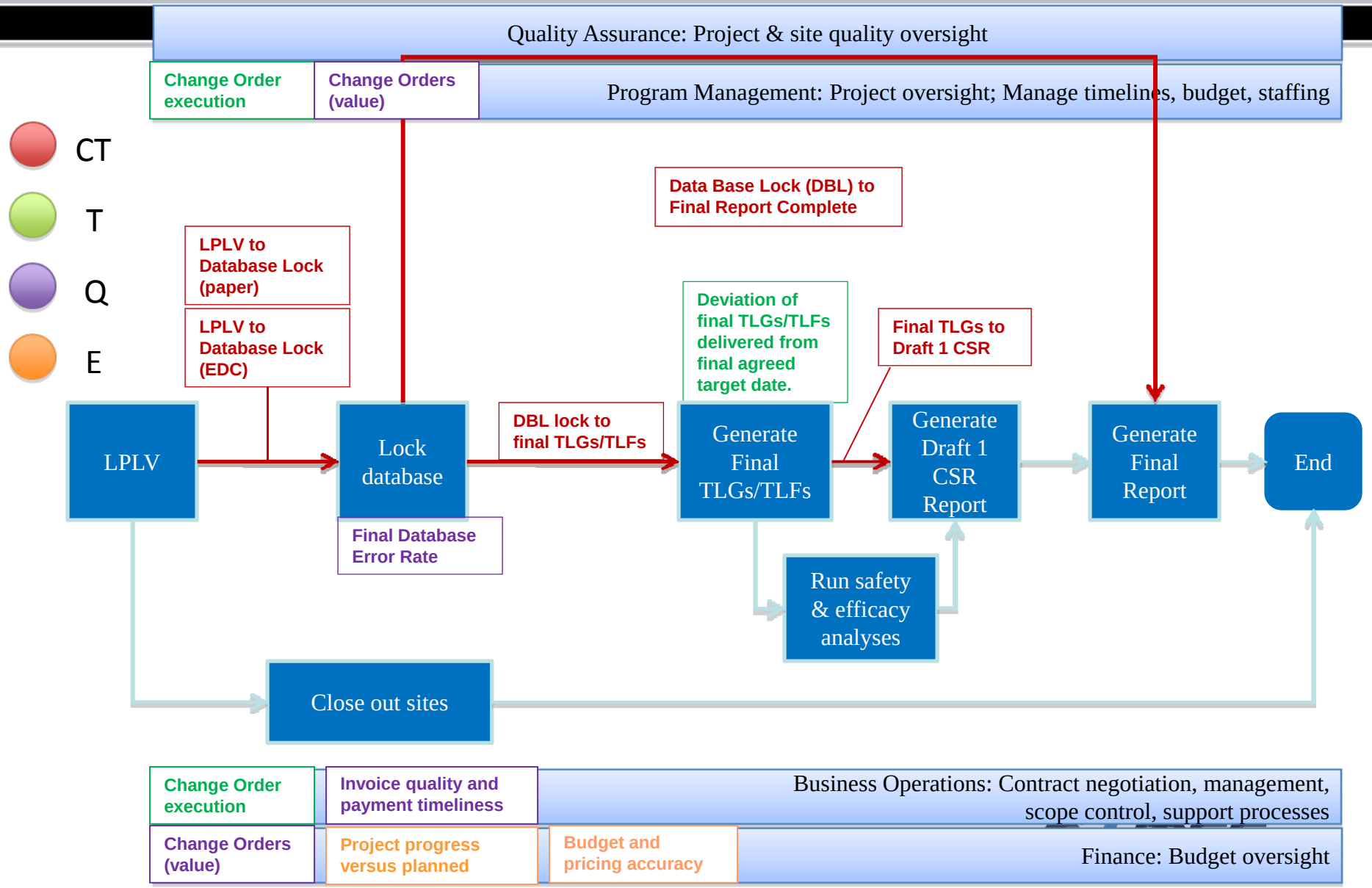
Study Start-up (SSU)



Study Conduct (SC)

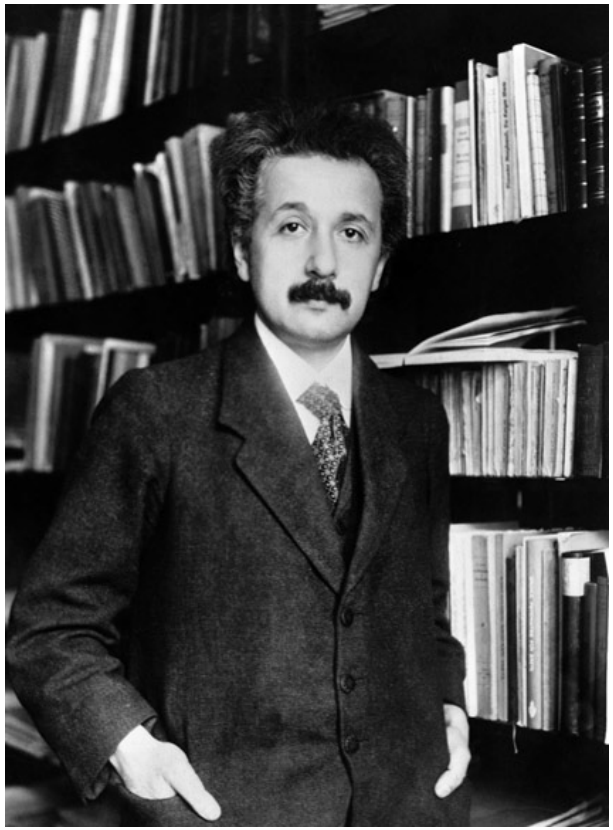


Study Closeout (SCO)



Process Improvement Work Group

Process Improvement WG



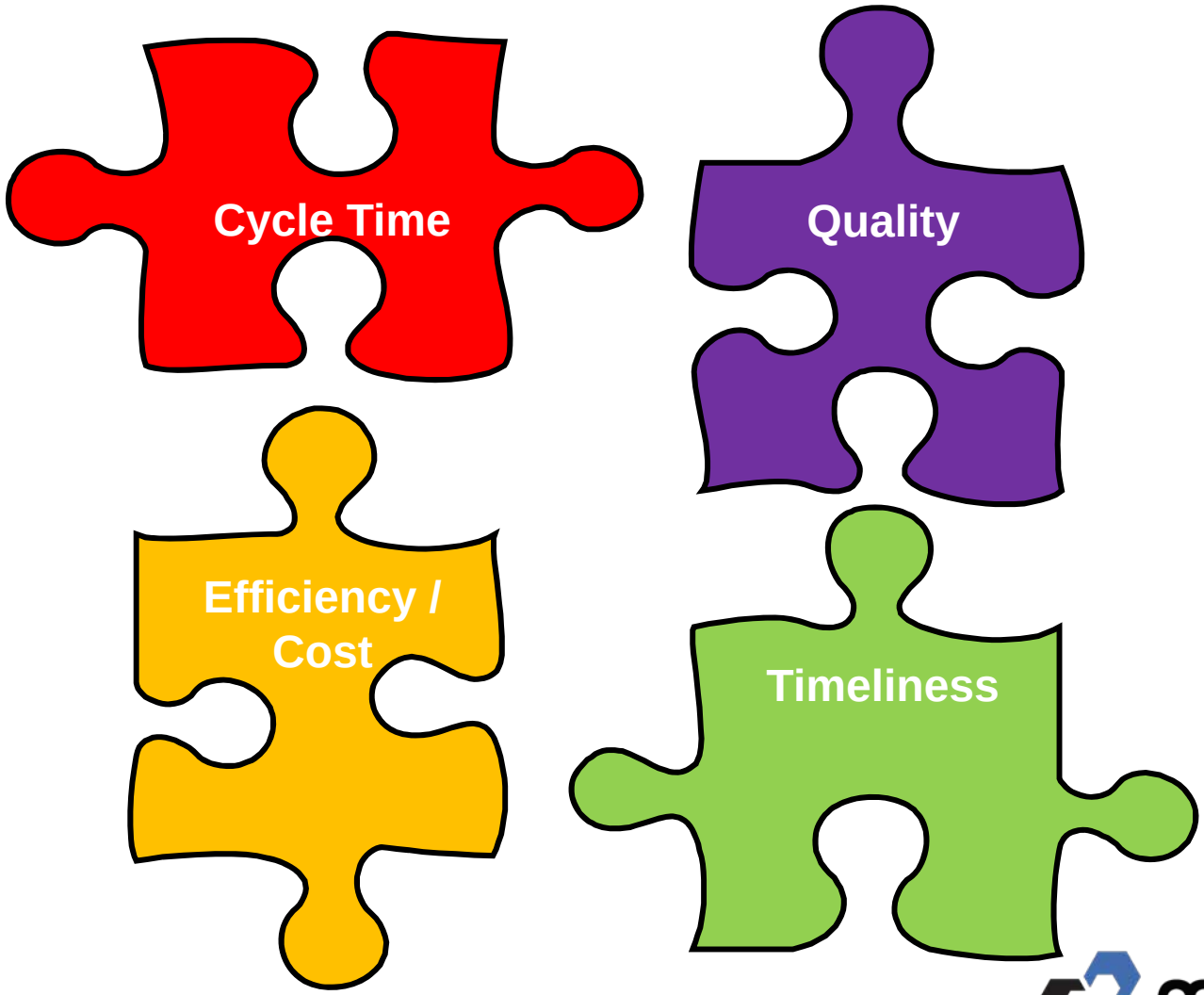
"Not everything that can be counted counts and not everything that counts can be counted."

Albert Einstein

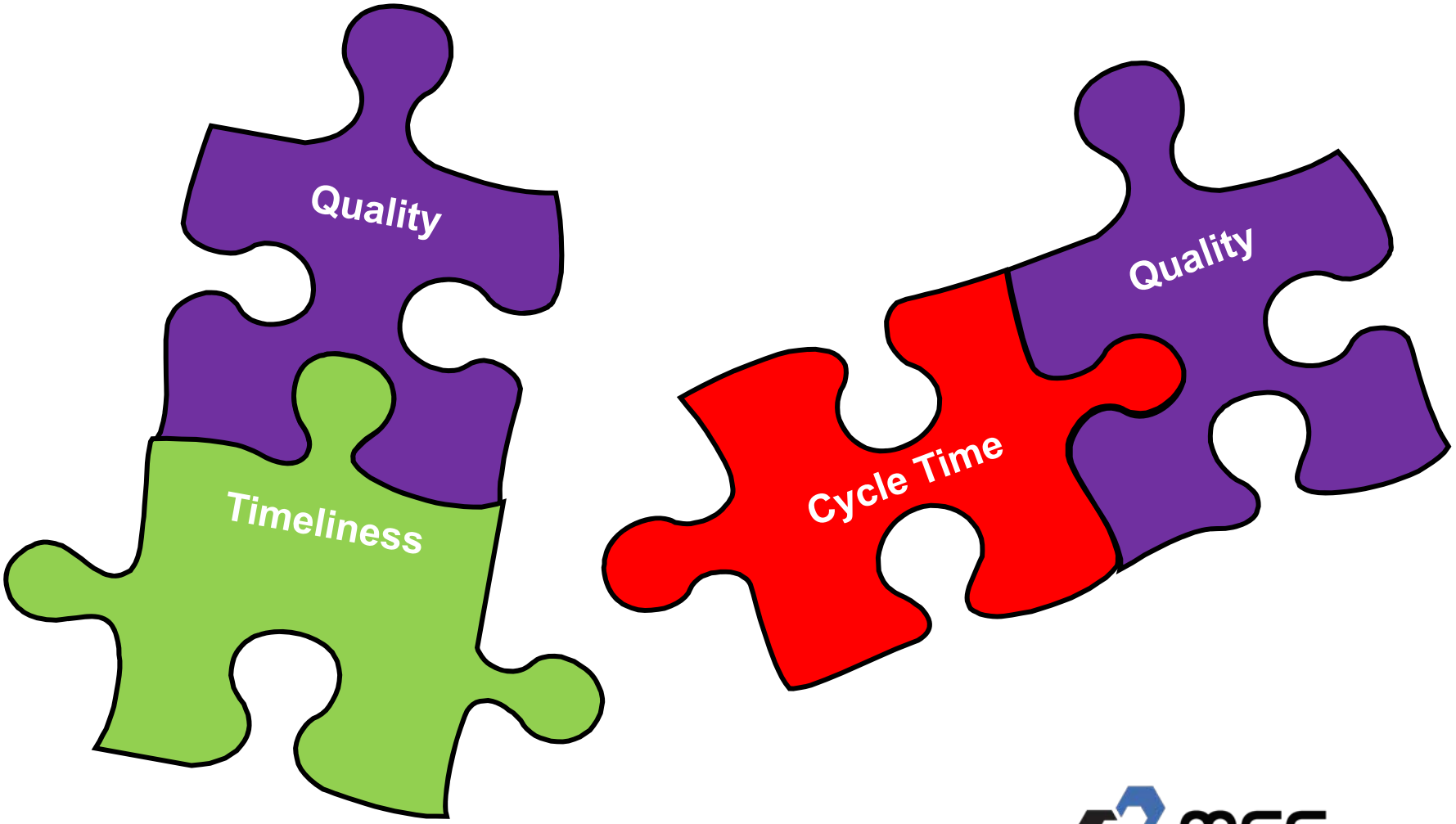
Process Improvement WG

- Reviewed all MCC Clinical Trial Performance Metrics (beta version) re: value for process improvement
- Conducted focused review of Study Start-up activities:
  - created new quality measures
- Developed guidance paper on “How to Use Metrics”:
  - Using the data for improvement and learning
  - Pitfalls eg.
    - Sub-optimization
    - Reacting to common cause variation
    - Losing sight of the final outcome
    - More is not always better
  - How to collect data and report

Types of MCC Performance Metrics

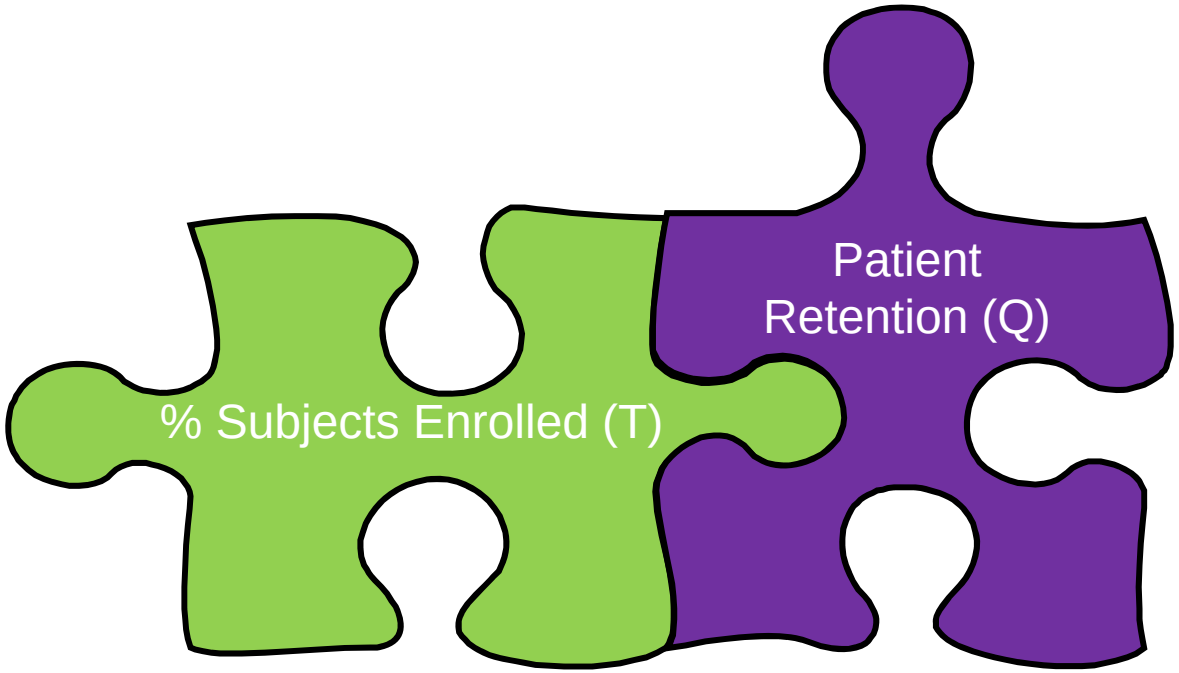


MCC Companion Performance Metrics



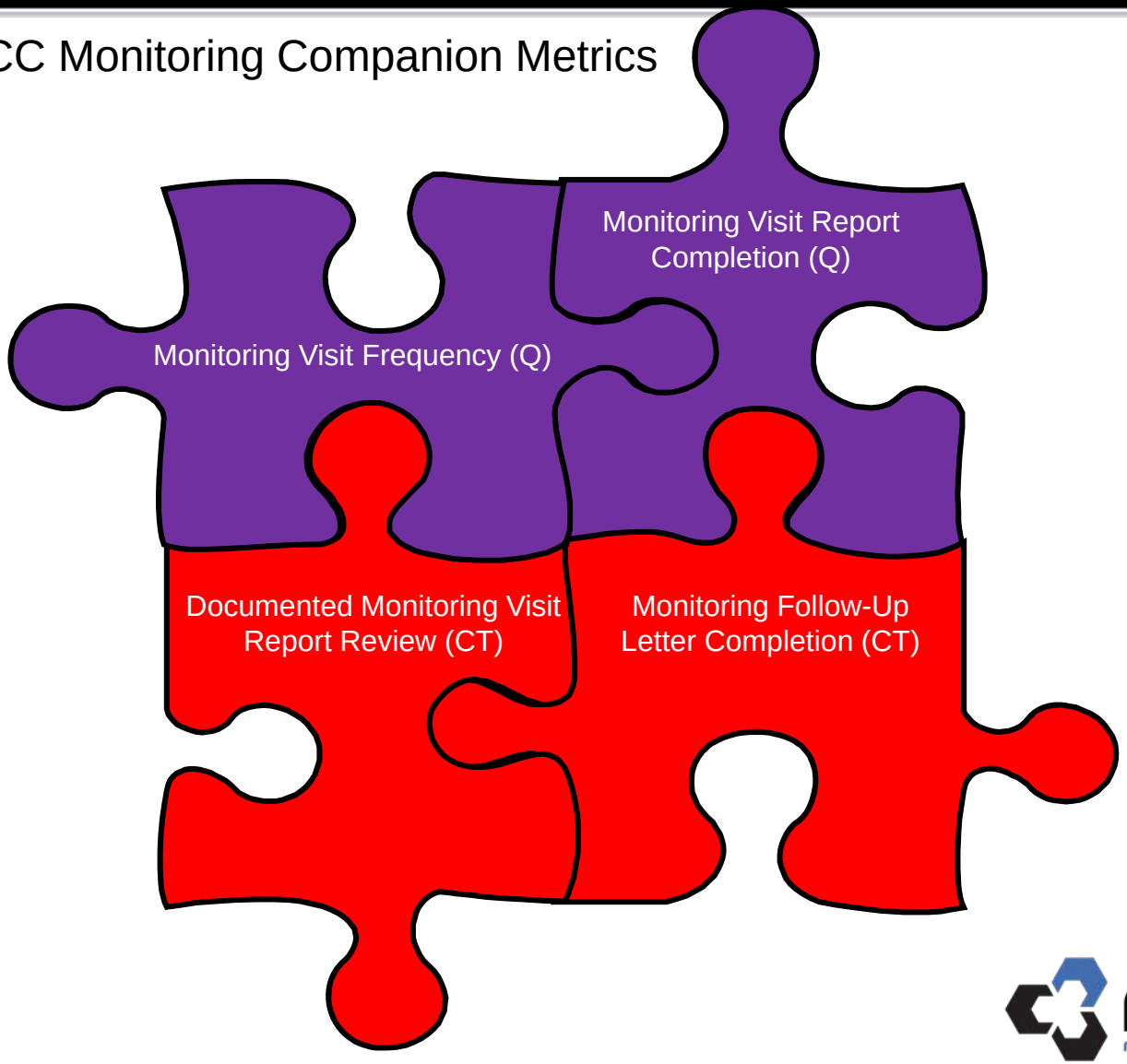
MCC Companion Performance Metrics

Example of MCC Patient Screening and Recruitment Companion Metrics



MCC Companion Performance Metrics

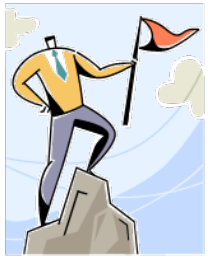
Example of MCC Monitoring Companion Metrics



Process Improvement WG

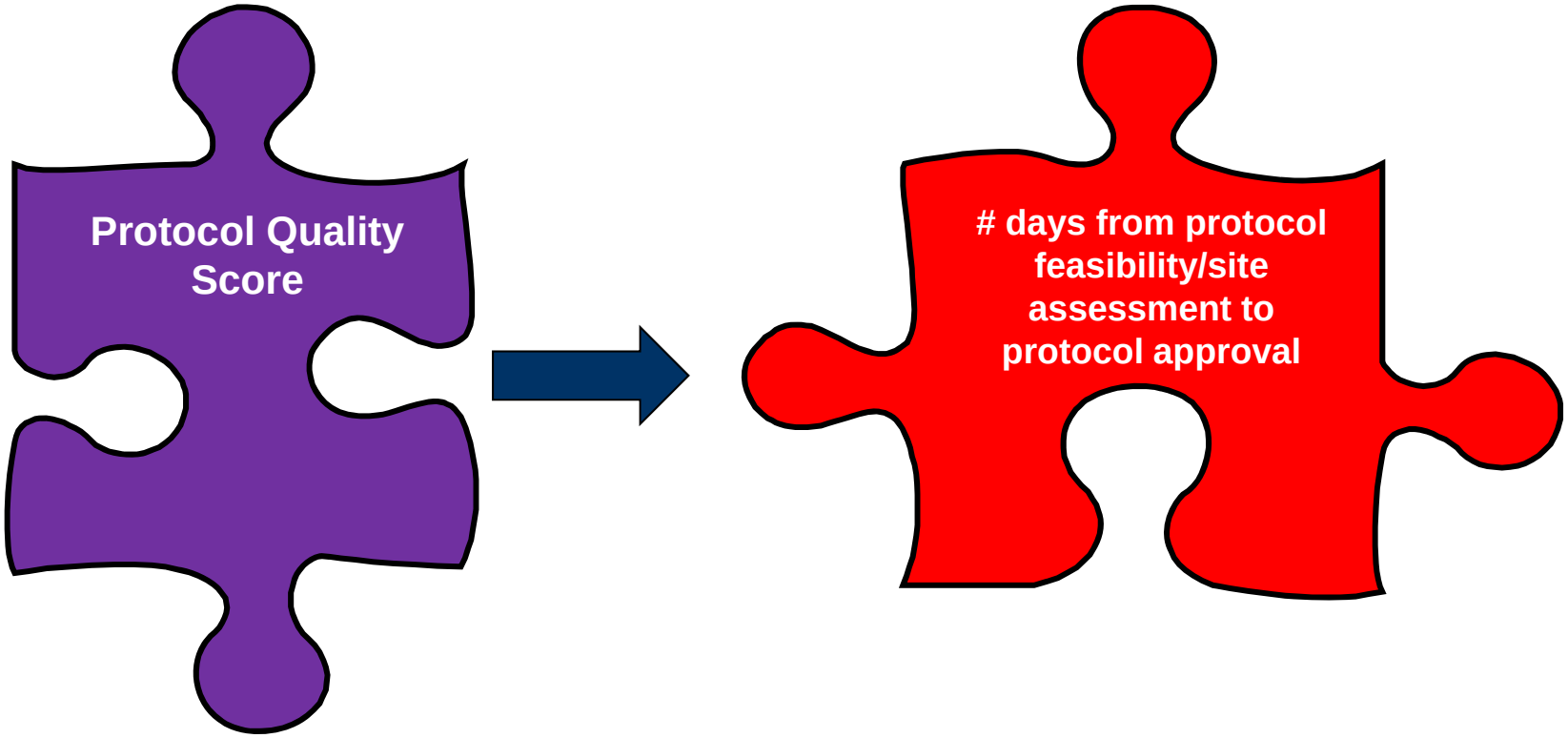
- Focused on study start up process –

High Quality Protocol + **Good Site Selection** = **High Chance of Successful Trial**

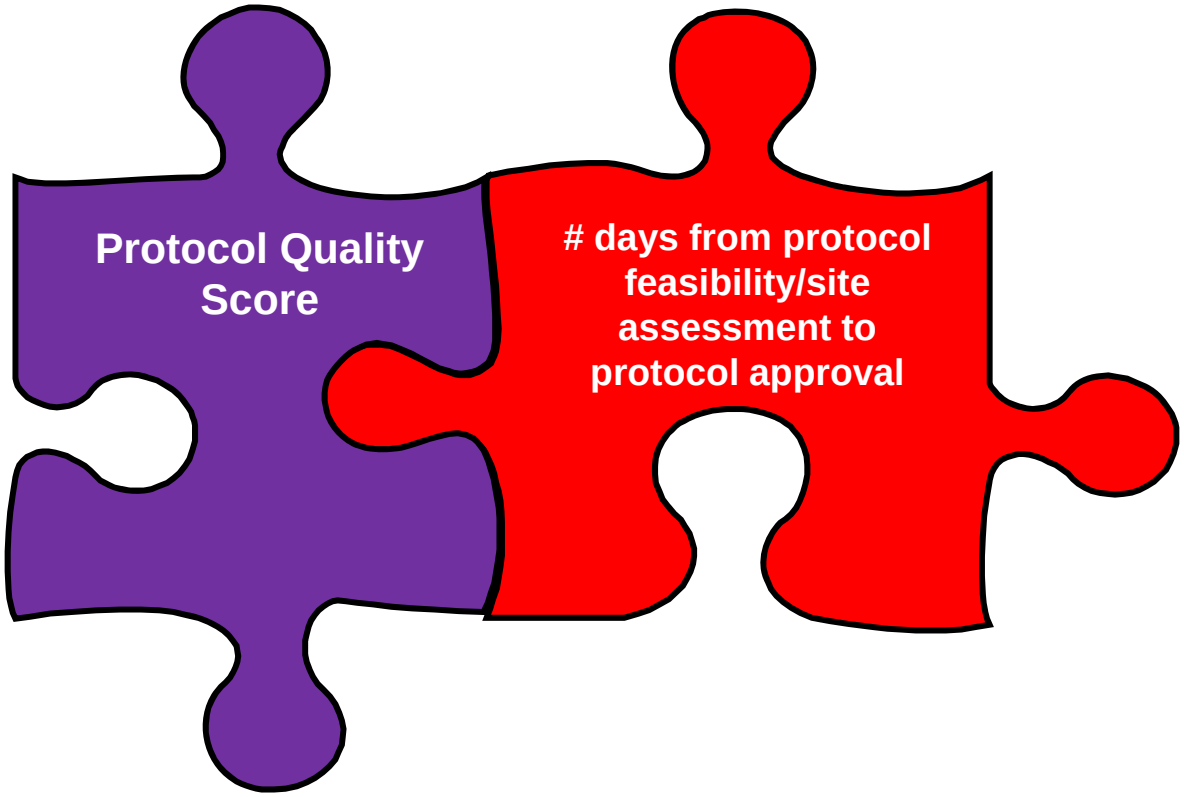


- Concerned that focusing only on cycle-time is likely to sub-optimise
- Defined two new metrics:
  - Protocol Quality
  - Site Selection Quality

MCC Companion Performance Metrics



MCC Companion Performance Metrics



Protocol Quality

Protocol Team answers 7 questions about the thoroughness of addressing:

1. Regulatory requirements/obligations
2. Dosage/formulation
3. Protocol design reflecting clinical practice
4. Study schedule
5. Screening is balanced
6. Procedures is reasonable
7. Protocol-specific equipment and materials availability

Protocol Quality

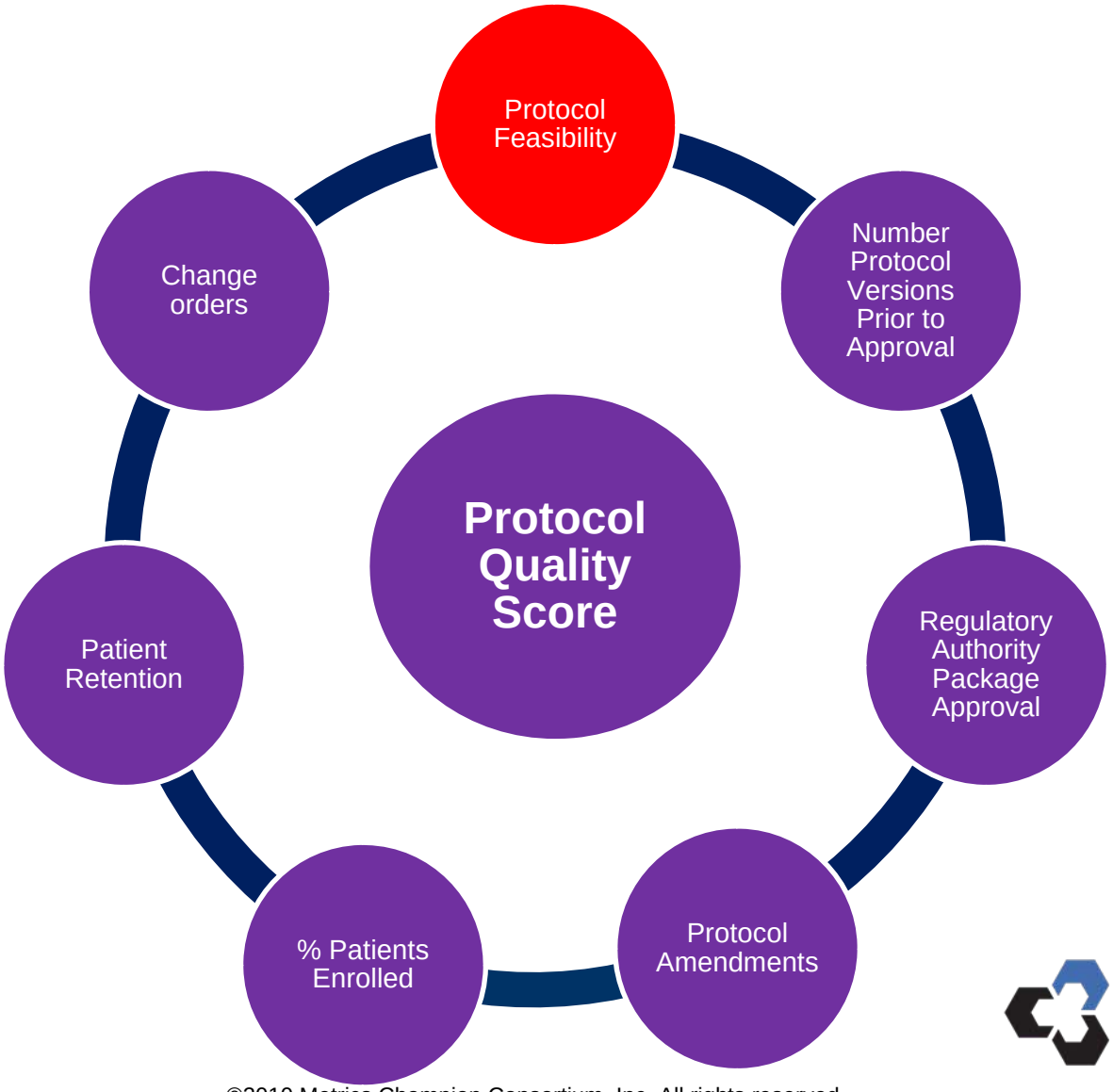
Scoring System

Score	Survey Type	Data Source	Protocol Mod
0	Didn't address this question		
1-3	Protocol synopsis & written feedback	Countries/regions only	None
4-6	Near-final protocol & brief interview	Some sites in some countries	Key mods only
7-9	Near-final protocol & extended interview	Some sites in all countries	All mods made
10	Protocol identical to previous. No risk		

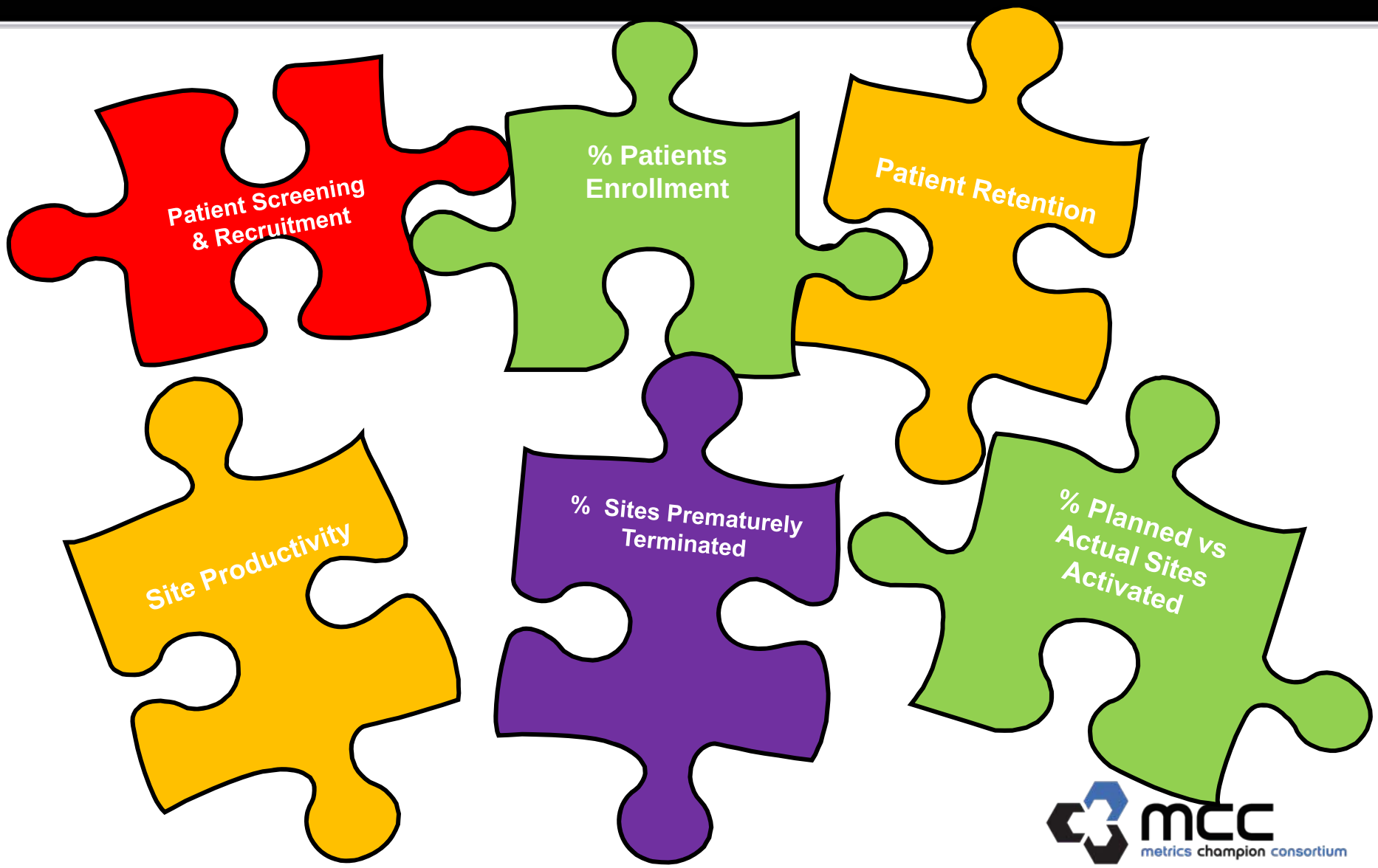
Protocol Quality

- Difficult to measure – but important for success
- Feedback on Protocol Quality metrics very positive:
  - Of 6 teams, 4 rated it as 9 or 10 out of 10 for recommending use to colleagues
  - “I think this tool is extremely helpful and hope that teams will adopt it.”
- Current discussions ongoing on piloting and validating this metric

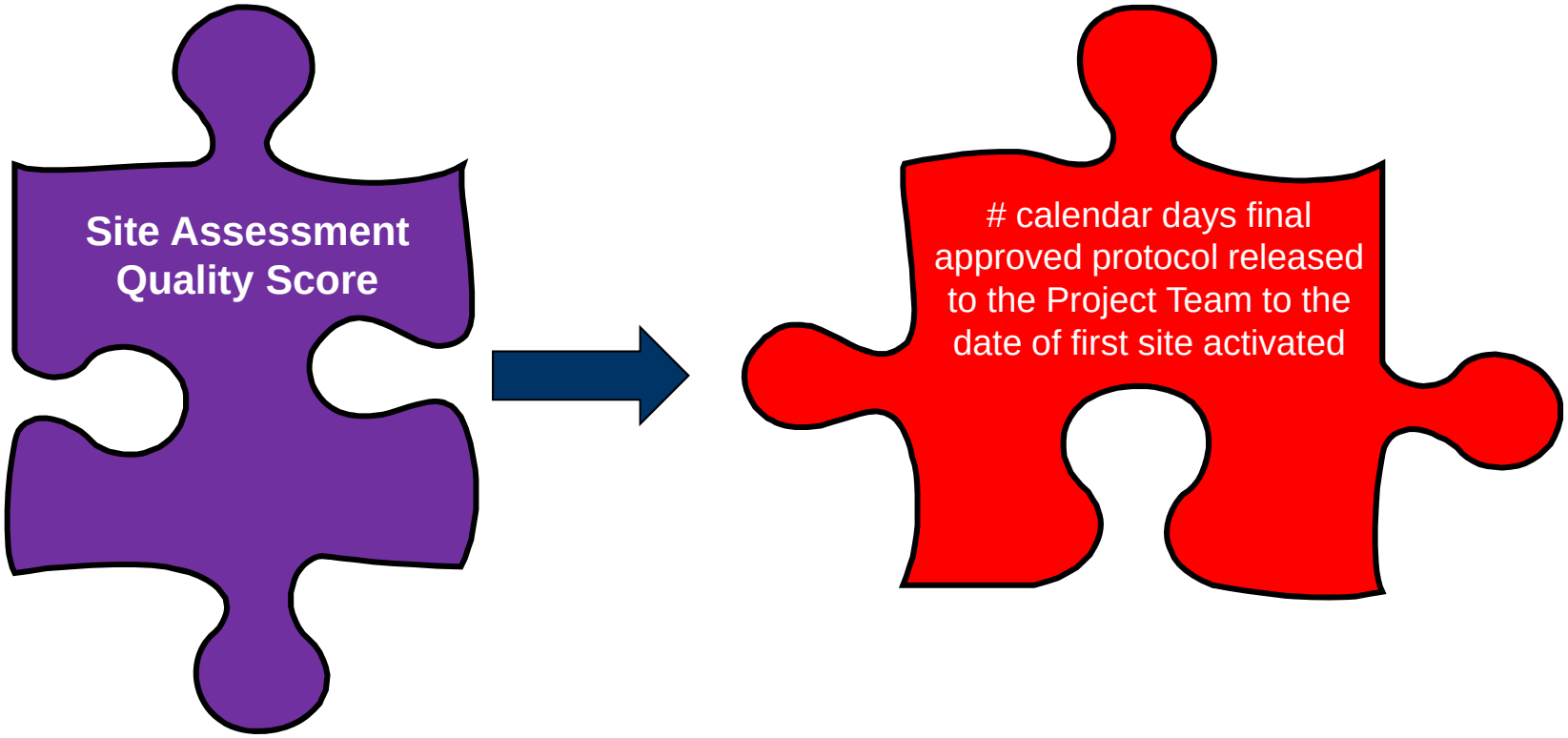
MCC Plans to Validate Protocol Quality Score



Typical Site Metrics



MCC Companion Performance Metrics



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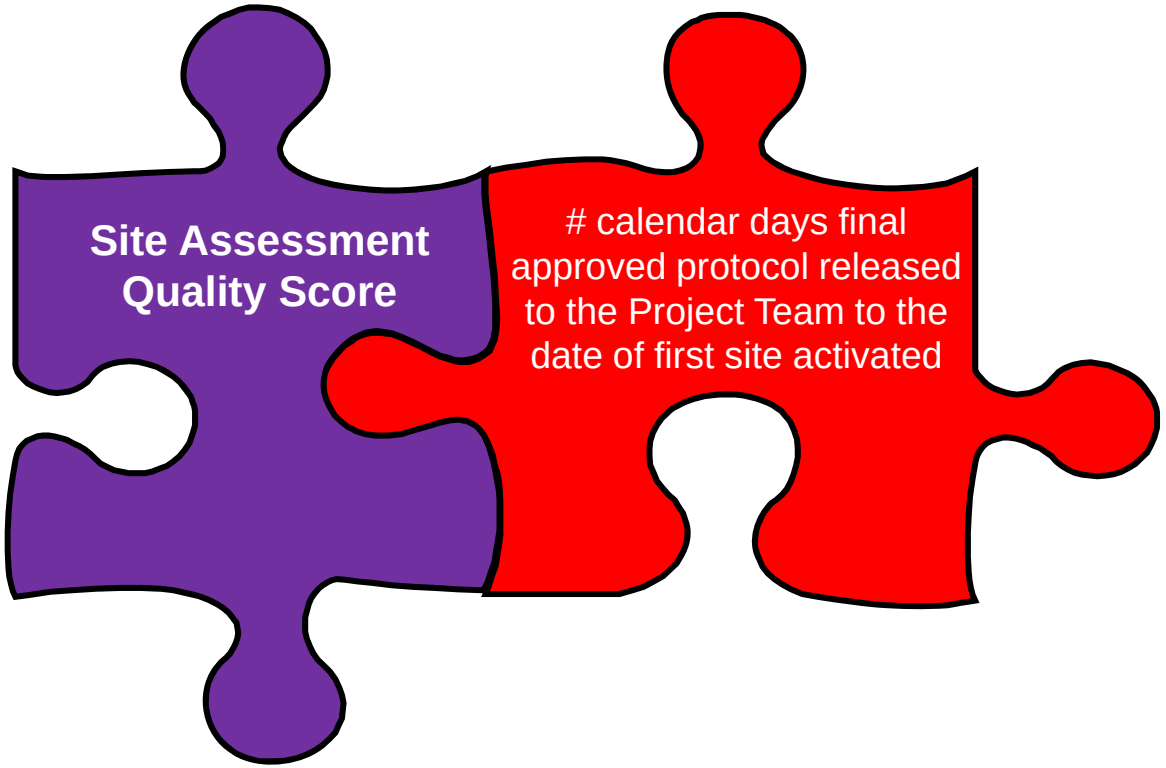


Site Assessment Quality Score

Criteria are weighted and then each site assessed:

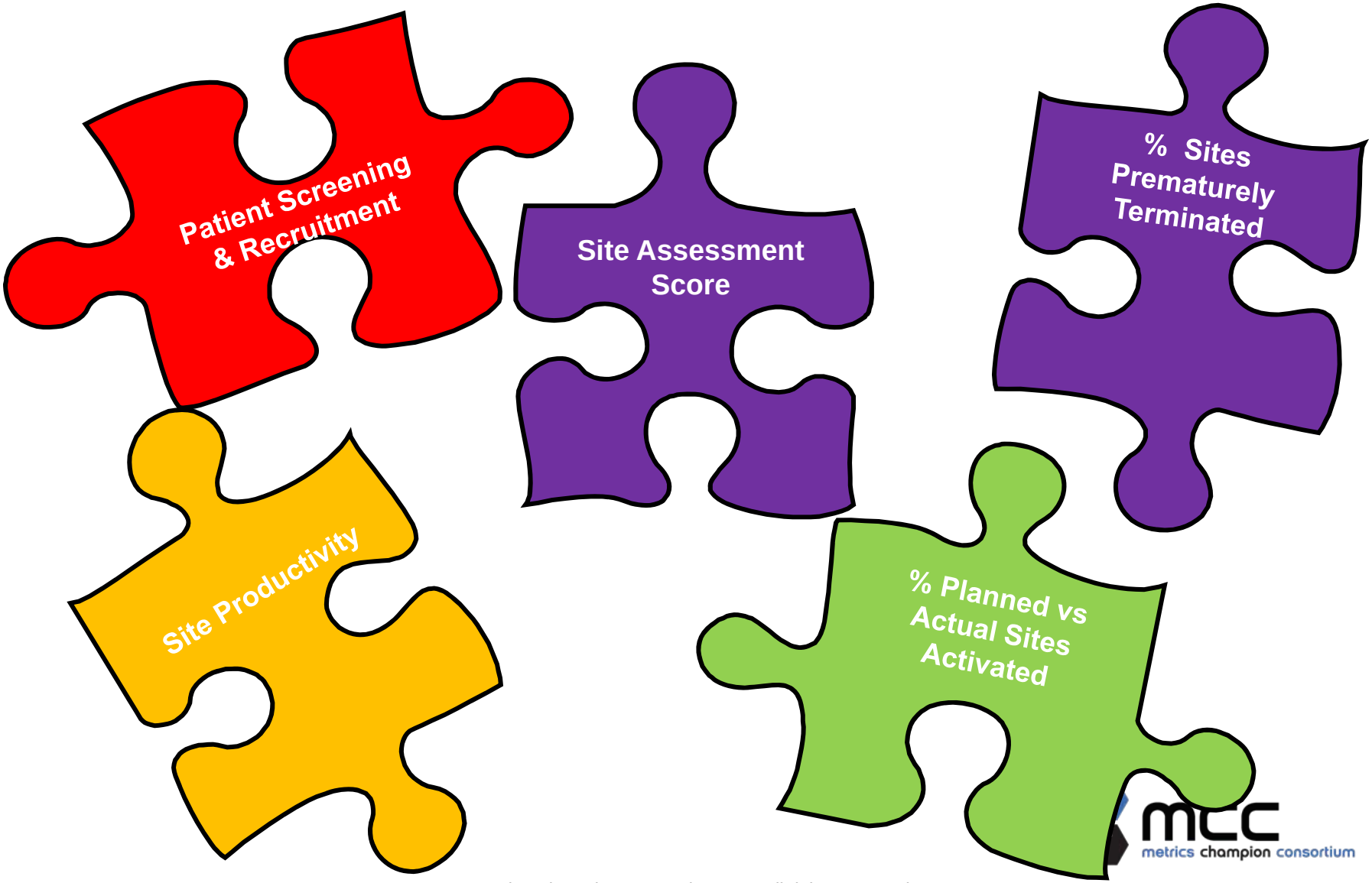
1. Proven ability to enroll subjects for this or a similar indication
2. No competing studies that impact this site
3. Appropriate standard of care
4. Investigator with relevant interest, background and experience
5. Experienced staff
6. Good facilities (including physical & electronic infrastructure)
7. Patient population is accessible and protocol appropriate
8. Can meet study start-up timelines within ethical & legal requirements
9. Proven ability to produce high quality data & is responsive to queries (paper or edc)
10. Site uses recruitment and retention plans

Site Assessment Quality Score

Scoring:

1. Team weights the 10 criteria
   - 1 = Least important for success in this protocol
   - 3 = Key to success for this protocol
2. Key Opinion Leader sites can be excluded from the rating
3. Team scores each site as yes or no for each of the criteria
4. Spreadsheet generates % score for each site
5. Overall weighted score is generated
6. This can then be modified by excluding sites
7. Overall weighted score is also calculated per country
8. Aim is to get a high score with the requisite number of sites

Site Assessment Score Can Be a Companion Metric for Other MCC Metrics



MCC Plans to Validate Site Assessment Score

Quality Scoring Approach

- Difficult to measure – but important for success
- The act of measuring should modify behaviour:
  - Is the team doing what is needed to get the best protocol?
  - Does a site lack skills and need specific training?
  - Have I got enough high quality sites in country X?
- Interest in developing additional Quality Scoring Approach for CRFs and CSRs

This is a paradigm shift for industry and difficult to measure, nevertheless, key to improving overall performance and compliance.

MCC Member Blinded Database

- MCC Board of Directors issued RFP to seek services of experienced metrics database vendor
- MCC is establishing 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

Spotfire Analytics Demo

Conclusions

- MCC Clinical Trial Performance Metrics (beta version) has been updated to version 1.0, which includes:
  - distinct metrics for paper vs edc processes
  - additional clinical operations metrics
  - key terms defined in online MCC Wiki
  - companion metric designations
  - 2 new quality scoring measurements (Protocol development and site assessments)
  - MCC Metrics Guidance Paper
- MCC – CMR International Alliance Partnership will provide MCC Sponsor & CRO Members the opportunity to participate in MCC Member Blinded Metrics Database

mcc
metrics champion consortium

Part II: Breakout Groups

LABORATORY metrics champion

ECG metrics champion

CLINICAL TRIAL metrics champion

IMAGING metrics champion

Breakout Groups

1. What do you see as the benefits to your organization, sponsor/CRO partnerships and the industry of utilizing MCC performance metrics to support/drive change in the drug development process?
2. Who are the stakeholders in your organization that can support the effective implementation and utilization of performance metrics?
3. What are the challenges your organization faces in effective implementation and utilization of performance metrics?
    a. Organizational structure?
    b. Culture?
    c. Technology?
    d. Training?
    e. Resources?

Part III: Incorporating Performance Metrics into CRO contracts

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Metrics: Historical Perspective

- By company approach to metrics
  - Frequently requested
  - Used at the project and functional service level
  - Internal tool with strategy differences at the product level
  - Seldom consistent from project to project
  - Often confusing
  - Mostly misinterpreted
  - Not appropriate for benchmarking

MCC approach

- Well defined including collection, reporting and analysis mechanisms
- Interpretable within and across participants
- Relevant to work performed
- Focused by process and function
- Facilitates cross-industry benchmarking

Rationale for Adopting in Contracts

- Centralized control introduces metrics into all projects
- May be defined once in MSAs
- Discussed in governance (regular discussion promotes better understanding)
- Adopted in working practices (process improvements)
- Adjunct to older internal metrics (but more focused)
- Assists with alignment of resources and goals
  - Timelines, quality gates, costs and reduces COs

MCC Metrics in the Outsourcing Continuum

RFI ⇒ Proposal ⇒ Contract ⇒ Operations

{ Repeat }

MCC Metrics in RFIs

- Distinguish operations based on a set of industry standards for timeliness and quality
  - Present tangible benefits to partner
  - Show where/how efficiencies have been achieved
- Set expectations for future engagements based on industry benchmarks
  - Reinforces marketing messaging with objective measures

MCC Metrics in Proposals

- Use internal benchmarks to identify risk potential in requested support
  - Unrealistic cycle times, inefficiencies in design, or inappropriate resource support levels and unattainable timelines spell trouble
- Propose better solutions based on benchmarked performance

MCC Metrics in Contracts

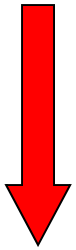
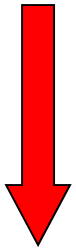
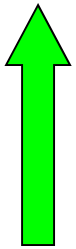
- Target Metrics add definition to scope
  - Cycles and turnaround times
  - Quality gates and rejection rates
- Better comprehension of deliverables expectations
  - Yields more accurate costs
  - Fewer out of scopes and over budget situations
- Define expectations for metrics reporting and output (performance) review

MCC Metrics Contracting Objectives

- Commit to essential metrics
- Adopt business metrics as well as ops metrics to understand cost impact of both business and operational process change
- Provide standard set of measures to compare within company and among partner performance
- Promote relationship management through metrics maintenance in governance
  - Standardization of reporting and performance appraisal leads to open dialog and process improvement
- Provide a platform for benchmarking and process improvement

MCC Metrics in Operations

- Helps identify where process change is needed to improve outcome

Time	Cost	Quality
		
Task execution	Resource use	Tolerance
Metric creation	B-I-C process	TAT
Reporting	B-I-C tools	Risk Management

Desired Outcomes

- Industry-wide definitions make reporting simpler and more efficient
- Metrics analysis helps with root cause determinations for failures
- Benchmarking helps **everyone** do better
- Documented solid performance encourages repeat performances
- Governance promotes awareness
- Non-fit risks may be identified early

Benchmarking

- Application of same metrics to **internal and external** process helps to evaluate process improvement opportunities
- Benchmark metrics can be used to score clients
  - Turn around or response times
  - DSOs
  - Helps identify potentially unrealistic expectations in evaluation of contracting risks

Relationship Management

Use industry-wide metrics to answer RFIs or drive behavior change:

Sponsor RFI Questionnaire:

- “Based upon your expertise, comment on what works well with/for other clients, but has not worked/been implemented with us. Where do you feel we can improve / realize efficiencies?”

Governance & Metrics

- Serves as foundation for operations-level win-win reviews
- Promotes constructive dialog leading to performance improvement
  - Move from provider to partner status
  - Mutually agreed practices or revised and updated SOPs
- Consideration of targets leads to better risk management strategies

Governance


Roles
Interaction
Forum for Executive Exchange
Review of performance metrics
Project timelines: target versus actual
Issue Resolution: Project completion date versus actual
Financial: Budget versus actual
Review of relationship
Resolve escalated issues
Meet 1-2 times per year or as needed
Steering Committee
Key project reviews
Critical issue reviews
Resource allocation
Quality (discussion of audit reviews, setting of standards)
Meet quarterly, or as needed
Operational Management Team
Review trial specific budget
Ongoing resolution of issues/questions
Resolution of trial specific issues
Meet as required: daily, weekly
Project Teams
Process Improvement
Metrics Analysis

Case Study #1

Labs Metrics: Getting Started

Getting Started

- Identify essential metrics from MCC list
- Review and agree definitions
- Test sources of data
- Refine reports and set frequencies for delivery
- Plan for meetings to discuss results
- Establish contracted obligation
- Iterative process so expect and accept change
- Be alert for divergence

Identify Essential Metrics

MCC Central Lab Metrics v 1.1

Metric	Category	Metric Title	Definition^	Reason for changes in v1.1
4	Data Cleaning	Percentage of queries from central laboratory to site based upon requisitions received	**Minimum:** The number of queries generated between the central laboratory and the sites, compared to the number of requisitions received by a central laboratory. **Additional analysis on a "for cause" basis:** a. The number of queries generated between the central laboratory and the site, compared to the number of requisitions received for a site, protocol, sponsor, and central laboratory by business unit. b. The reasons which resulted in these calls by central laboratory defined by site, protocol, sponsor, and central laboratory by business unit.	This metric was refined to reflect the organization's overall ability and track record in query levels across all their studies. Sponsor level and study level are optional additional metrics.
5	Data Cleaning	Average turnaround for resolution of queries from central laboratory to site	**Minimum:** Average time required for resolution of queries from central laboratory to site based on the requisitions received by a central laboratory. **Additional analysis on a "for cause" basis:** The amount of time required to resolve these queries by reason for a site, protocol, sponsor, and central laboratory by business unit.	This metric captures the time to resolve the queries by the lab across all their studies. Sponsor level and study level are optional additional metrics.
6	Site Support Services	Percentage of queries from site to central laboratory based upon requisitions received with average turnaround time	**Minimum:** The number of queries generated between the site and the central laboratory, compared to the number of requisitions received for a sponsor and central laboratory, and the average time to resolution **Additional analysis on a "for cause" basis:** The number and type of queries generated between the site and the central laboratory, compared to the number of requisitions received by protocol.	Type of query was added to this metric as a clarifier for the reasons why the queries are occurring. Title, formula, and target were clarified to match the benefit statement.

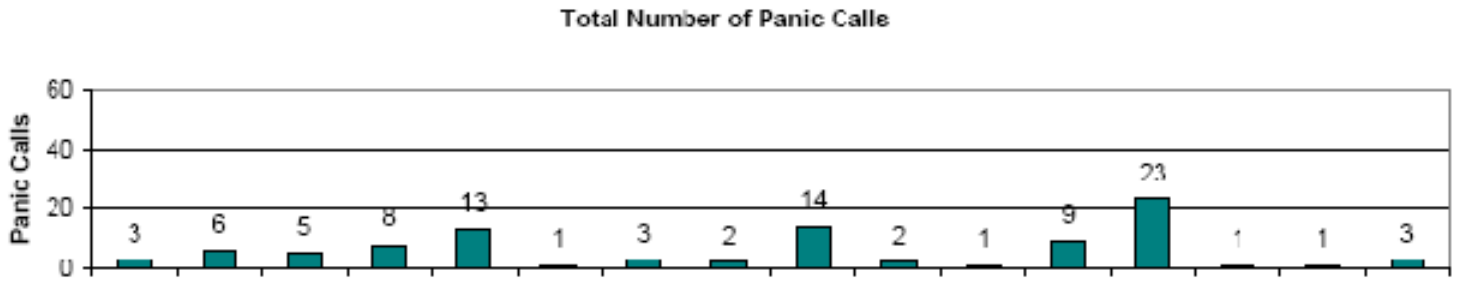
Metrics Reporting

ICON Central Laboratories METRICS

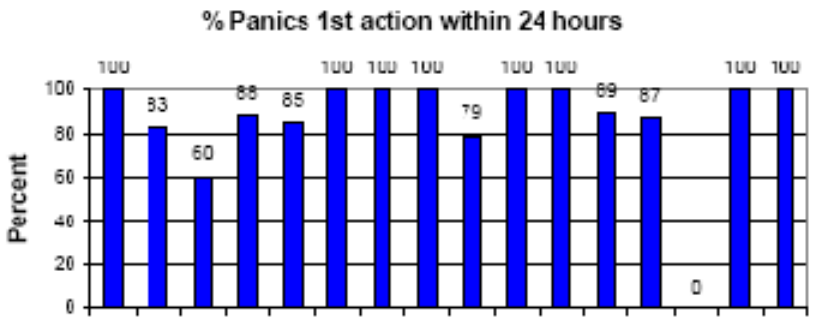
Print Date: Report Description: **2009-Q1**	ICON Central Laboratories (ICL) have begun the initiative of providing quarterly metrics based on Central Laboratory Metrics Consortium's Guidelines. We, in partnership with our Clients, are now providing the 5 most important of the Standard MCC Metrics to evaluate study success. ICL has committed to continuing to deliver those Standard MCC Metrics that are deemed useful for your use in the future.

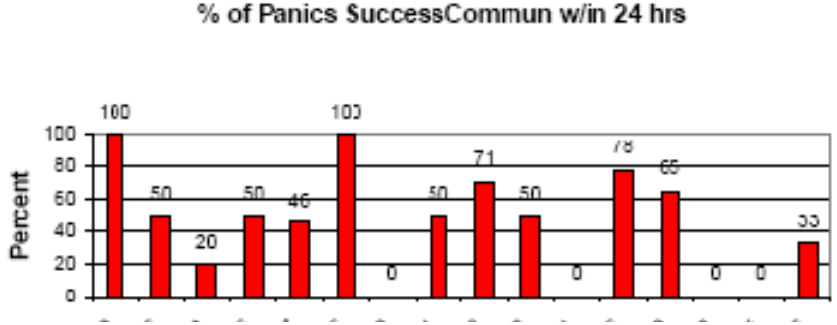
Metrics Report for Sponsor A 2009-Q1

Metric	Category	Laboratory Metrics Champions Definition (v2.0)	ICL Definition (per study/ per Quarter)	Unit of Measure	Target
4	Data Cleaning	The number of queries generated between the central laboratory and the sites, compared to the number of requisitions received by a central laboratory.	The number of visits that needed an outgoing query to sites, compared to the number of total visits received by ICL.	Total N and Percentage	<20%
6	Site Support Services	The number of queries generated between the sites and central laboratory, compared to the number of requisitions received for a sponsor and a central laboratory.	The number of incoming queries generated by sites, compared to the number of total visits received by ICL.	Total N and Percentage	>95%
8	Safety	Percentage of panics that had both 1st attempt made and were successfully communicated to the sites within the defined turnaround times overall by sponsor and central laboratory.	Percentage of call lists that contained at least one panic value that had an action and have been successfully communicated to the site. Successful communication is defined by either an email reply, signed fax, or repeated value telephone confirmation. (Note that values are not limited to business days or hours and therefore Sunday data is represented in totals)	Total N and Percentage	>95%



Project Numbers Deleted





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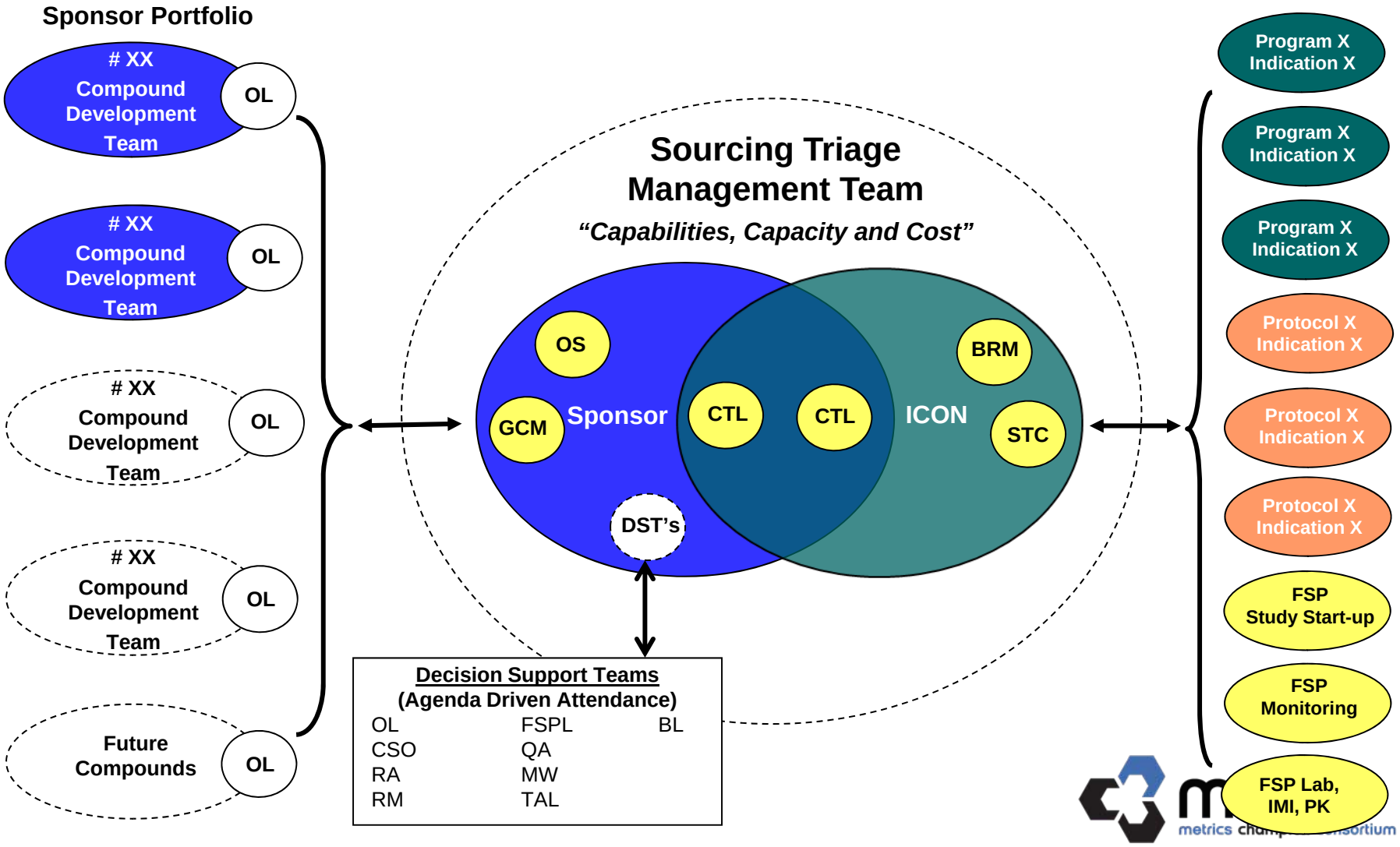
Discuss: Leverage the Sourcing Strategy



Apply Governance

- Governance active in deciding which metrics will be used to measure health of relationship
- Contracted metrics collected at operations level and reported up to operational and business leadership
- Analysis of trends is formalized as agenda in Governance meetings
- Executive Leadership in Governance drives transformational change into partnership

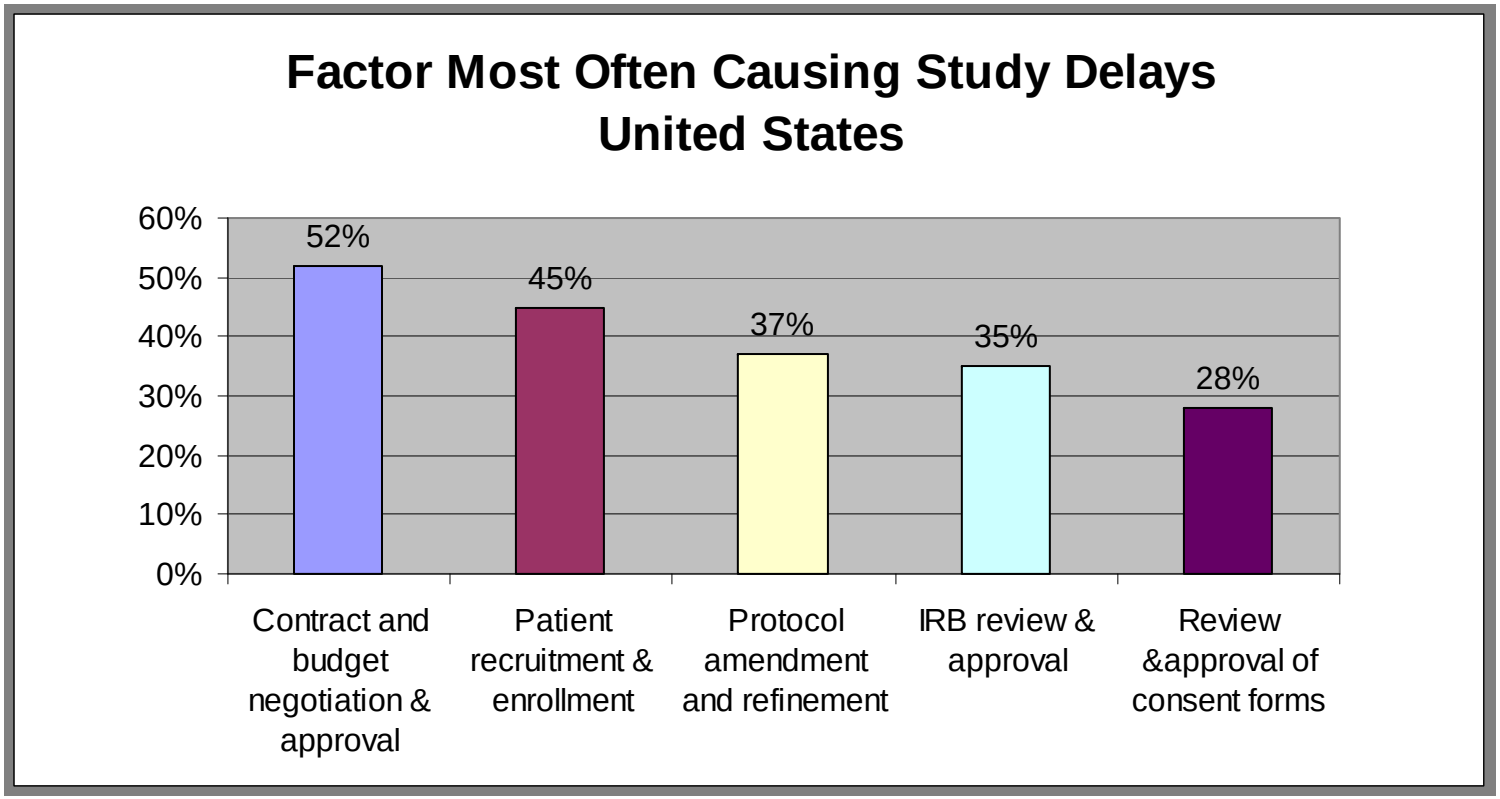
Learnings

- Not all metrics can be reported without systematic or programmatic change
  - Assess cost/benefit
  - Accept? redefinition è divergence
- Understand the root causes for failures when considering performance
  - e.g., ACP definition for completed lab contact for panic value is different from industry
- Use program to improve process
  - We have instituted Sunday staffing in ICL for panic reports
  - Does not improve metric but improves outcome for patient

Case Study #2

Functional Services Contracted
Metrics Driven Process
Improvement

Identify Relevant Processes



Source: Thomson CenterWatch 2005 Survey of 612 Investigative Sites in the U.S.

Case Study: Reg Docs Approval

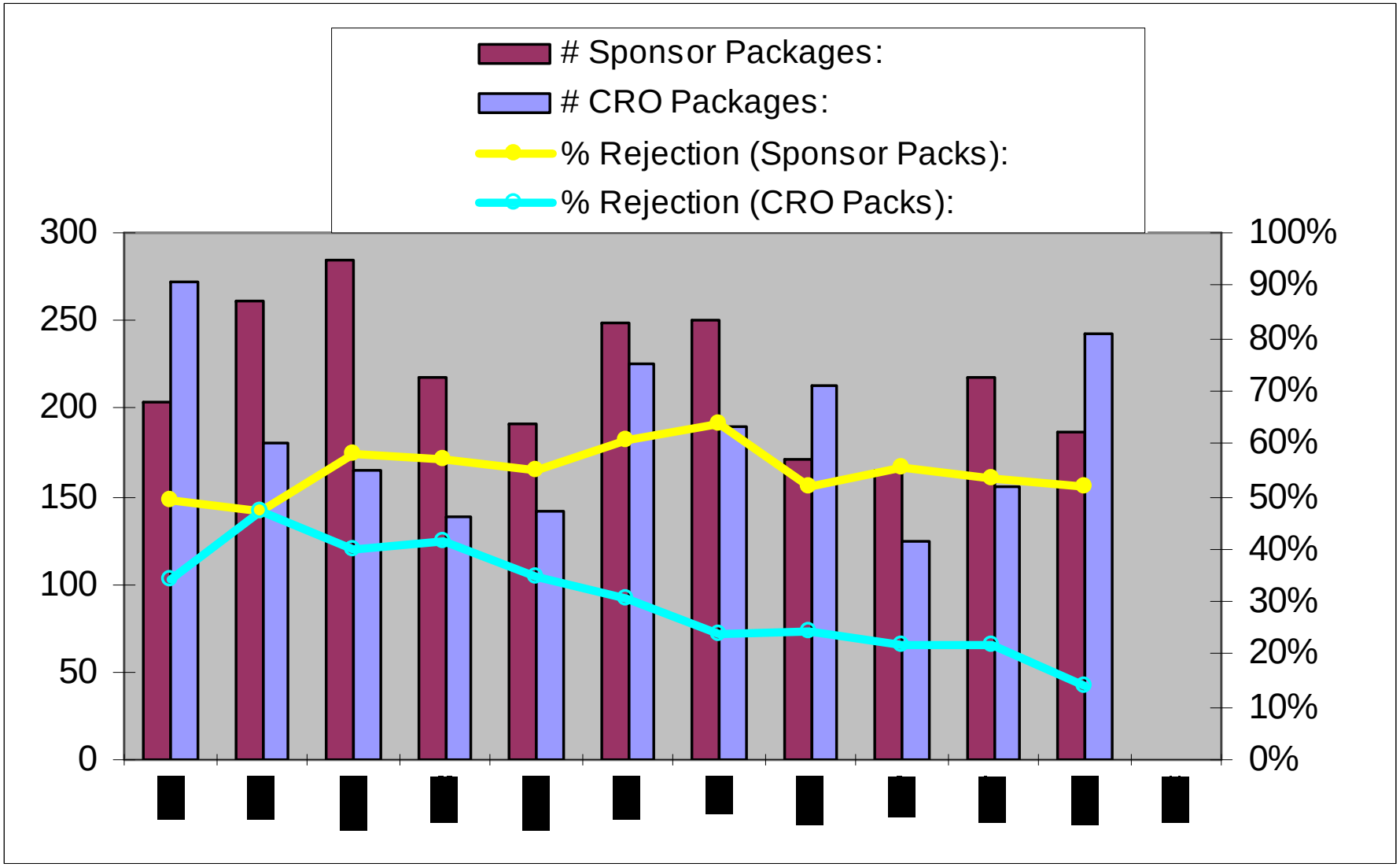
- Observation
  - Regulatory packages approval is rate limiting to start-up
- Contracted Essential Metrics
  - Cycle time for approval
  - Rejection rate

Contract features

- Functional Services
- Approval rate target
- Turnaround target
- Continuous improvement incentive
- Monthly metrics reporting
- Governance Board
  - Monthly functional review
  - Quarterly management review

CLINICAL TRIAL metrics champion

Metrics Data



Outcomes

- Internal and external benchmarking identified process improvement opportunities
- Significant improvement in cycle times and lowered rejection rates resulted
  - For Sponsor – faster start-up
- Sustained quality improvement achieved by CRO
  - Reduced oversight (and headcount) required by Sponsor
  - Incentives achieved by CRO
- Expanded assignment of work to CRO

Outlook for use of MCC Clinical Metrics

Viewpoint for adoption of MCC

- Overall, the industry has to become more efficient
  - Drowning in data: starved for information
- To improve efficiency, we must characterize and benchmark the baseline
- Industry must pull standardized metrics into its contracting tool kit
  - Similar to TORO, TOM, etc.
- Business metrics will be valuable when analyzed in tandem with operational metrics
  - e.g., Metric #27 (change orders) as related to operational process (protocol finalization before/after proposal, feasibility before/after proposal, etc)

Viewpoint cont'd

- Cross Industry collaboration has improved MCC beta version
  - Definitions and reporting
- Centralized metrics reporting will help the industry become more efficient by identifying better practices
- Best practices should be shared to improve industry performance
- MCC provides a new level of information sharing for the Industry

Questions?

Part IV: Breakout Group Feedback

Breakout Group Feedback

1. What do you see as the benefits to your organization, sponsor/CRO partnerships and the industry of utilizing MCC performance metrics to support/drive change in the drug development process?

- ID Process Improvement targets
- Common language for contracts
- ID of new metrics (Q)
- Decision drivers for future relationships
- Drive process improvement across projects
- Start up efficiency
- ID gaps and issues
- Share best practices
- Reduce oversight
- Real time analysis
- Facilitates discussions
- Quantitative / Qualitative
- Standardization of review

Breakout Group Feedback

1. What do you see as the benefits to your organization, sponsor/CRO partnerships and the industry of utilizing MCC performance metrics to support/drive change in the drug development process?

Sponsor	CROs

• Adoption/Standardization
• "Internal market" to collect metrics
• FDA compliance acceptability
• Help relationship with common platform
• Common language to measure all vendors
• Cut through "metrics fog"
• Work group dialogue
• Improvement in execution A-Z (in – sourced)
• No blame
• Quality / auditable
• Reduce errors / variability
  – before, not after
• Benchmarking made easier
• Setting industry expectations
• Better understanding of what you can get or due
	• Consistency
	• Realistic project management & decrease risk
	• How performance is evaluated helps motivation
	• Continuous process improvement
	  – fact based, objective criteria
	  – reduces variability
	• Customer satisfaction
	• Competitive edge
	• Showing – yes we can
	• Better definitions
	• Standard expectations

Breakout Group Feedback

2. Who are the stakeholders in your organization that can support the effective implementation and utilization of performance metrics?

- Senior Mgmt
- Corporate / regional /local reps
- VP Clin Ops
- Finance
- Procurement / Contracts
- Clinical directors
- Therapeutic area head
- Functional lines
- Global project manager
- IT
- Quality
- Sites

Breakout Group Feedback

3. What are the challenges your organization faces in effective implementation and utilization of performance metrics?

- Senior leadership buy-in
- Business structure
- Governing body
- Increasing expectations for excellence
- Resistance to change
- Agreement of definitions
- CRO want to be unique
- Varying data sources
- Utilizing metrics to make decisions
- Process improvement vs “punishment”

Breakout Group Feedback

3. What are the challenges your organization faces in effective implementation and utilization of performance metrics?

- Internal/external factors
- Infrastructure – IT/Logistics/Technology/Systems
- Budget
- Quality metrics can be difficult
- Communication
- Multiple providers: agreement on criteria
- Training
- ROI - value
- Procurement vs Ops
- Big Pharma vs little pharma
- Number of metrics: core vs too many

mcc
metrics champion consortium

Part V: Q&A Panel Discussion

LABORATORY metrics champion
ECG metrics champion
CLINICAL TRIAL metrics champion
IMAGING metrics champion