



Deploying Process Improvement and Quality Metrics that Fundamentally Improve the Clinical Drug Development Process

Keith Dorricott
Director, Quality Improvement, i3 Research

Linda Sullivan
VP of Operations, MCC

Dave Zuckerman
President, Customized Improvement Strategies, LLC

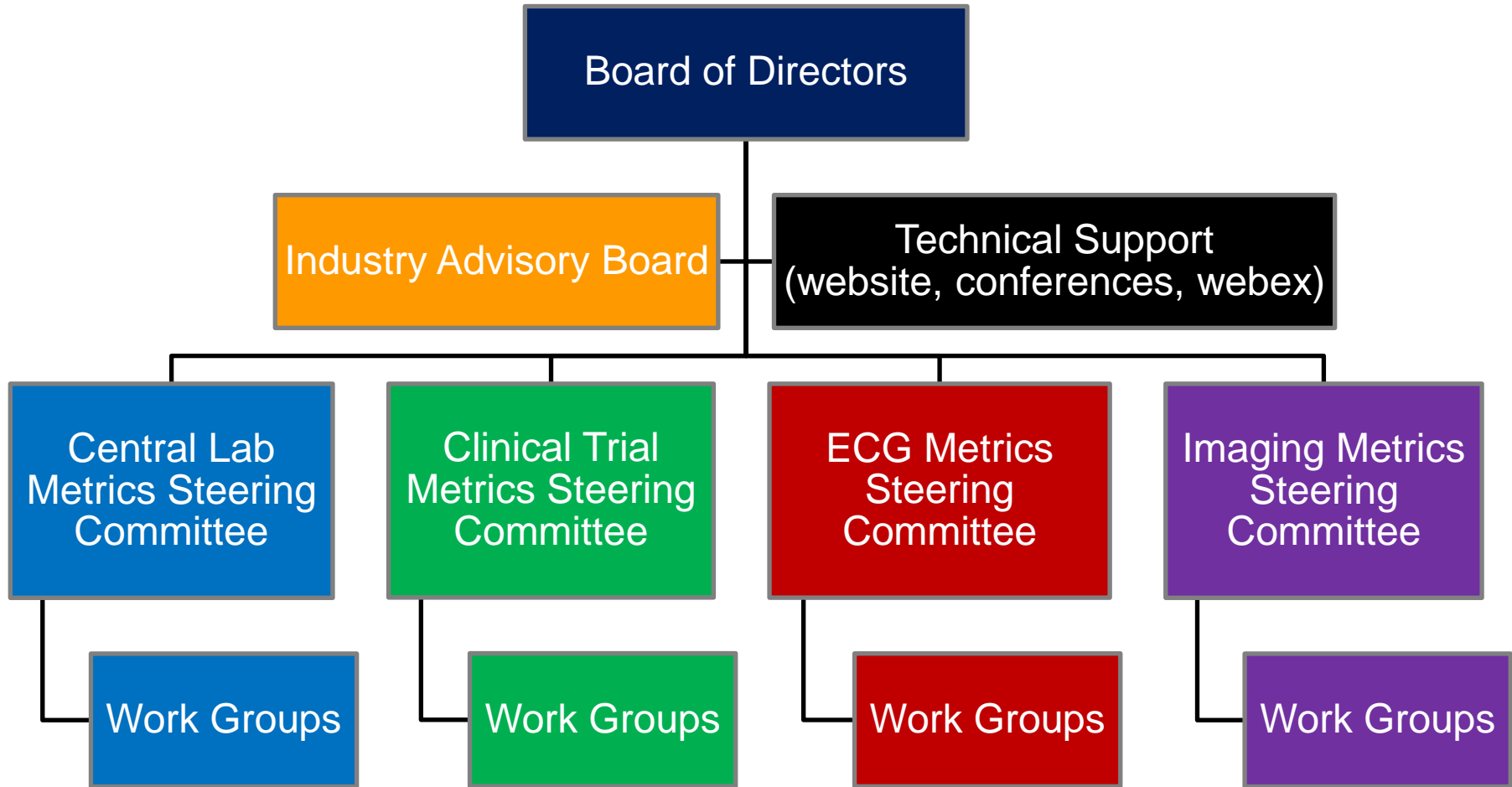
March 24, 2010

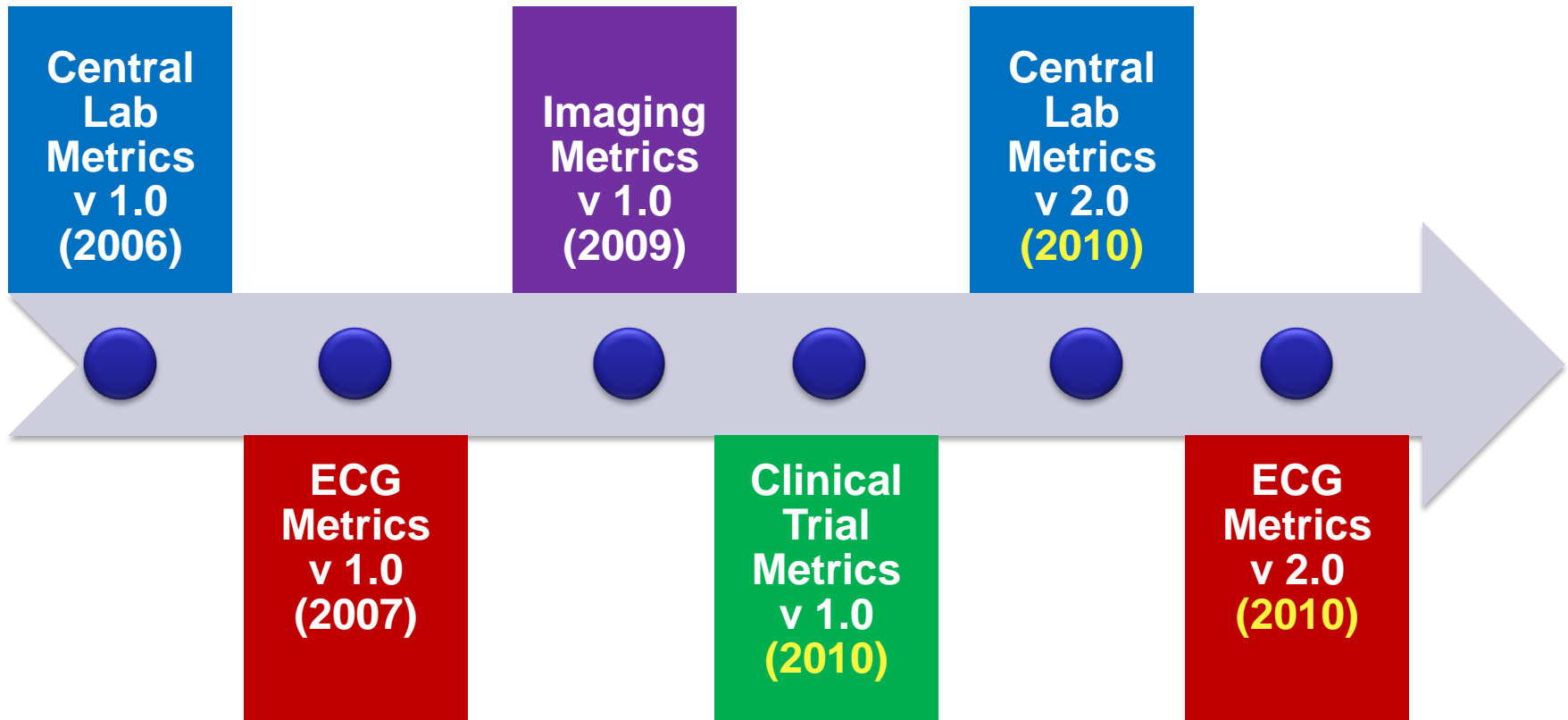


- MCC Overview
- What are the pitfalls of current industry metrics?
- What are some new approaches to measuring quality?
 - Site Selection
 - Protocol Writing
- How will organizations pilot and deploy these new metrics?
- How will new metrics impact protocol and product development performance?
- Conclusion

A group of biotechnology, pharmaceutical and service provider organizations helped form a not-for-profit organization, the Metrics Champion Consortium (MCC), where member organizations 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.

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 drug development process.







MCC Clinical Trial Performance Metrics



Clinical Trial Metrics Steering Committee

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

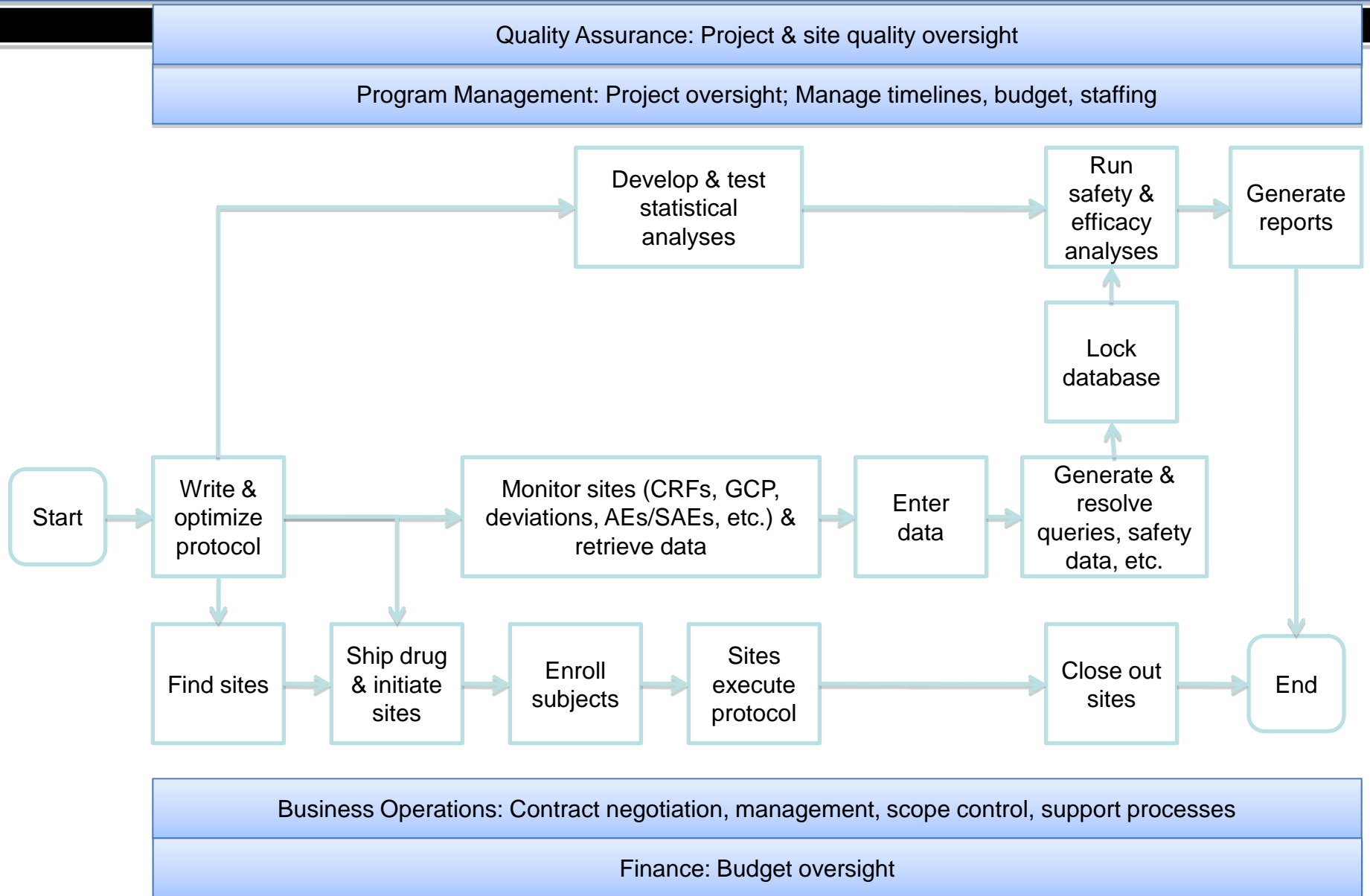
Proposed Metric - Qualities

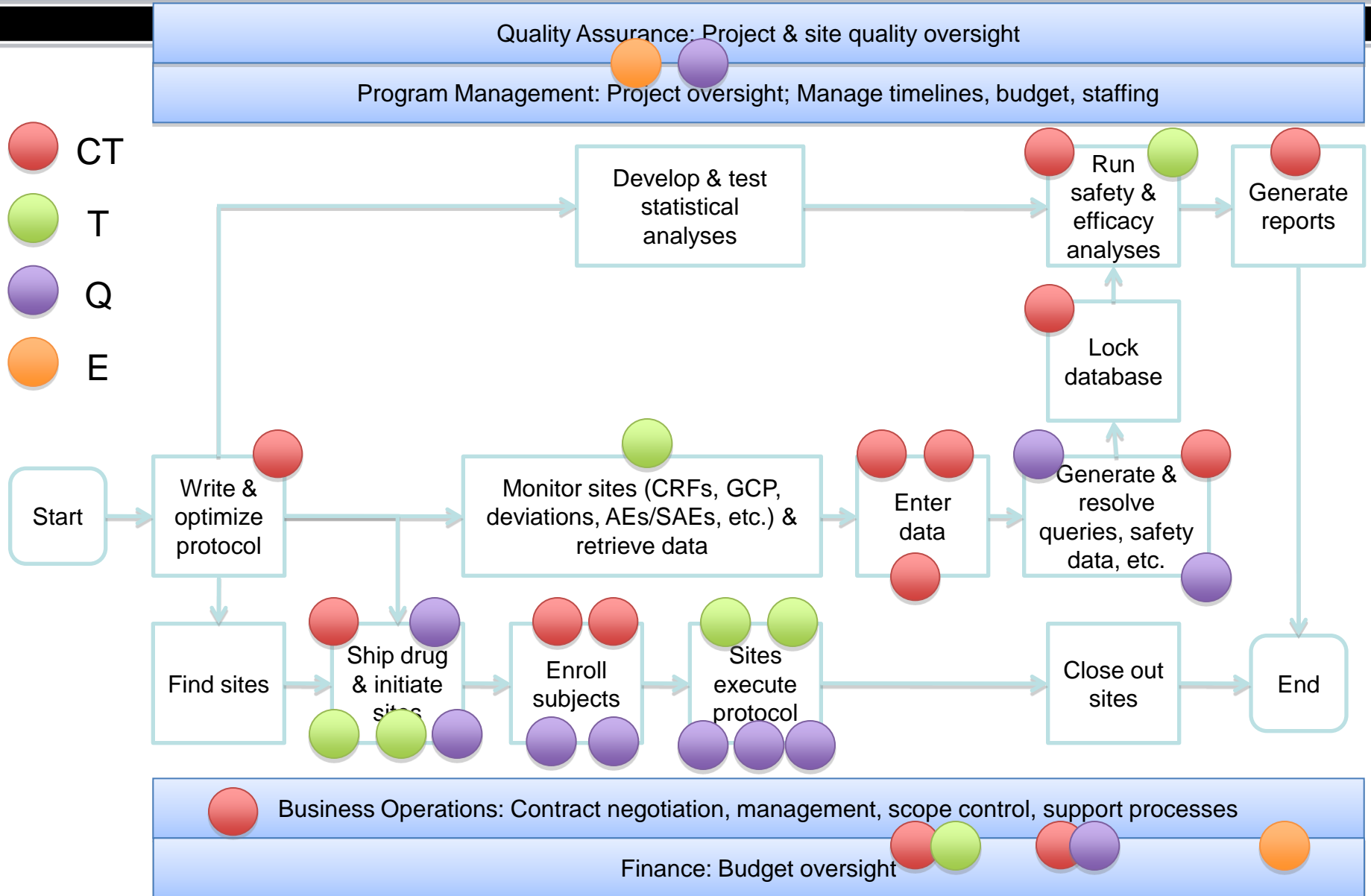
- Well defined
- Be measurable
- Be high level – but allow for further analysis
- Provide a benefit to Sponsor and Service Provider
- Add Value

Proposed Metric – Qualities

- Timeliness (T)
- Cycle Time (CT)
- Efficiency / Cost (E)
- Quality (Q)
- Leading Indicator - Lagging Indicator
- Business Driver / Benefit Statement
- Relationship metrics will be added in future version

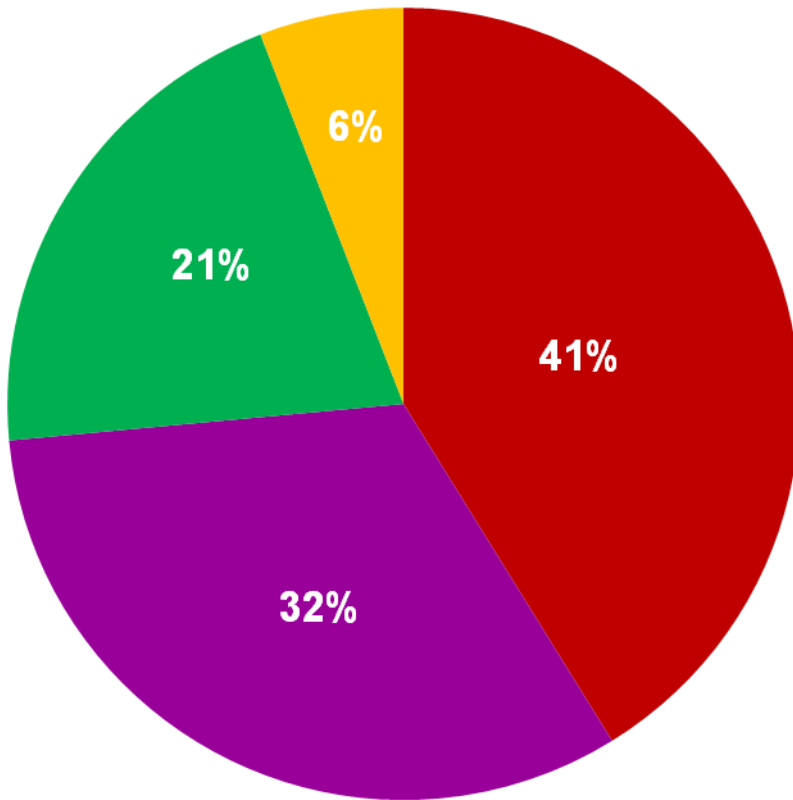
Typical Trial-Level Process



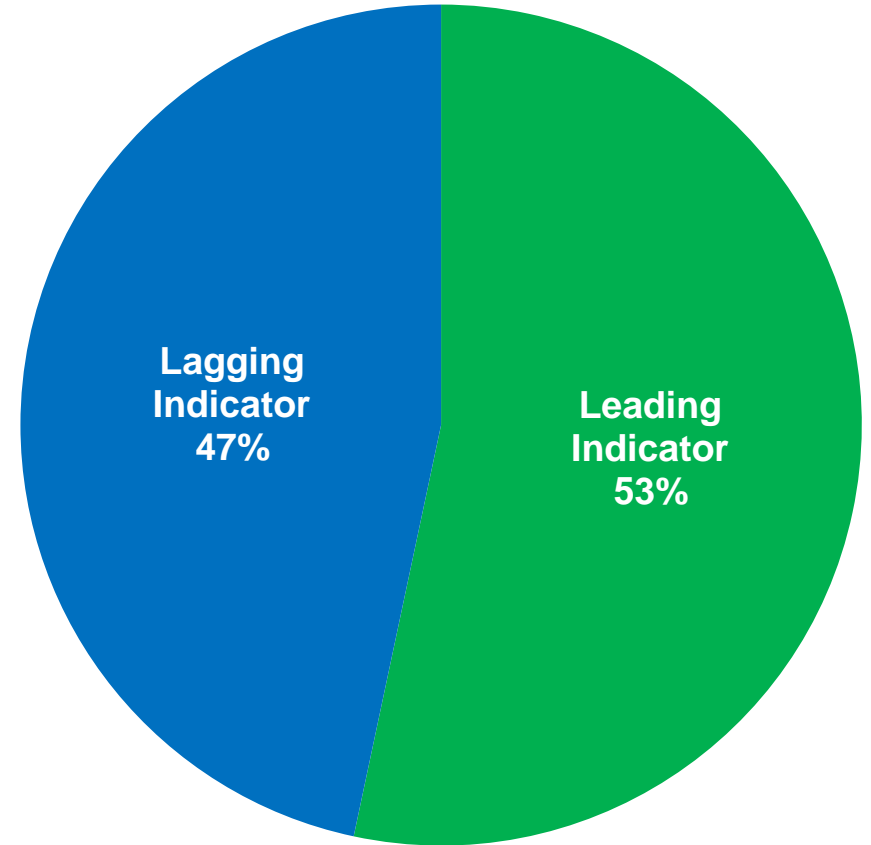


Beta Metrics - Metric Types

■ Cycle Time ■ Quality ■ Timeliness ■ Efficiency



Beta Metrics - Metric Types

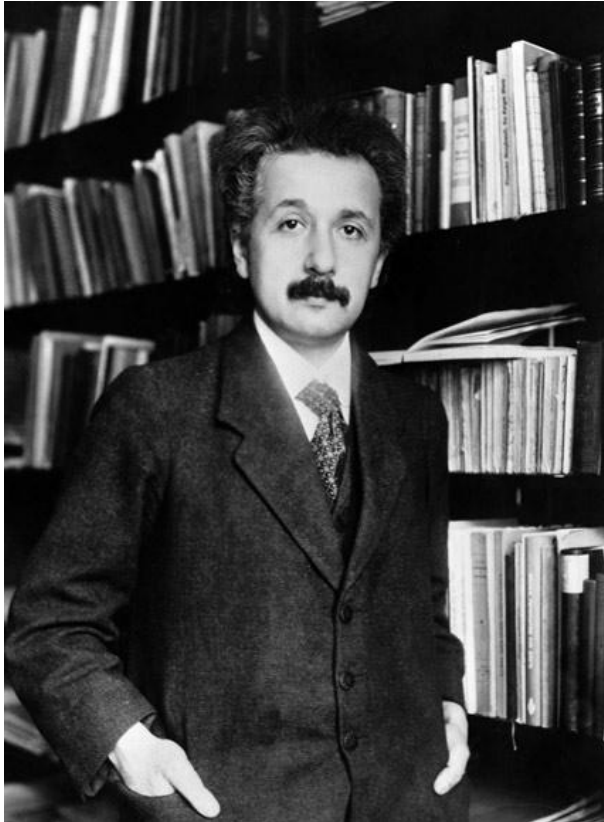






Process Improvement Work Group





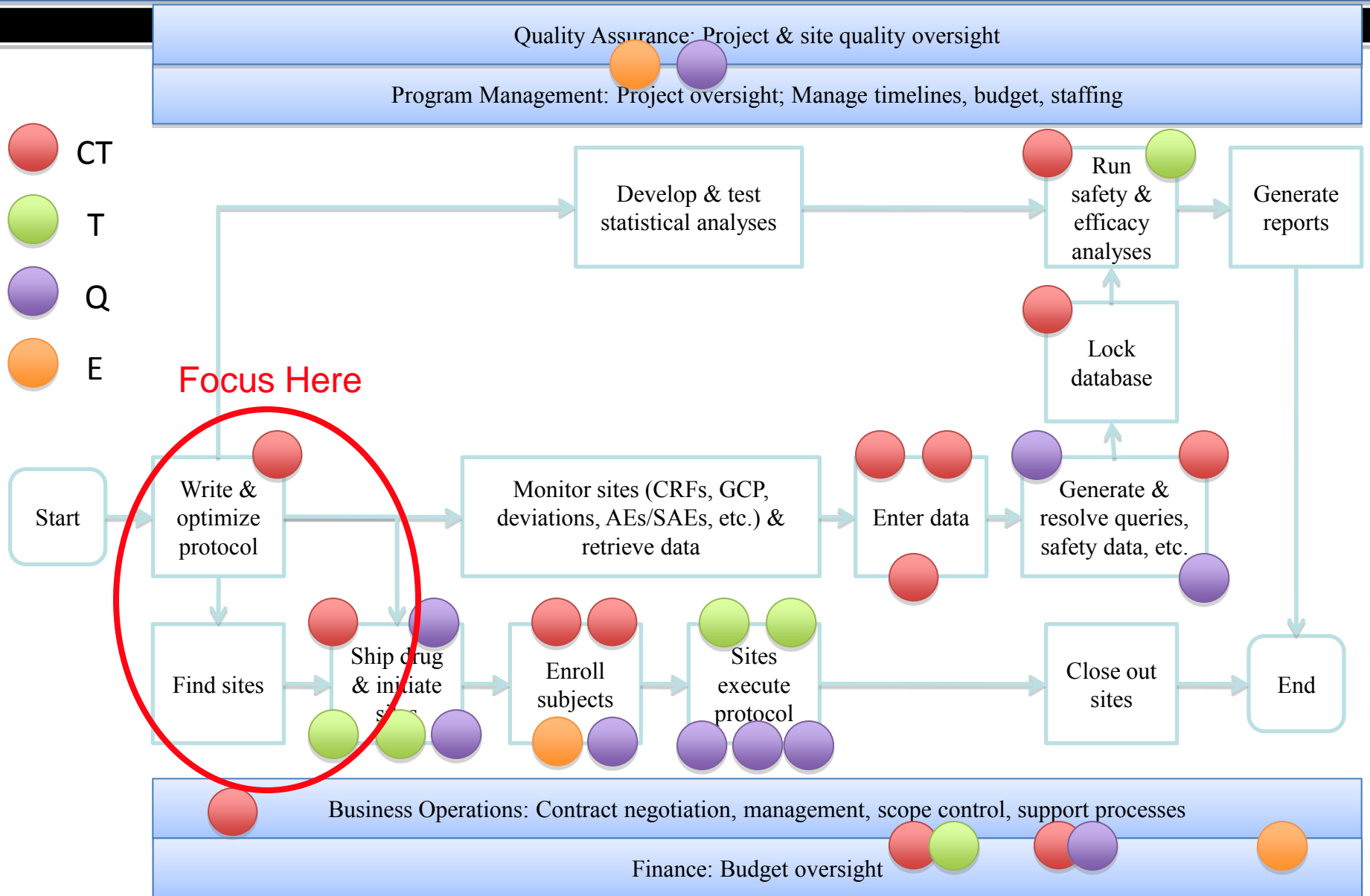
“Not everything that can be counted counts and not everything that counts can be counted.”

Albert Einstein

- Develop guidance on use of 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
- Review Beta metrics holistically and individually with regards to process improvement
- Generate new quality measures as needed

Lynne Deans	Cerexa
Joseph Giuliano	CHDI Foundation
Dave Zuckerman	Customized Improvement Strategies
Vince Romano	Eli Lilly and Company
Keith Dorricott	i3
Brian Peters	ICON Clinical Research
Judyth Zahora	INC Research
Eli Alford	INC Research
David Rodin	Merck
Jeff Ralston	Perceptive
Marty Valania	PharmaNet
Jeanne Green	Execupharm (Pfizer)
Michael Roosevelt	Regeneron

Missing Metrics



- Focus on start of the process –

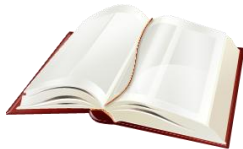
**High Quality
Protocol**

+

**Good Site
Selection**

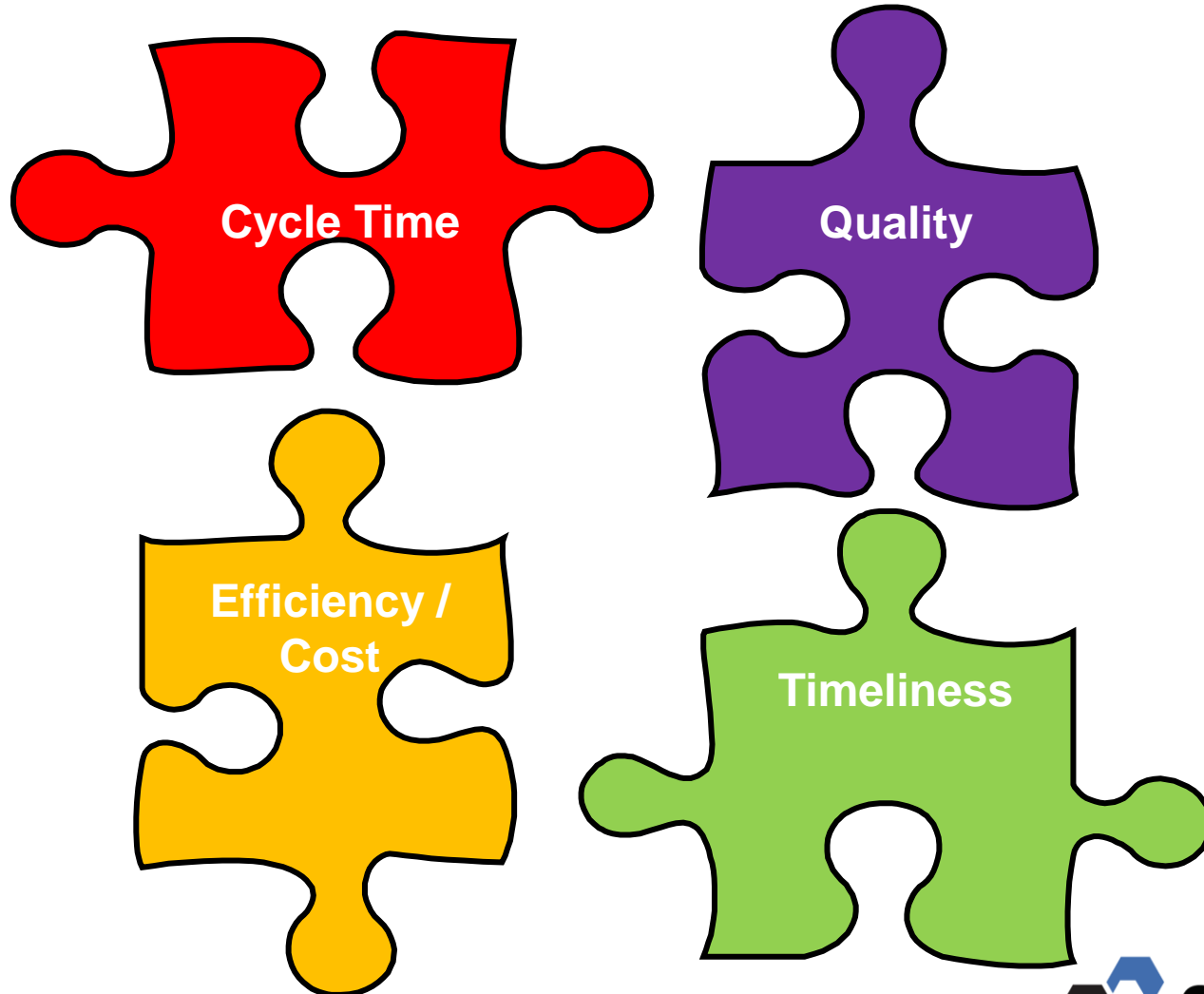
=

**High Chance of
Successful Trial**

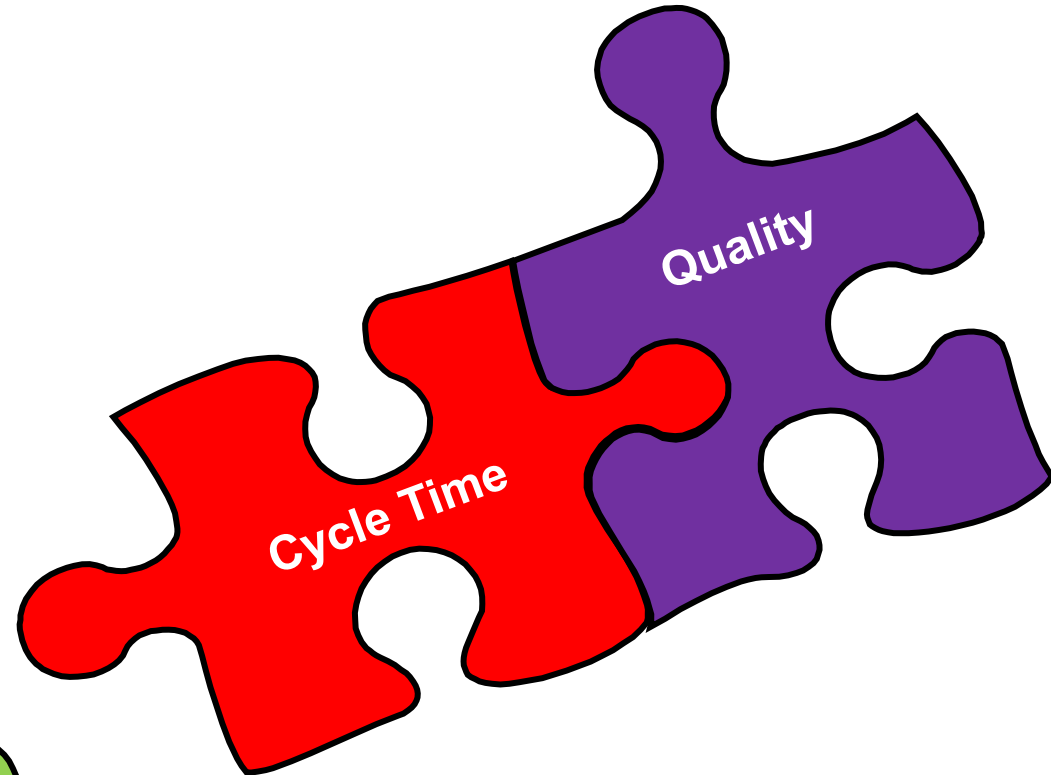
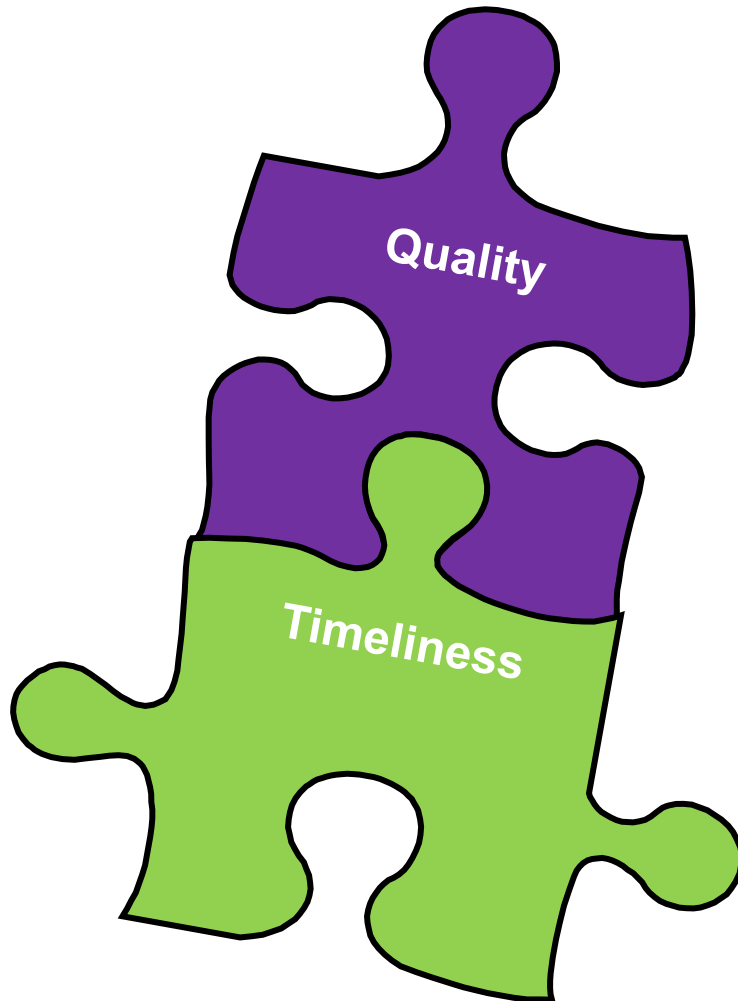


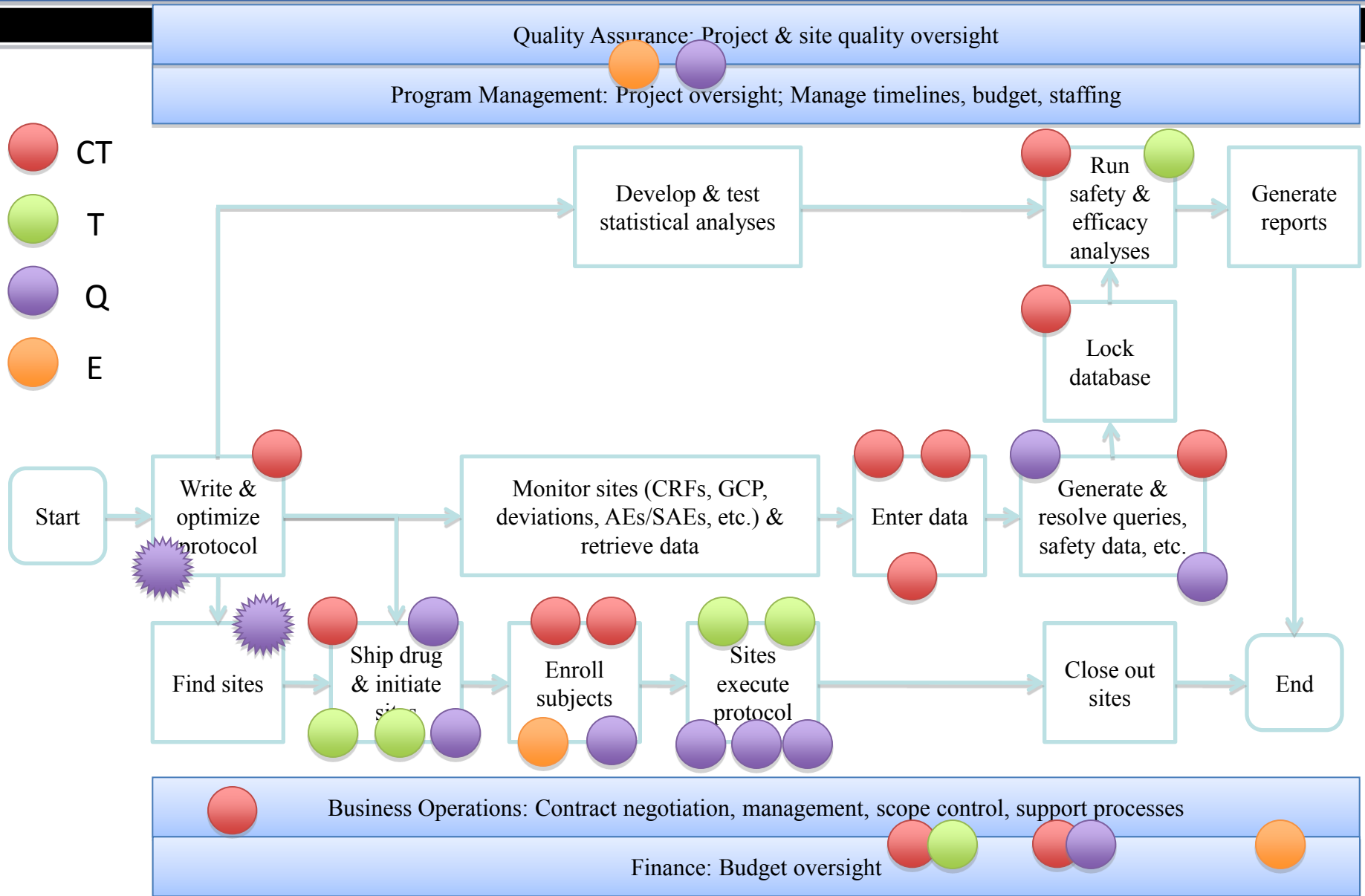
- Focus only on cycle-time is likely to sub-optimize
- Defined two new metrics:
 - Protocol Quality
 - Site Selection Quality

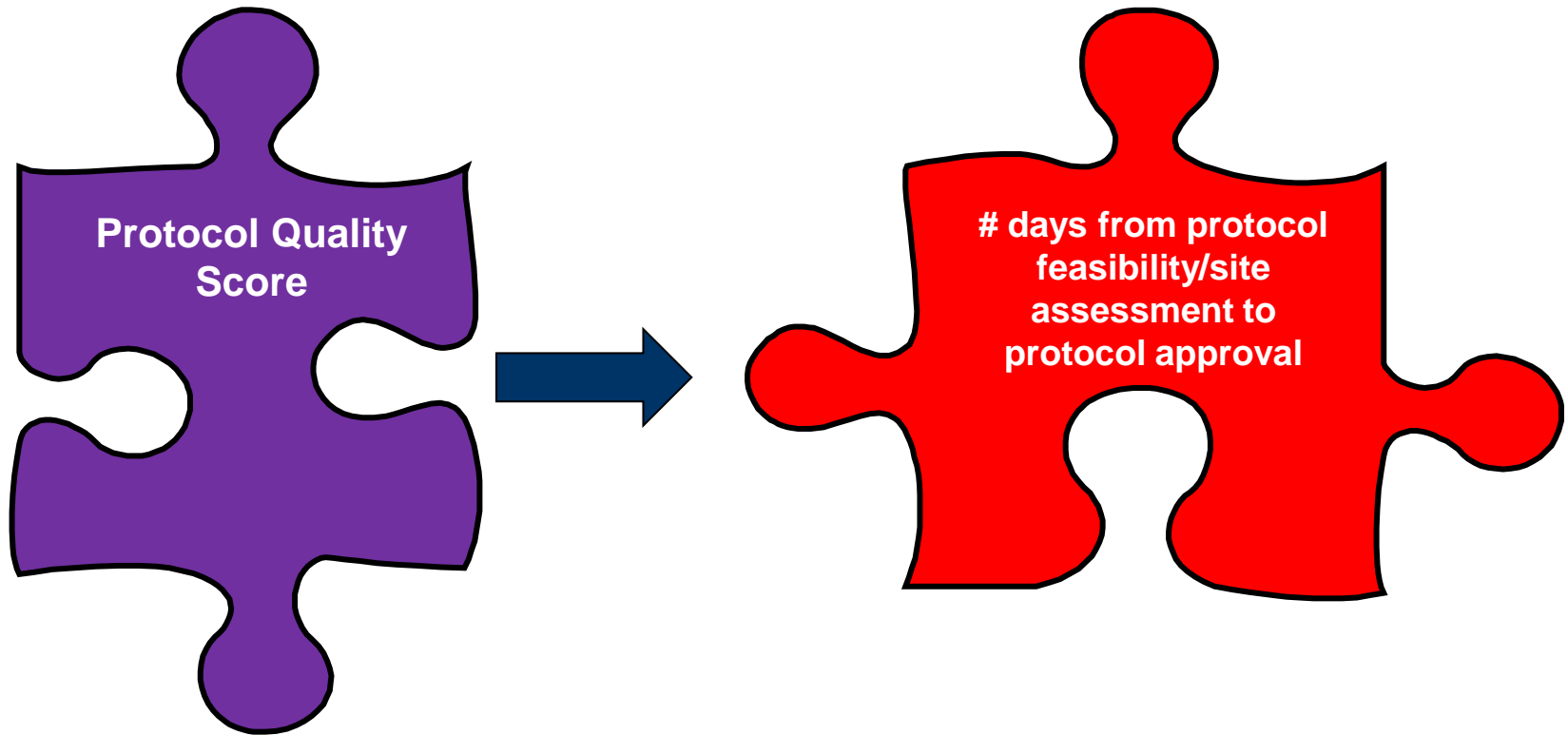
Types of MCC Performance Metrics



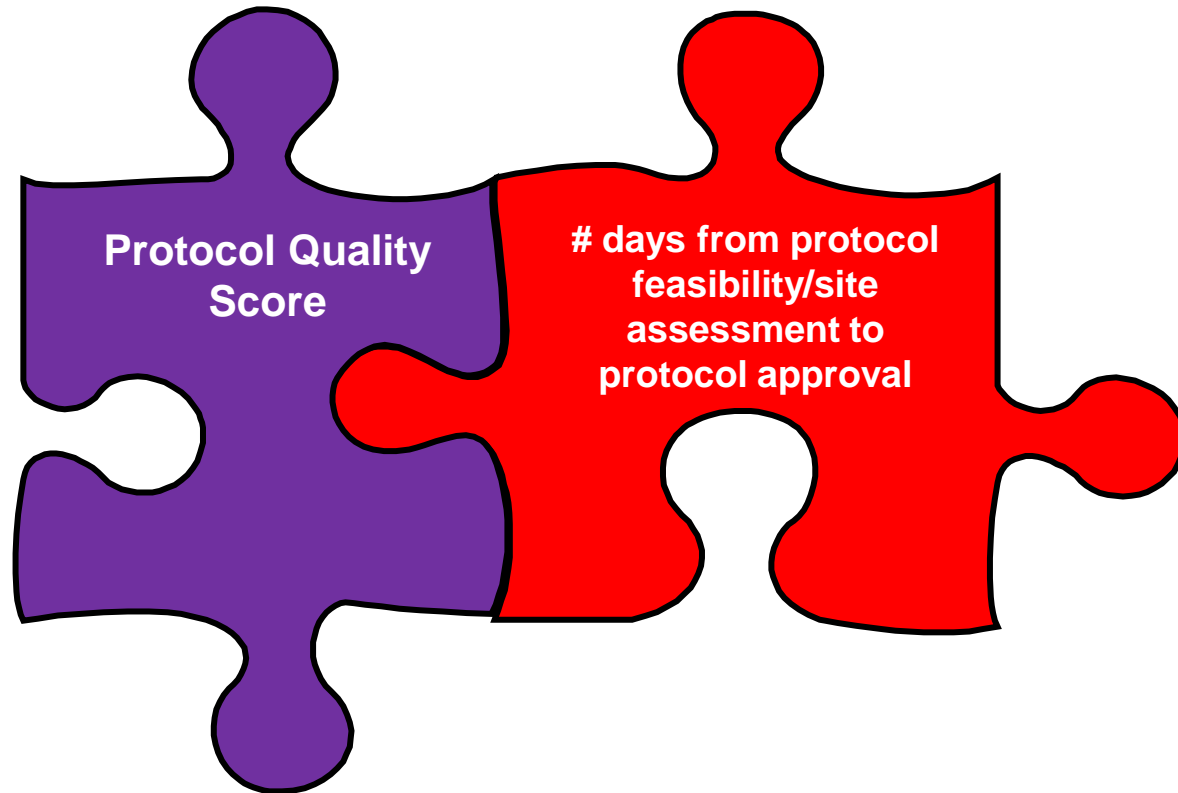
MCC Companion Performance Metrics







MCC Companion Performance Metrics



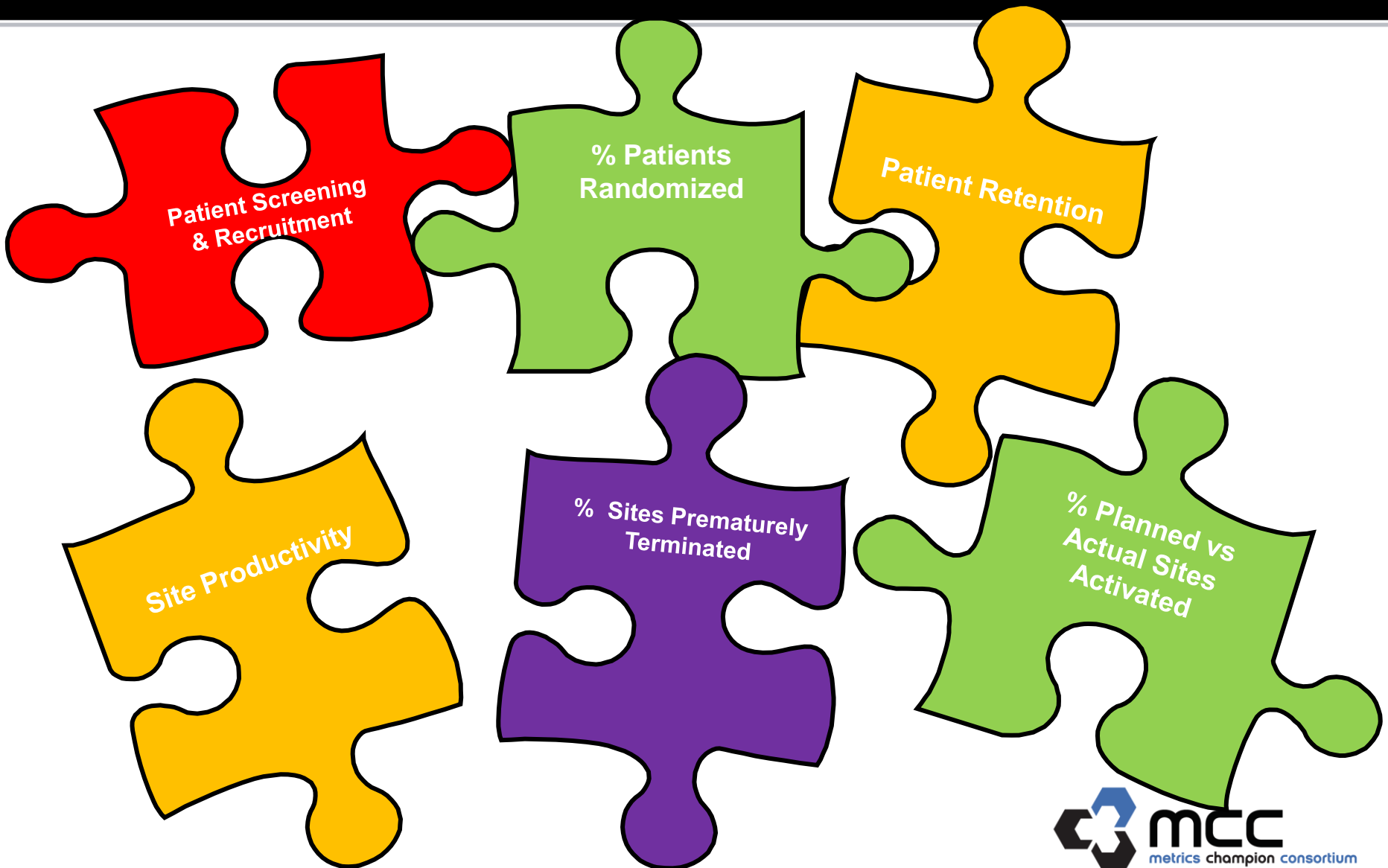
Protocol Team answers 7 questions about the thoroughness of addressing:

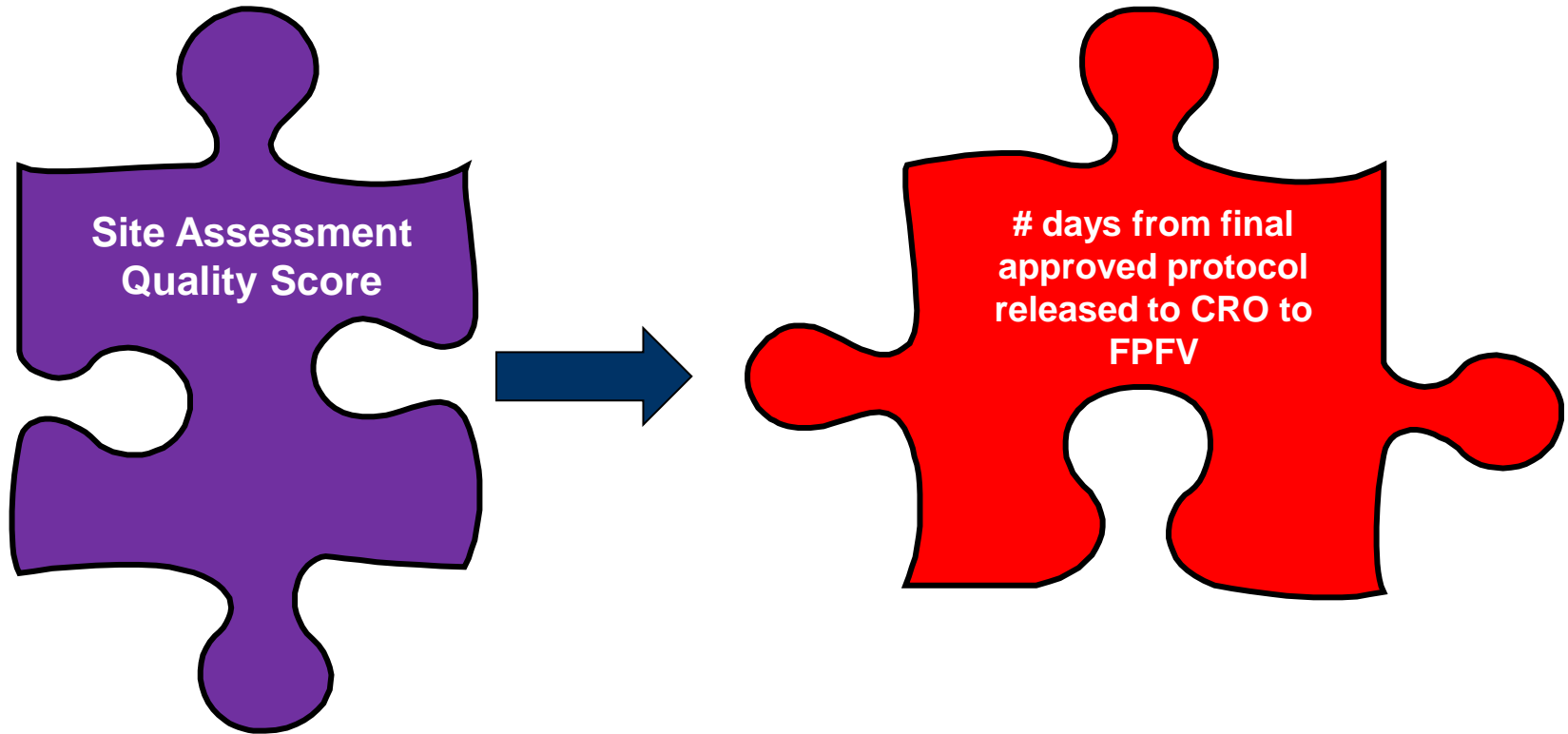
1. Regulatory requirements/obligations
2. Dosage/formulation
3. Protocol design reflecting clinical practice
4. Study schedule
5. Screening is balanced
6. Procedures is reasonable
7. Protocol-specific equipment and materials availability

Scoring System

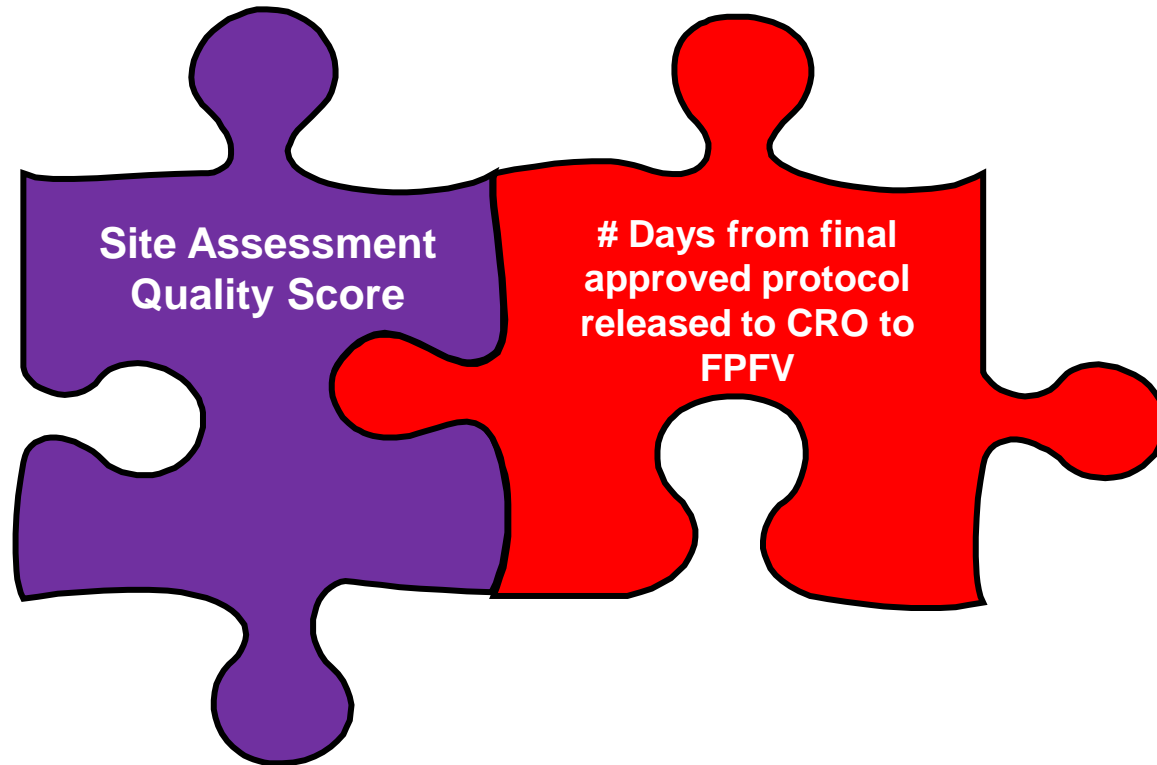
Score	Survey Type	Data Source	Protocol Mod
0	Didn't address this question		
1-3	Protocol synopsis & written feedback	Countries/regions only	None
4-6	Near-final protocol & brief interview	Some sites in some countries	Key mods only
7-9	Near-final protocol & extended interview	Some sites in all countries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

- 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 Companion Performance Metrics



UPDATED SLIDE

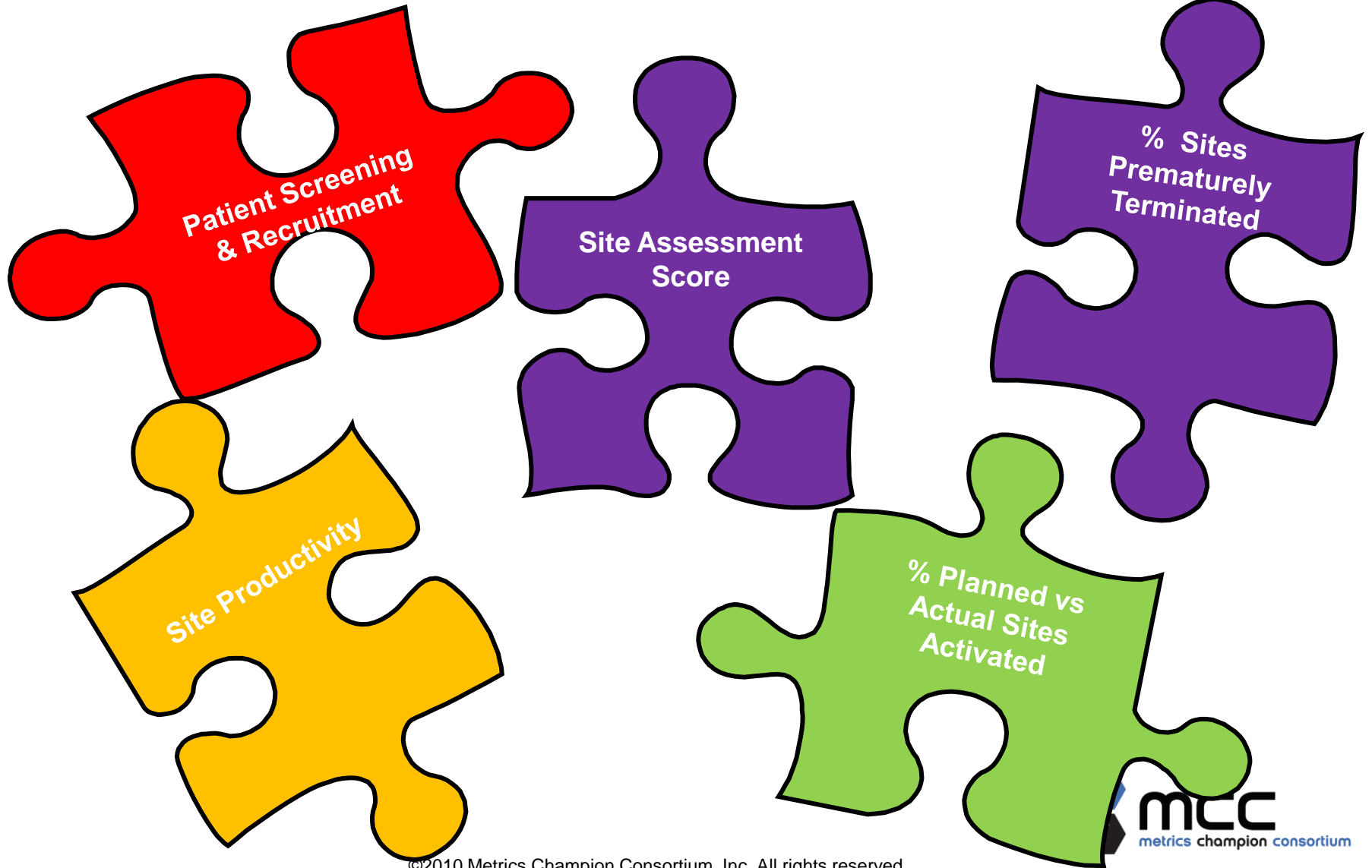
Criteria are weighted and then each site assessed:

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

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 are excluded from 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



- 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?
- Feedback so far very positive on Protocol Quality:
 - 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 validation of the metrics

We welcome your feedback on these metrics:

- Have you tried to implement something like this?
- Could the metrics have a positive benefit on the clinical trial process?
- Any suggestions on how we can validate the metrics?

