



# **MCC UPDATE:** How the Industry-Wide Effort to Develop and Implement Standardized Clinical Trial Performance Metrics Helps BD's Relationship with their Clients

Guy Mascaro, *Metrics Champion Consortium*

Elizabeth Shewell, *Incyte Corporation*

Gary Urban, *Paragon Biomedical*

ExL Pharma 2<sup>nd</sup> Annual Effective Business Development for Clinical Trial Service Providers

July 14, 2010 Arlington, VA





# Agenda

Part I: MCC Update: MCC Clinical Trial Performance Metrics, Quality Scoring Tools and Industry Database  
Guy Mascaro, Metrics Champion Consortium

Part II: Utilizing metrics to improve clinical trial performance and strengthen sponsor/CRO relationships  
Elizabeth Shewell, Incyte Corporation

Part III: Incorporating performance metrics into contracts to be used to better manage sponsor/CRO relationships and improve business outcomes  
Gary Urban, Paragon Biomedical



# *MCC Update: MCC Clinical Trial Performance Metrics, Quality Scoring Tools and Industry Database*

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## *Building Partnerships Around Standardized Performance Metrics*

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.



# *Mission Statement*

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 Member Organizations*

**Abbott Laboratories**

**AstraZeneca**

**BARC Global Central Lab**

**BioClinica**

**Biogen Idec**

**Biomedical Systems**

**Cardio Analytics**

**Cardiocare**

**Carefusion**

**Cerexa**

**CHDI**

**Clinsys Clinical Research**

**Covance**

**Duke Clinical Research  
Institute**

**ERT**

**Esoterix Clinical Trial  
Services**

**Eurofins Medinet**

**ExecuPharm**

**Genentech**

**Genzyme**

**i3**

**ICON**

**Imaging Endpoints**

**INC Research**

**Incyte**

**Lilly**

**M2S**

**MacroGenics**

**Medidata Solutions**

**Medtronic**

**Merck**

**New England Research Institute**

**Novartis**

**Paragon Biomedical**

**Perceptive Informatics**

**Pfizer**

**PharmaNet**

**PPD**

**Quest Diagnostics**

**RadMD**

**RadPharm**

**Regeneron**

**Research Point**

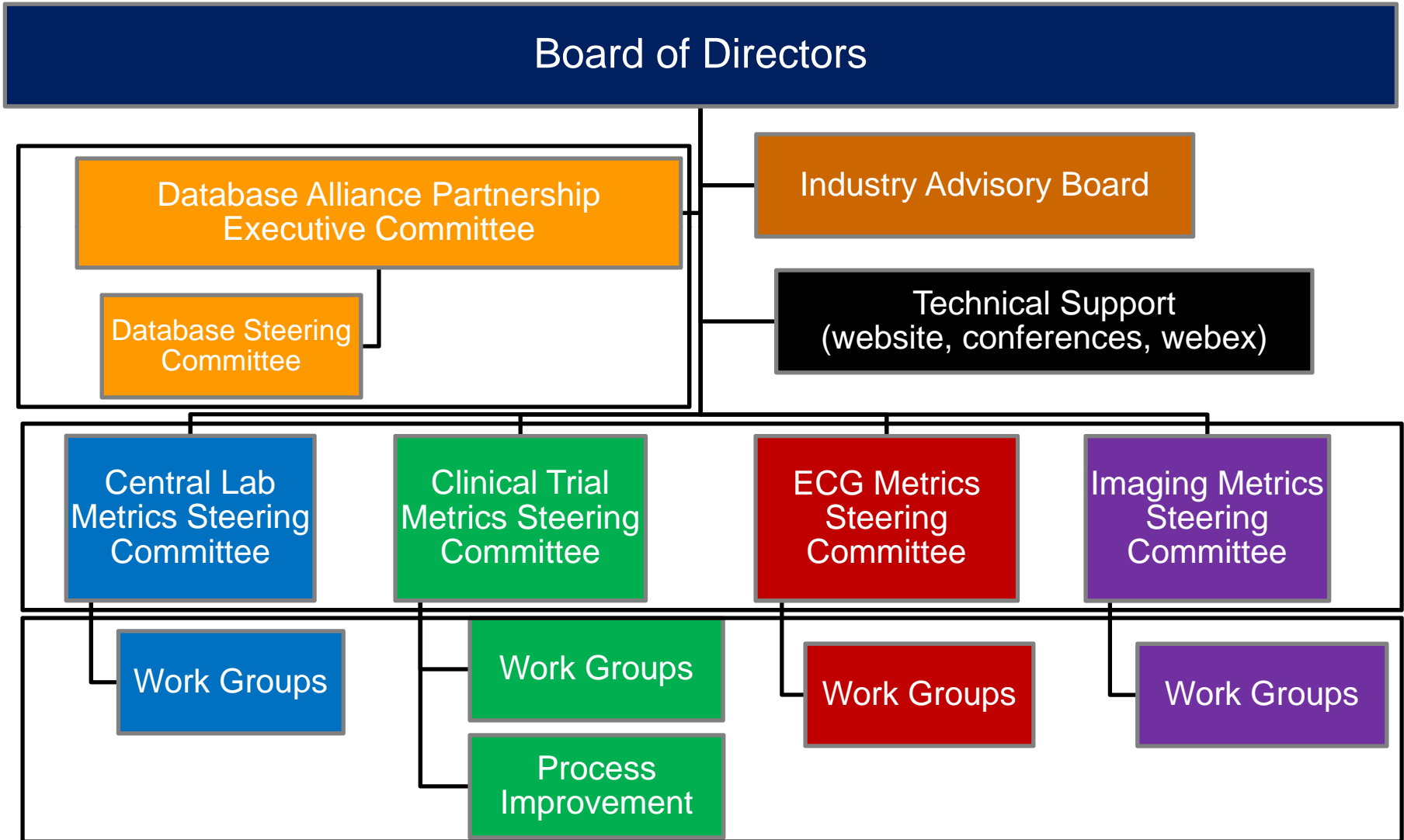
**Synarc**

**Virtual Scopics**

**WorldCare Clinical**

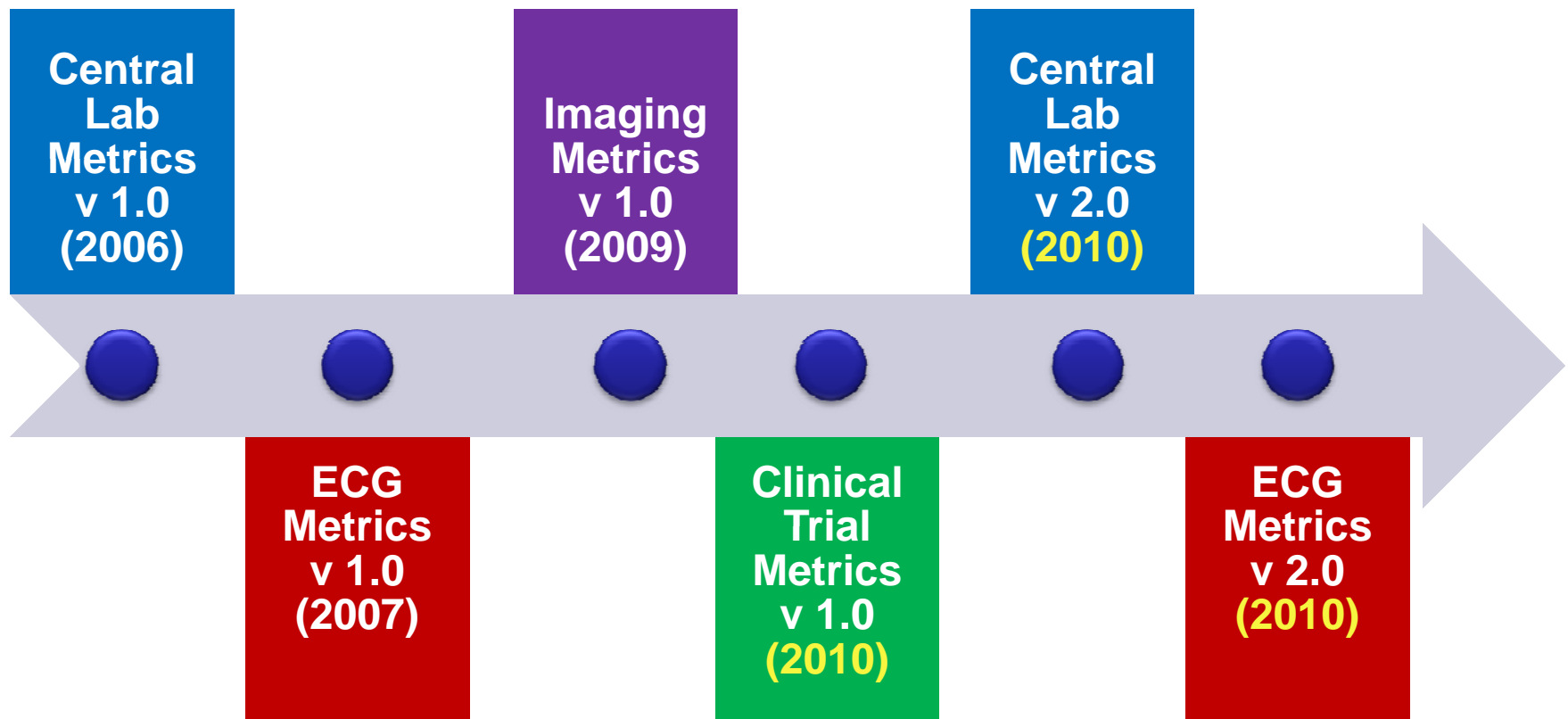


# Organizational Structure





# Metrics Development Timeline





# *Utilizing a collaborative approach to developing standardized metric definitions*



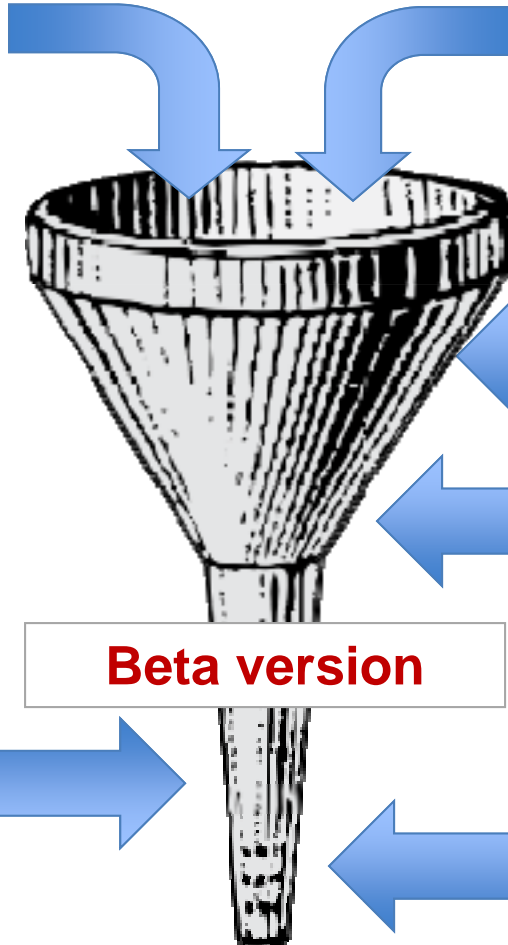


# MCC Metrics Development Process

## Brainstorm Metrics Lists

- Industry meetings
- Surveys

Gather Existing Metrics  
MCC SC & WG members



Create Process Maps  
MCC SC & WG members

Screen Metrics With  
Mapping Tool  
MCC SC & WG members

Solicit Industry  
Feedback

Revise Metrics  
MCC SC & WG members

**Metrics version 1.0**



# *Metric Characteristics*

Each Steering Committee is given the same criteria for its initiative's metrics:

- Create metrics that can be **key indicators** of performance and allow for “additional for cause analysis”
- Clearly define measurement criteria
- Provide benefit to Sponsor and Service Provider (must add value)
- Add relationship metrics in future versions



# *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

Metric #	Metric Type	Metric Title	Category	Metric Indicator	Part of Study
		<b>Definition</b>	<b>Formula / Example</b>	<b>Reporting Detail</b>	
				<b>Unit of Measure</b>	
		<b>Business Driver(s) / Benefit Statement</b>	<b>Additional Analysis on a "for cause" basis</b>	<b>Reporting Frequency</b>	<b>Target</b>
<b>Companion Metrics</b>					

# Example: MCC Clinical Trial Performance Metrics v 1.0 DRAFT

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
<b>Definition (see Wiki for detailed definitions)</b>		<b>Formula / Example</b>		<b>Reporting Detail</b>	
Number of calendar days from final approved protocol to final approved eCRF.  <b>See MCC Wiki for definitions</b>		Formula: $X - Y = \# \text{ calendar days}$ $X = \text{date eCRF final}$ $Y = \text{date protocol final}$  Example: Final Protocol Date = 01Jan2008; Actual approval of eCRF is 26Jan 2008 $[26 \text{ Jan} - 1 \text{ Jan}] = 25 \text{ calendar days}$		Study / Therapeutic Area / Portfolio levels	
				<b>Unit of Measure</b>	
				Calendar days	
<b>Business Driver(s) / Benefit Statement</b>		<b>Additional Analysis on a "for cause" basis</b>		<b>Reporting Frequency</b>	<b>Target</b>
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
<b>Companion Metrics</b>		Need to develop e-CRF Quality metric			



The screenshot shows the MCC Clinical Trial Performance Metrics Wiki interface. At the top, there is a navigation bar with the MCC logo and the text 'Clinical Trial Initiative'. Below this is a secondary navigation bar with tabs for 'MCC Home', 'Members', 'Central Lab Initiative', 'ECG Initiative', 'Clinical Trial Initiative' (selected), 'Imaging Initiative', 'Board of Directors', 'Industry Advisory Board', and 'Admin'. A search box is located in the top right corner.

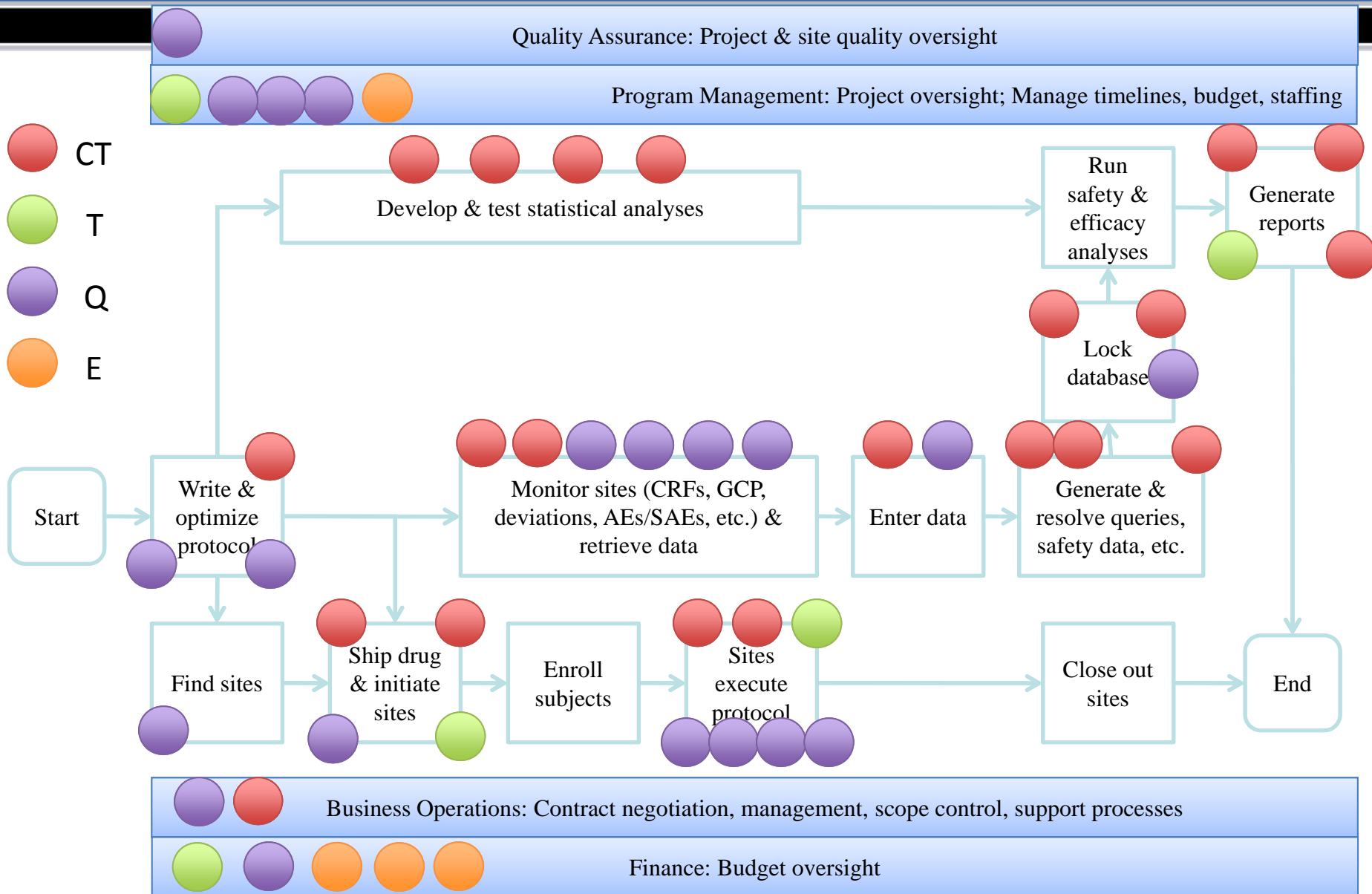
The main content area displays the title 'MCC Clinical Trial Performance Metrics Wiki' and a breadcrumb trail: 'Metrics Champion Consortium > Clinical Trial Initiative > MCC Clinical Trial Performance Metrics Wiki'. Below the title, there are tabs for 'New', 'Actions', and 'Settings', and a 'View: All Pages' dropdown menu.

The main content is a table listing various documents. The table has columns for 'Type', 'Name', 'Modified By', 'Modified', 'Created By', and 'Created'. The documents listed include:

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

On the left side of the interface, there is a sidebar with a 'View All Site Content' button and several sections: 'Documents' (listing various working groups like Steering Committee, Biometrics WG, etc.), 'Lists' (listing Clinical Trial Initiative WG), 'Discussions' (listing Steering Committee Discussion Area and WG Discussion Area), 'Sites', and 'People and Groups'. At the bottom of the sidebar is a 'Recycle Bin' icon.

# MCC Clinical Trial Performance Metrics v 1.0 DRAFT





# *Using metrics to drive process improvement*





## *MCC Collaborative Learning*

MCC Metric Initiative Steering Committee and Working Group meetings provide members the opportunity to share:

- Ideas & challenges
- Case studies
- Lessons learned

October 2009 – launched Clinical Trial  
Performance Metrics Process Improvement WG

Process Improvement WG tasked with following purpose:

- Review Beta metrics to ID significant gaps in coverage of the clinical trial process
- Assess each proposed metric to:
  - determine how it could be used for process improvement
  - ensure data formats support process improvement activities
- Create *How to use the metrics for process improvement* guidance paper

- Focused on study start up process –

**High Quality  
Protocol**

+

**Good Site  
Selection**

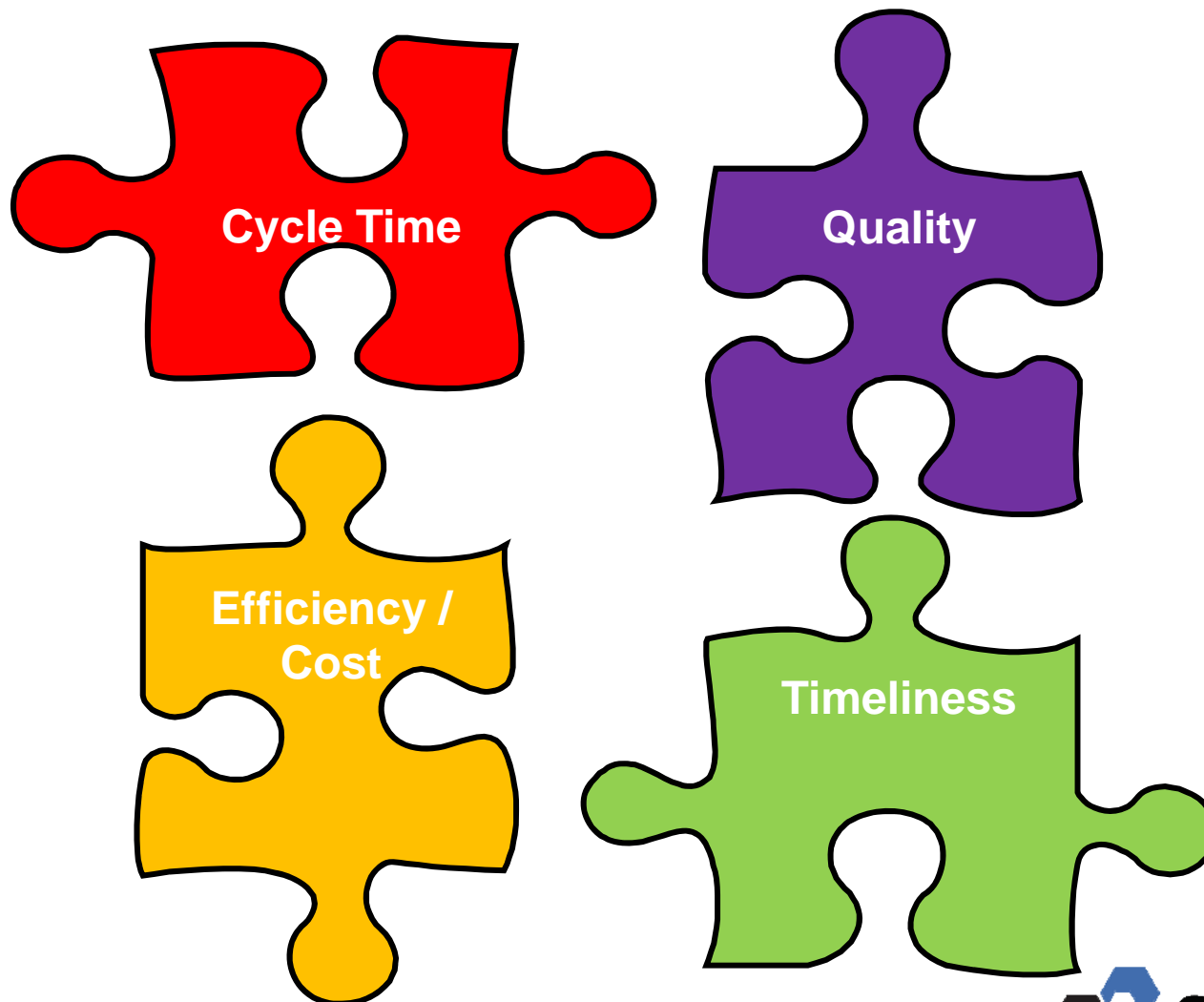
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**High Chance of  
Successful Trial**

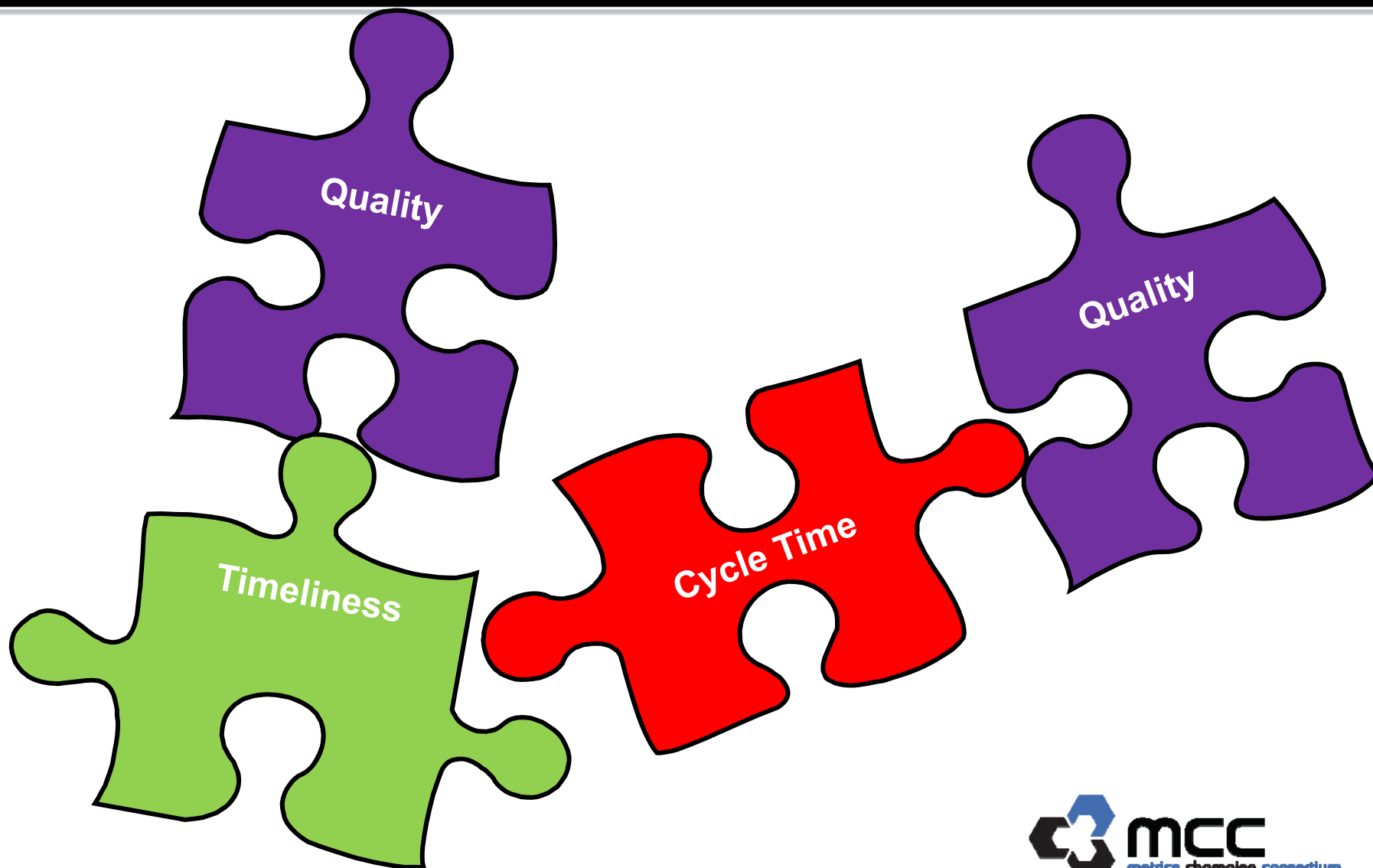


- Concerned that focusing only on cycle-time is likely to sub-optimize
- Defined two new metrics:
  - Protocol Quality
  - Site Selection Quality

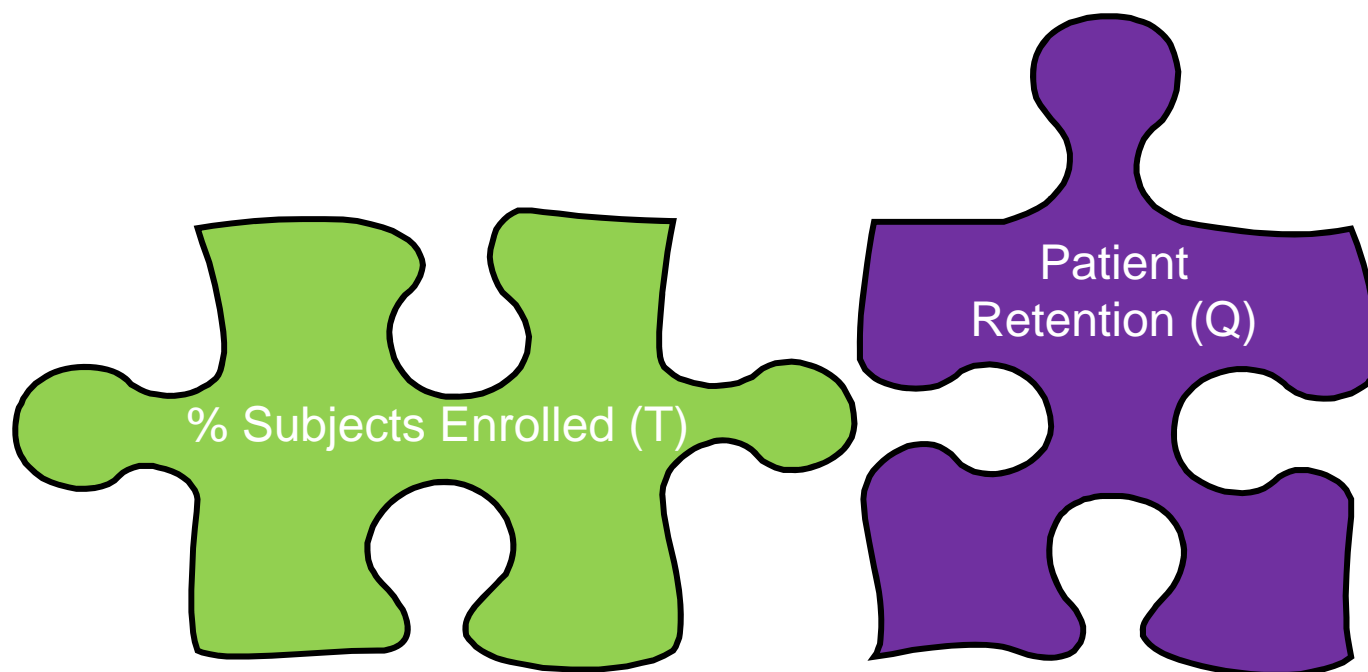
# Types of MCC Performance Metrics



# MCC Companion Performance Metrics



Example: MCC Patient Screening and Recruitment Companion Metrics

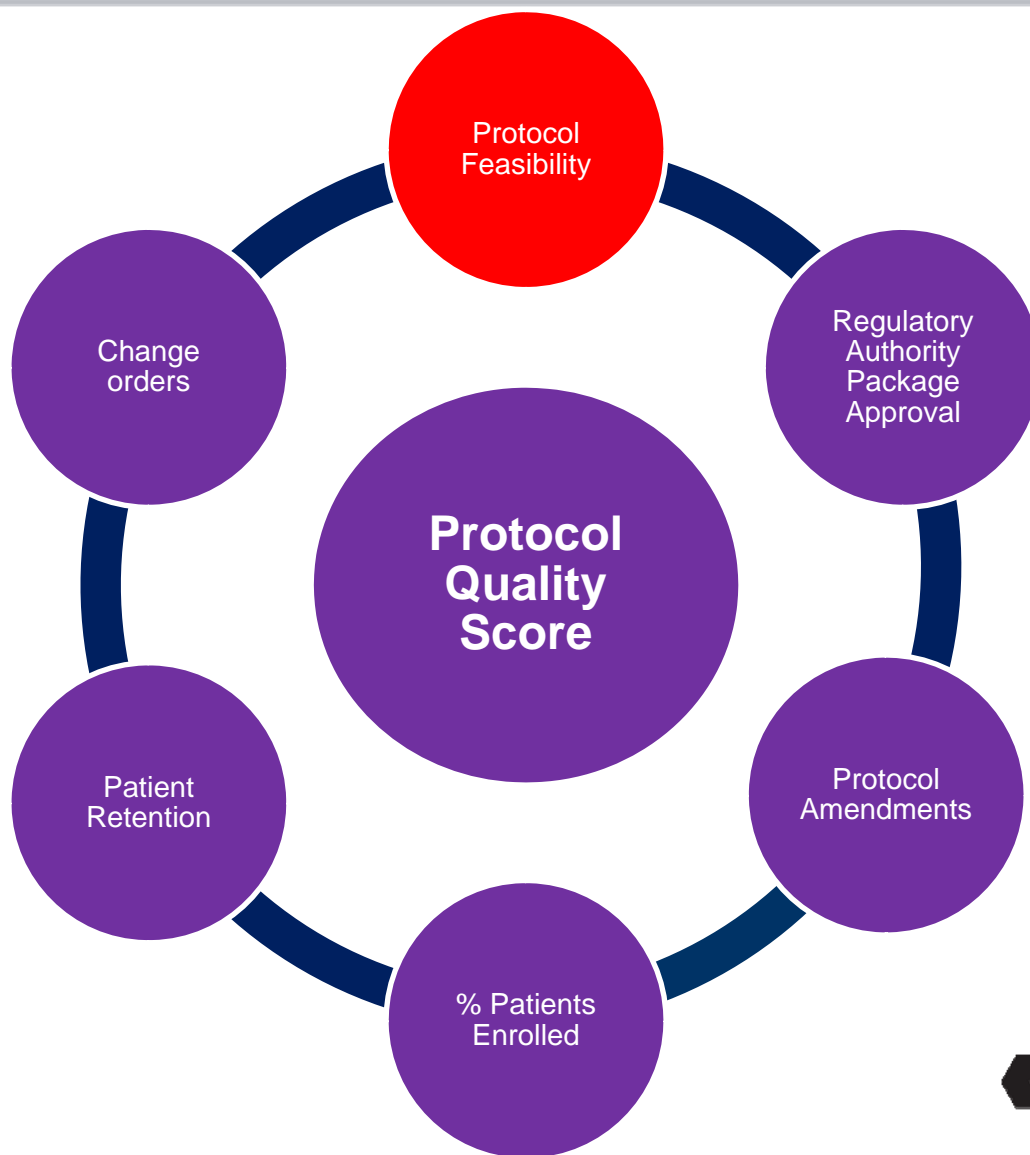


## Key Features:

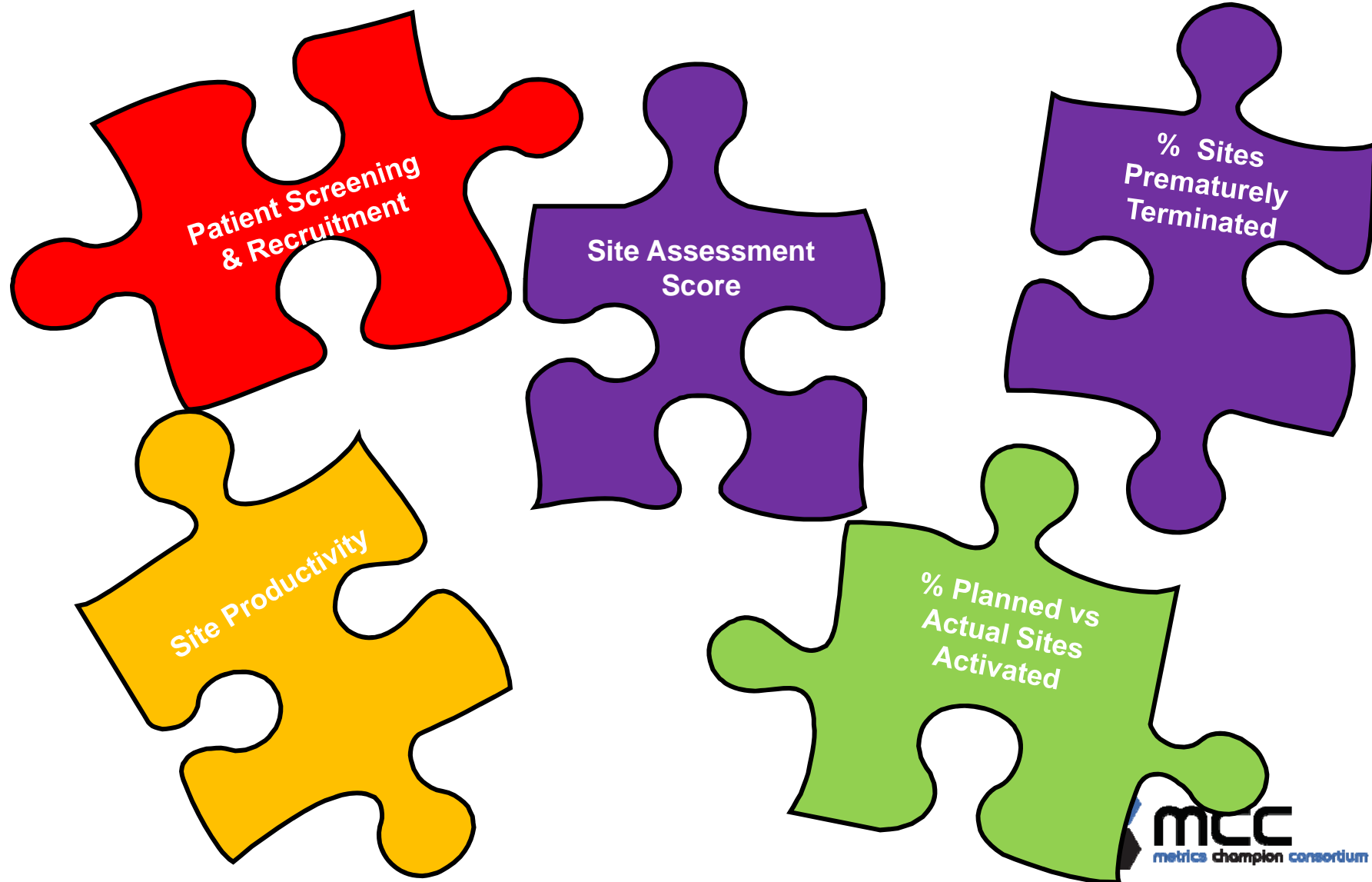
- Provides Protocol Development and Site Selection teams with specialized quality scoring tools
- Team completes quality survey to determine how the protocol or sites selected score against the appropriate quality criteria
- If the quality score is below expectations, the team should consider addressing the areas they scored poorly on and redoing the survey to get a higher score



# MCC Plans to Validate Protocol Quality Score



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



# MCC Plans to Validate Site Assessment Score





- Quality is difficult to measure – but important for success
- The act of measuring should modify behaviour:
  - Is the team doing what is needed to produce the best protocol?
  - Does a site lack skills and need specific training?
  - Are there enough high quality sites selected in country X?
- Interest in developing additional Quality Scoring Approach for Site Performance, CRFs and CSRs



# *Building an industry benchmarking database*





## *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



# *MCC Member Blinded Database*

## **Executive Committee**

- Julia Amo – PharmaNet (EC Chair)
- Nick Astley – Pfizer
- Paul Colvin – PPD
- Chris Davis – Eli Lilly
- Jorge Guerra, MD – Biogen Idec
- Randy Krauss – Genzyme
- Tom Lawler – AstraZeneca
- Guy Mascaro – MCC
- Phil Miller – CMR



# *MCC Member Blinded Database*

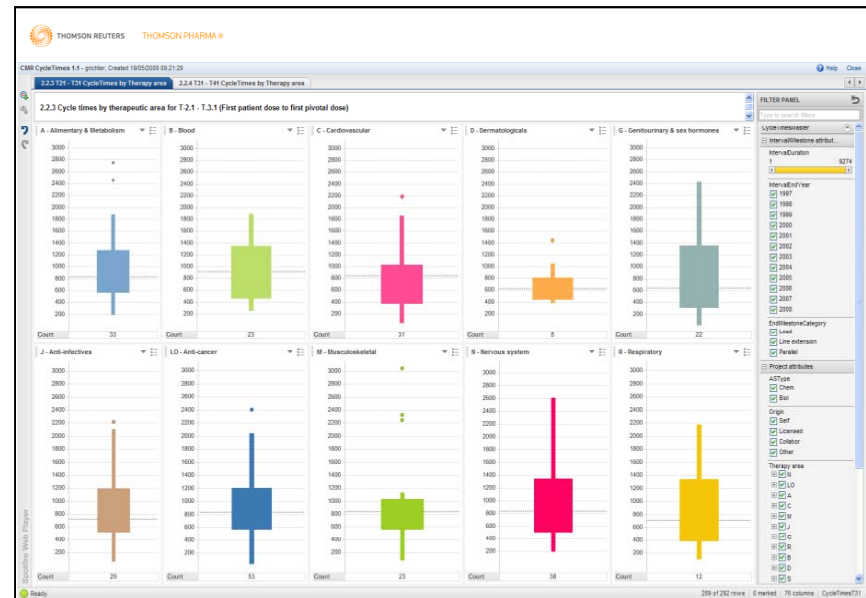
## **Steering Committee**

- Jeanne Green – ExecuPharm (Co-Chair)
- TBD Pharma/Biotech (Co-Chair)
- Ned Connell – Abbott Laboratories
- Brian Hass – PPD
- Jasmin Mehta – CMR
- Mike Neidl - Genzyme
- Matthew Riddell – Biogen Idec
- Linda Sullivan – MCC
- Julie Tucharland – Novartis
- Dave Zuckerman
- Additional members TBD

*“Spotfire offers a visual and interactive experience that helps professionals quickly discover new and actionable insights in information. Distinguished by its speed to insight and adaptability to specific business challenges, Spotfire rapidly reveals unseen threats and new opportunities.”*

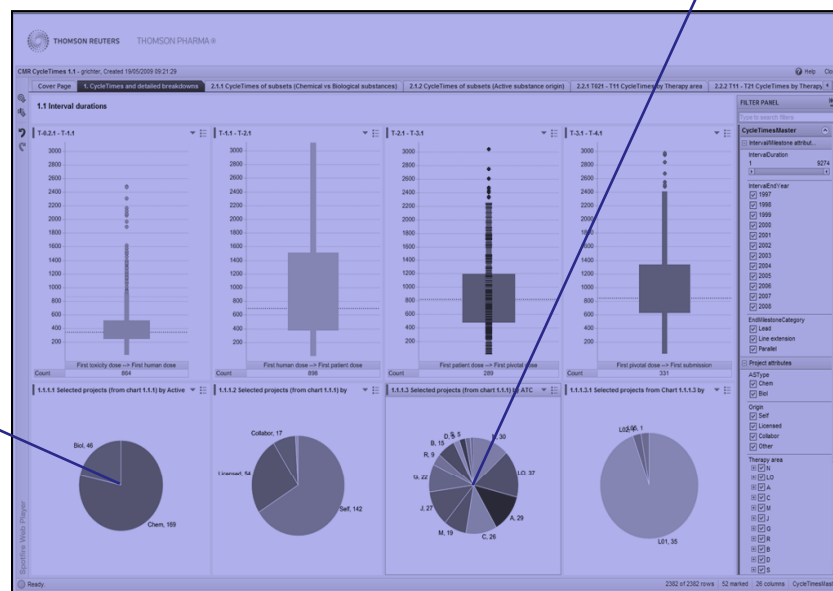
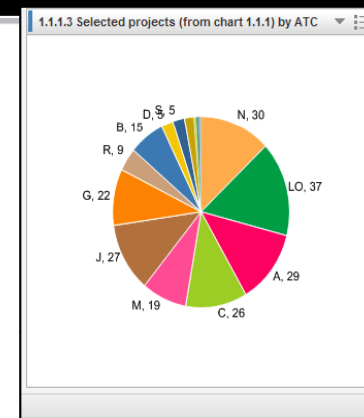
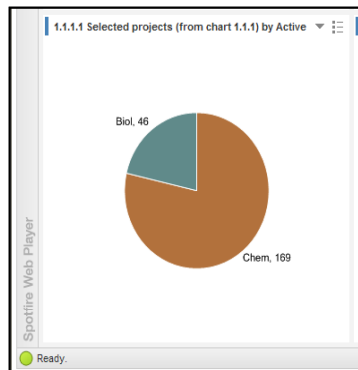
– Spotfire Corporate Website

- Data visualization and analytics tool
- Interactive platform
- Used for:
  - Business Intelligence
  - Enterprise analytics
  - Decision analysis



# What Can Spotfire Offer?

- Easy point and click interface allows users to interrogate the data
- Large amounts of data can be instantly analysed without any manual calculations
- Can be used to produce *dynamic* digital reports and *customised* applications
- Offers more *insight* into data





## *Conclusions*

- 2010 MCC Clinical Trial Performance Metrics initiative activities:
  - Release version 1.0 and support metrics implementation
  - Process Improvement WG will oversee creation and validation of new quality metrics
- MCC – CMR International Alliance Partnership will provide MCC Sponsor & CRO Members the opportunity to participate in MCC Member Blinded Metrics Database



*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

Elizabeth Shewell, *Incyte Corporation*

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*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

## How Organizations can utilize metrics:

Improve Clinical Trial Performance

Strengthen Sponsor/CRO relationships



*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

Measurement has a long tradition in natural sciences. At the end of the last century, physicist Lord Kelvin (1824-1904) formulated the following statement about measurement (Kelvin, 1891):

*“When you can measure what you are speaking about, and express it into numbers, you know something about it; but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meager and unsatisfactory kind: It may be the beginning of knowledge, but you have scarcely in your thoughts advanced to the stage of science.”*



*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

Pharmaceutical companies (pharma) and clinical research organizations (CROs) have been working vigorously to improve their productivity and return on investment by modifying processes, decreasing cycle times, and implementing improvements wherever possible.<sup>1</sup>

*E. Pena, "Making Metrics Matter: The Changing Paradigm of R&D Metrics," PharmaVoice, 8–20 (March 2005).*

*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

The value of performance metrics has taken on a dual meaning:

1) to measure and compare performance between service providers;

and

2) to analyze operational proficiencies that reveal potential elements to be adjusted during the conduct of the clinical trial.

Both support the improvement in clinical trial performance.

*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

## What metrics can do...

- Metrics can communicate and reinforce a clear set of standards for performance and provide measurement of performance against those standards;
- Identification of areas for improvement and potential issues can be achieved in a timely manner, allowing for early corrective action;
- Performance against key metrics can provide an objective source for feedback to the Vendor and serve as a means of comparison between the service providers;
- Metrics which anticipate future problems are invaluable.

*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

- How metrics can improve clinical trial performance:
  - Measurement of overall progress of the clinical trial and forecasting of future trends can be accomplished with the use of selected metrics;
  - Financial and budgetary status measurement and forecasts can be provided through analysis of performance metrics;
  - The fact-based and objective information and feedback provided by well-designed metrics serve as a sound foundation for fair and consistent relationships between the sponsor client and Vendor;
  - Metric system goal is to support joint improvement in quality and efficiency.

*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

## Keys to remember...

- The performance metrics chosen should be relevant to the role of a vendor within the clinical trial process.
- The performance metric should provide information and insight that is actionable by both the vendor and sponsor.
- The primary strategic goals driving the performance metrics process should be directly reflected in how you design, implement, and manage the metrics you utilize.
- The metrics used should periodically be reviewed for impact and utility—those rarely noted or used can be eliminated and replaced with more meaningful measures.

*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

## A few lessons learned...

- Use caution in the degree in which data from performance metrics are used to forecast study progress, in both the operational and financial sense;
- The performance metrics should be applied consistently from design through implementation and use;
- A disciplined approach to application of performance metrics is critical in keeping the process manageable and meaningful.

# Strengthen Sponsor/CRO relationships



# Strengthen Sponsor/CRO relationships

## Pharma Perspective

- Contracts on-time
- Consistent, high-quality deliverables
- High customer satisfaction
- Experienced people
- Continuity
- Financial transparency
- Divulging weaknesses
- Continuous improvement
- Exclusivity

## Vendor Perspective

- Clear expectations
- Financial growth
- Respect
- Trust
- Protocol stability
- Timely information sharing
- Fast response times
- Time dedicated to relationship-building

# Strengthen Sponsor/CRO relationships

A clearly defined set of performance metrics is essential in selecting and managing a service provider.

- Help to pinpoint areas for improvement, which are in turn measured by study outcomes;
- By following the "process versus outcome" model and designing and implementing relevant and meaningful performance metrics, sponsor teams can develop well-balanced scorecards that accurately measure performance.

*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

What metrics can be:

- Use of performance metrics is a powerful asset in managing the performance of Vendor;
- Use to drive efficiencies during the life of the trial by focusing on both outcomes and processes;
- Use as an overall relationship management strategy.

*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

What metrics are not:

- It is not a panacea, nor a substitute for a robust process for relationship management;
- Not a punitive device or weapon.

*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

## Keys to remember:

- Having realistic expectations regarding the utility and impact of metrics on the overall relationship is essential;
- Metrics are balanced across relationship: Performance, Satisfaction and Growth.

*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

## **Afterword:**

- WARNING: You'll get what you measure.
- Abraham Lincoln: "If I had eight hours to chop down a tree, I'd spend six hours sharpening my ax."
- The Metricator's Maxim: Not all that counts can be counted; not all that can be counted counts.

*Learn how organizations can and should utilize metrics to improve clinical trial performance and strengthen sponsor/CRO relationships.*

Key to a good measurement system is making sure both sides share the pain AND the gain.





*Discuss ways that performance metrics can be successfully incorporated into contracts to be used to better manage Sponsor/CRO relationships and improve business outcomes.*

Gary Urban, *Paragon Biomedical*

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*Discuss ways that performance metrics can be successfully incorporated into contracts to be used to better manage Sponsor/CRO relationships and improve business outcomes.*

- **Why incorporate metrics into contracts?**
  - Clear-cut documentation of responsibilities and performance expectations
  - Joint accountability
  - Mutual protection
  - MSA or IPA?
  - Example: Protocol approval to first site activated
    - +/- 14 days per contract, by geography (Green)
    - Within 14-28 days per contract by geography (Yellow)
    - >28 days per contract by geography (Red)
  - Implications



*Discuss ways that performance metrics can be successfully incorporated into contracts to be used to better manage Sponsor/CRO relationships and improve business outcomes.*

- Better management of Sponsor/CRO relationships
  - Party neutral
  - Common goals
  - Speaking the same language
  - Using the same measurements & formulas
  - Efficiency for all



*Discuss ways that performance metrics can be successfully incorporated into contracts to be used to better manage Sponsor/CRO relationships and improve business outcomes.*

- Improved Business Outcomes
  - Supplier sourcing through close-out
  - Quantifiable reference of past performance
  - More accurate projections for future studies
  - Improved risk management and response



# Questions & Answers

