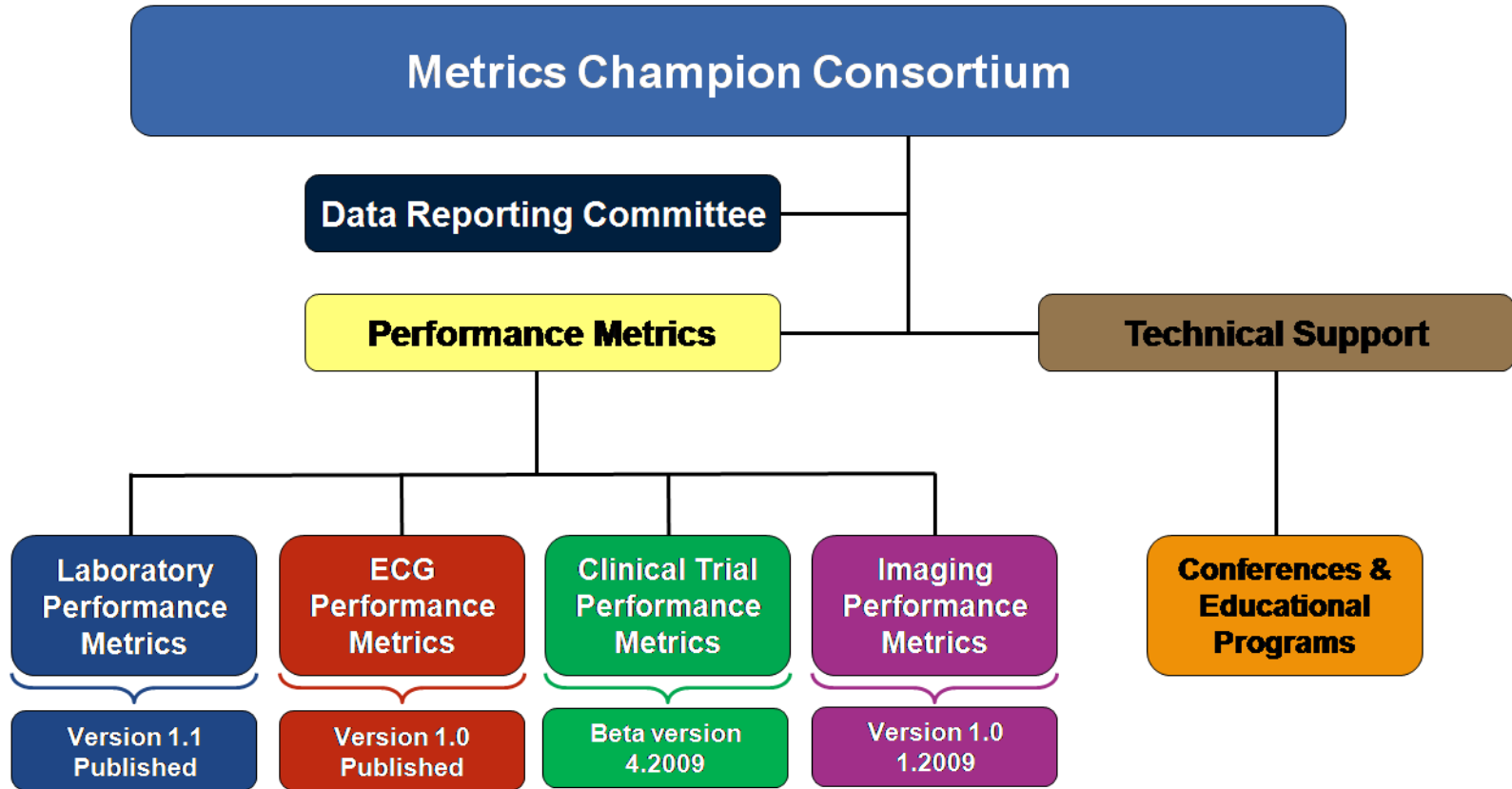


# *Overview of the Metrics Champion Consortium (MCC) Clinical Trial Metrics Initiative: A Collaborative Effort to Jointly Improve Performance*

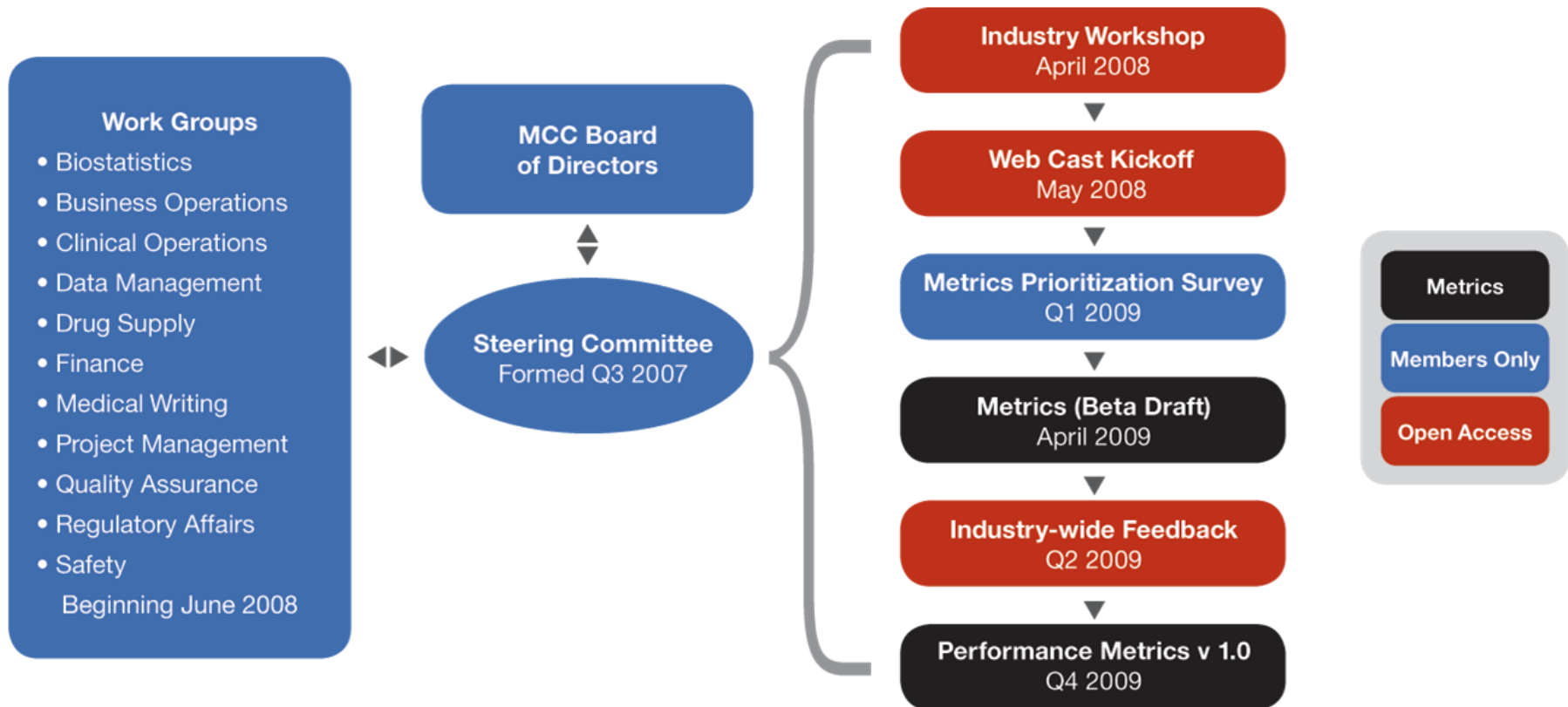
**Cory Gutterman, Abbott Laboratories**

April 28, 2009





# Metrics Development Process



## Launching Clinical metrics initiatives:

- Steering Committee established in late 2007
- Work groups launching March 2008
- Workshop at IIR Meeting April 2008
- Work groups met throughout 2008
- Workshop in November 2008
- Release beta version of metrics in early 2009:
  - CRO metrics - April 2009
  - CRO metrics – June 2009

## CRO Steering Committee

- Cory Gutterman / Abbott
- Ed Cannon / AstraZeneca
- Holly Hankins / Lilly
- Colleen McCoy / Genentech
- Keith Dorricot / i3 (new)
- Pam Howard / ICON (new)
- Kathe Balinski / Medarex
- Maga Woolard / Merck
- April Davis / Perceptive Informatics
- Lorraine Waring / Pfizer
- Julie Szabo / PharmaNet
- Monika Frey / Quintiles
- Paul Shin / Valeant



# Work Group Participants

Abie Ekangaki	David Rodin	Joan Farrington	Lee Davis	Ned Connell
Allison Houghteling	Dawn East	Joanne Bailey	Li Ding	Nicolle Keally
Andrew Marvuglio	Dawn Porthouse	Joanne Machalaba	Linda Donahoe	Nobuhide Shimizu
Andy Bakker	Deidre Bevard	John Griffin	Linda Dunford	Olga Crowther
April Davis	Diane Mizerak	John Humphreys	Linda Gala	Pam Howard
Beth Cabage	Dianne Laumann	Joseph Giuliano	Linda Stevens	Patric Donaghue
Bonnie Beaver	Elise Kayson	Judith Chiostrri	Lisa Chen	Patty Godfrey
Brenda Muldrow	Dorothy Hartley	Judith Goud	Lorene Bottom	Piper Laird
Brett Bishop	Ed Cannon	Julia Amo	Lori Carman	Randy Krauss
Brian Schrock	Eileen Ryan	Julie Engel	Lorraine Waring	Renee Lafaive
Carol Zhao	Elizabeth Shewell	Julie Szabo	Louis Grue	Richard Brotherton
Cassandra Kelley	Elizabeth Stankevich	Julie Tscharland	Louise Rochon	Richard Musselman
Catherine Elliott	Eric Hildebeitel	Kate Haratonik	Lynn Watson	Robert Holman
Charles Chesson	Eric Strait	Kathe Balinski	Magaly G. Woolard	Ronald Knickerbocker
Chili Li	Eva Kantanas	Karl Kieburzt	Marc Hamm	Rose Braxton
Christine Fitzpatrick	Gary Urban	Karl Meyer	Mary Baldovsky	Ryan Shortreed
Christopher Oligny	Gene Trimble	Karolyn Jackson	Mathew Bryant	Scott Sawicki
Cindy Casaceli	Gina Petrizio	Kathy M Haag	Matthew Stephens	Stacy Gletzakos
Colleen McCoy	Goran Kecman	Kati Gutierrez	Michael Malicsi	Stephanie Chan
Connie Seckel	Gordana Vucinic	Keith Dorricott	Michael Neidl	Stephen Kay
Connor Blakeney	Greg Pendell	Kelly Mizer	Michael Sobczyk	Sunshine Watkins
Cornelia Kamp	Guy Mascaro	Kelly Ong	Melika Davis	Tara Coughlan
Cory Gutterman	Hannah Legesse	Kelly Vaillant	Michael Bruns	Teleen Norman
Courtney Bryant	Hartmann Ammann	Krista Peters	Michael Friedman	Tess Pangan
Cynthia Hooper	Heidi Shea	Kristen Tomita	Michelle Stevens-Brogan	Thomas Purcell
Danie Montinard	Holly Hankins	Kristin Lucas	Mike Lange	Tiffany Crowell
Daniel Christen	Jean Pan	Kristy Morgan	Mike Soenen	Tracy Mayer
Daniela Popa	Jeff Marquis	Kristyn Karas	Monica Reddy	Vickie Crocker
Darren Hart	Jennifer Sugarman	Lakshmi Mahadevan	Monika Frey	Yvonne Baran
David Chambers	Jeremy Hemiup	Larry Blankstein	Morgan Shethah	Yvonne Ulrich
David Polakovs	Jim Wyatt	Lauren Freese	Nancy Yeates	

## Clinical Trial Metrics Work Groups

1. Business Operations
  2. Finance
  3. Clinical Operations
  4. Drug Supply
  5. Project Management
  6. Data Management
  7. Biostatistics
  8. Medical Writing
  9. Quality Assurance
  10. Safety
  11. Regulatory Affairs
- Work groups are chaired by Clinical Trial Metrics Steering Committee members
  - All MCC organizations are entitled to have multiple representatives on the Clinical Trial metrics work groups
  - Work groups launched April 2008

# MCC Clinical Trial Metrics Development Process

## Clinical Trial Metrics Work Groups

Work Group	Sub Groups
<b>Leader(s)</b>	<b>Peggy Schrammel &amp; Connor Blakeney</b>
<b>Biometrics WG</b>	<p><b>Biostatistics:</b> Defined as process and activities related to the analysis of data. For example, development of the statistical analysis plan, creation of SAS programs, data listings, tables, and figures</p>
	<p><b>Data Management:</b> Defined as processes and activities related to the input of data into a database to be used for statistical analysis of the clinical trial, such as data validation plan, query management, edit check specifications, CRF design and producti</p>

# MCC Clinical Trial Metrics Development Process

## Clinical Trial Metrics Work Groups

Work Group	Sub Groups
Leader(s)	Kathe Balinski
Business Operations WG	<p><b>Business Operations:</b> Defined as process and activities that are required as part of the clinical trial but are not generally governed by SOPs and Regulations. Examples include bidding process, contract process, investigator agreements, etc.</p>
	<p><b>Finance:</b> Defined as processes and activities related to project funding, invoicing and payment, spend Vs. budget, etc.</p>

# MCC Clinical Trial Metrics Development Process

## Clinical Trial Metrics Work Groups

Work Group	Sub Groups
<b>Leader(s)</b>	<b>Holly Hankins &amp; Lorraine Waring</b>
<b>Clinical Operations WG</b>	<b>Clinical Operations:</b> Defined as processes and activities related to the monitoring and site management of the clinical trial including trip reports, patient recruitment, patient enrollment, etc.
	<b>Medical Writing:</b> Includes but is not limited to protocol drafting, protocol writing, clinical study report, ISS, ISE, manuscripts/publications
	<b>Project Management:</b> Defined as processes and activities related to the overall management of the clinical trial with particular attention to management of timelines and deliverables.

## Clinical Trial Metrics Work Groups

<b>Work Group</b>	<b>Sub Group</b>
<b>Leader(s)</b>	<b>April Davis &amp; Ed Cannon</b>
<b>Drug Supply WG</b>	<b>Drug Supply:</b> Defined as process and activities related to the supply of study product to sites. May include IVRS, packaging, labeling, shipment, import/export licenses, other clinical supplies, insurance.

# MCC Clinical Trial Metrics Development Process

## Clinical Trial Metrics Work Groups

Work Group	Sub Group
Leader(s)	Ed Cannon
QA, Regulatory & Safety WG	<p><b>Quality Assurance:</b> Activities related to the assessment of quality related to the conduct of the clinical trial. Includes but is not limited to supplier audits, clinical site audits, protocol audits, database audits</p>
	<p><b>Regulatory Affairs:</b> Activities related to drug release, IRB submissions, MOH submissions IND annual update reports, CTA and IND filings and PSURs.</p>
	<p><b>Safety:</b> Defined as processes and activities related to fulfilling IND safety reporting obligations such as IND safety reports, MedWatch/CIOMS reports. Also includes reporting of adverse events, creation of narratives for SAE, etc.</p>

## In Scope:

- Develop a list of key metrics
- Create metrics that can be key indicators of performance
- Clearly define measurement criteria

## Out of Scope:

- Determining pass/fail criteria
- Assigning accountability

## Proposed Metric - Qualities

- Timeliness
- Cycle Time
- Cost
- Quality
- Efficiency
- Relationship
- Leading Indicator
- Lagging Indicator



UNDER CONSTRUCTION



## Proposed Metric - Qualities

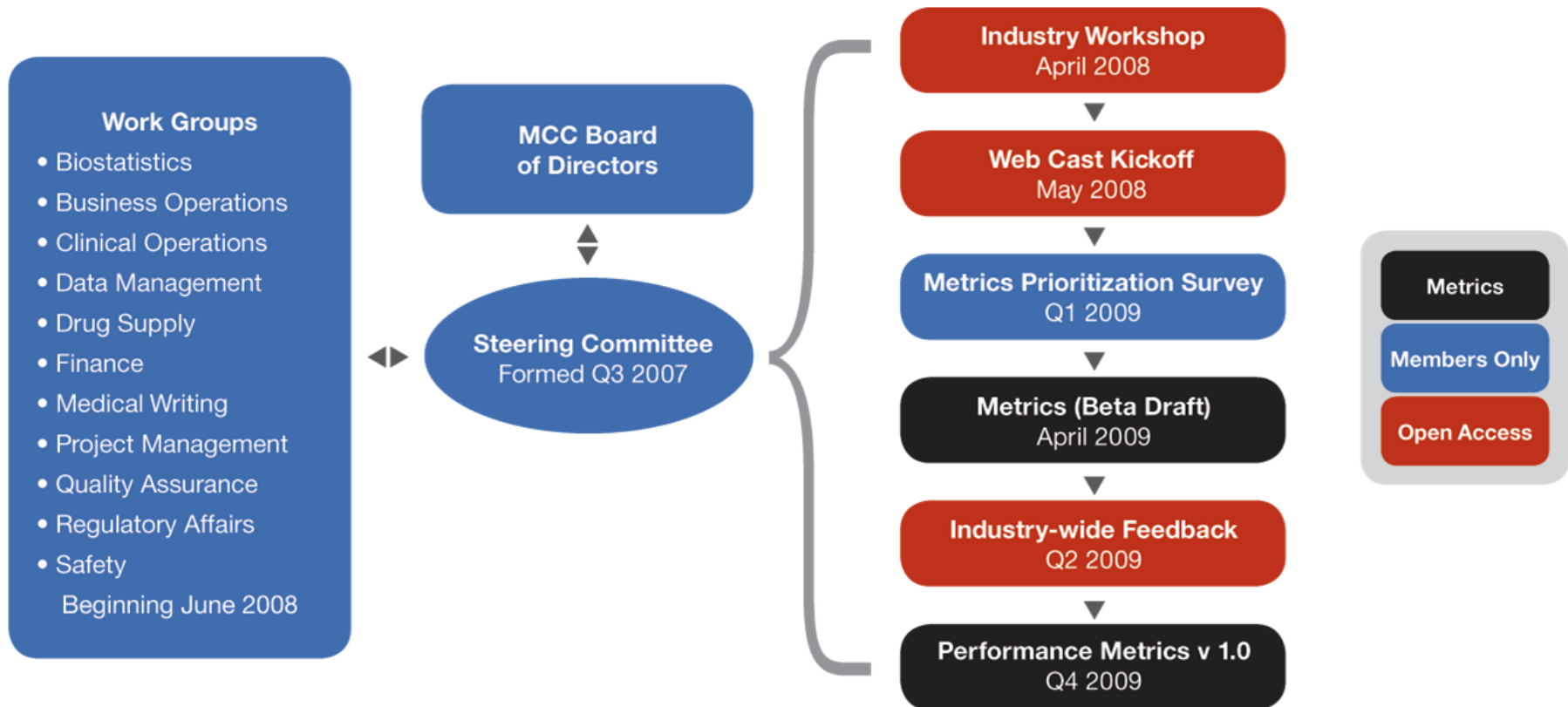
- Well defined
- Be measurable
- Be High Level – but allow for further analysis
- Provide a benefit to Sponsor and Service Provider
- Add Value



UNDER CONSTRUCTION



# Metrics Development Process



## Activities 4/08 – 4/09

- Created workgroups and members
- Reviewed metrics proposed at IIR workshop
- Created additional proposed metrics based on input from MCC workgroup members
- Used Process Task Definition Tool
- Refined list of metrics to be considered
- Developed Definition, Formula, Unit of measure, Frequency, Targets, Example, Benefit Statement



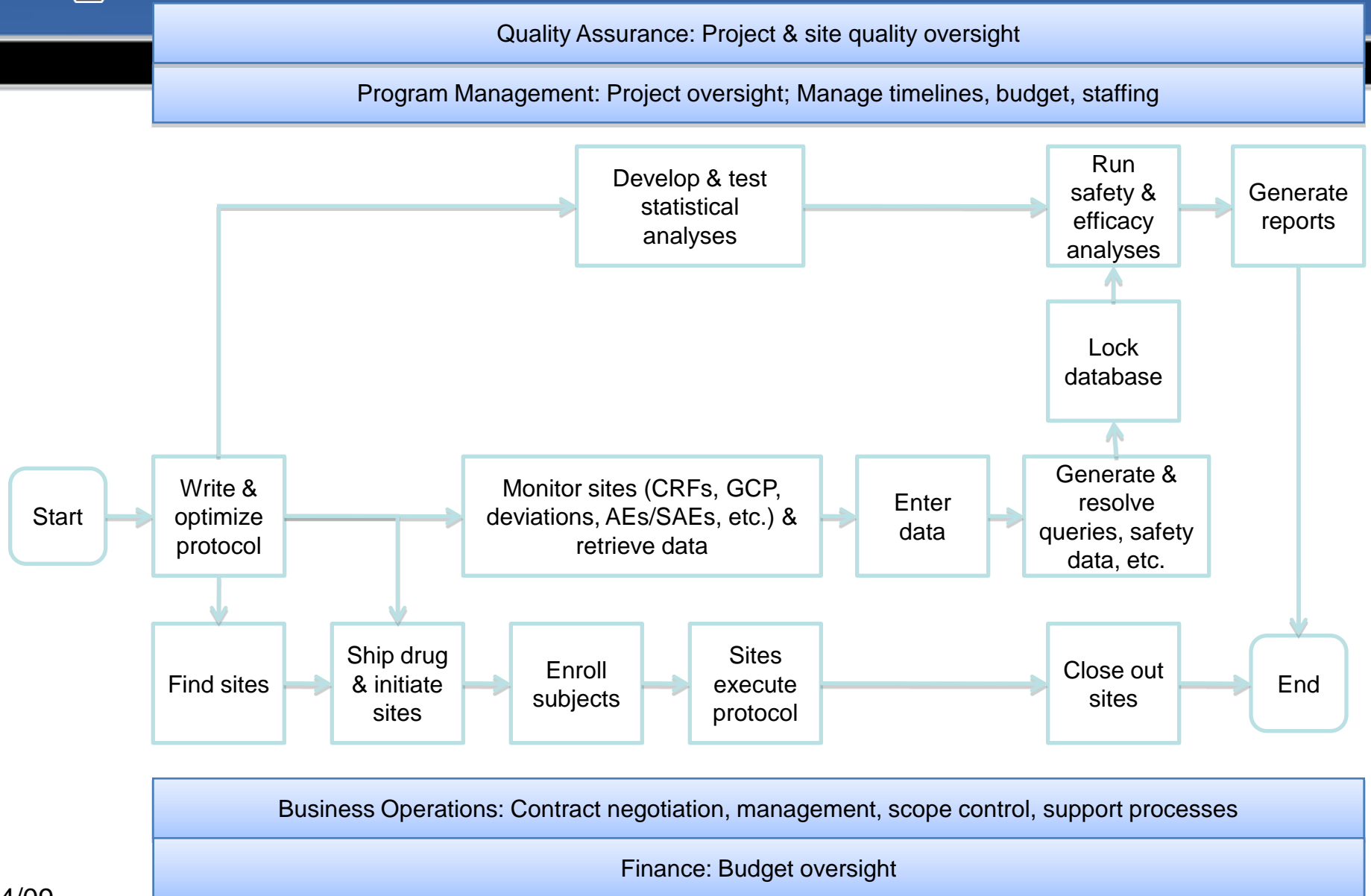
UNDER CONSTRUCTION



## Anatomy of a MCC Clinical Trial Metric

Metric #	Metric Type	Metric Title	Category	MCC Work Group	Definition	Formula / Example	Additional analysis on a "for cause" basis:	Metric Indicator	Reporting Detail	Unit of Measure	Reporting Frequency	Target	Business Driver(s) / Benefit Statement	Comments

# Metrics Distribution



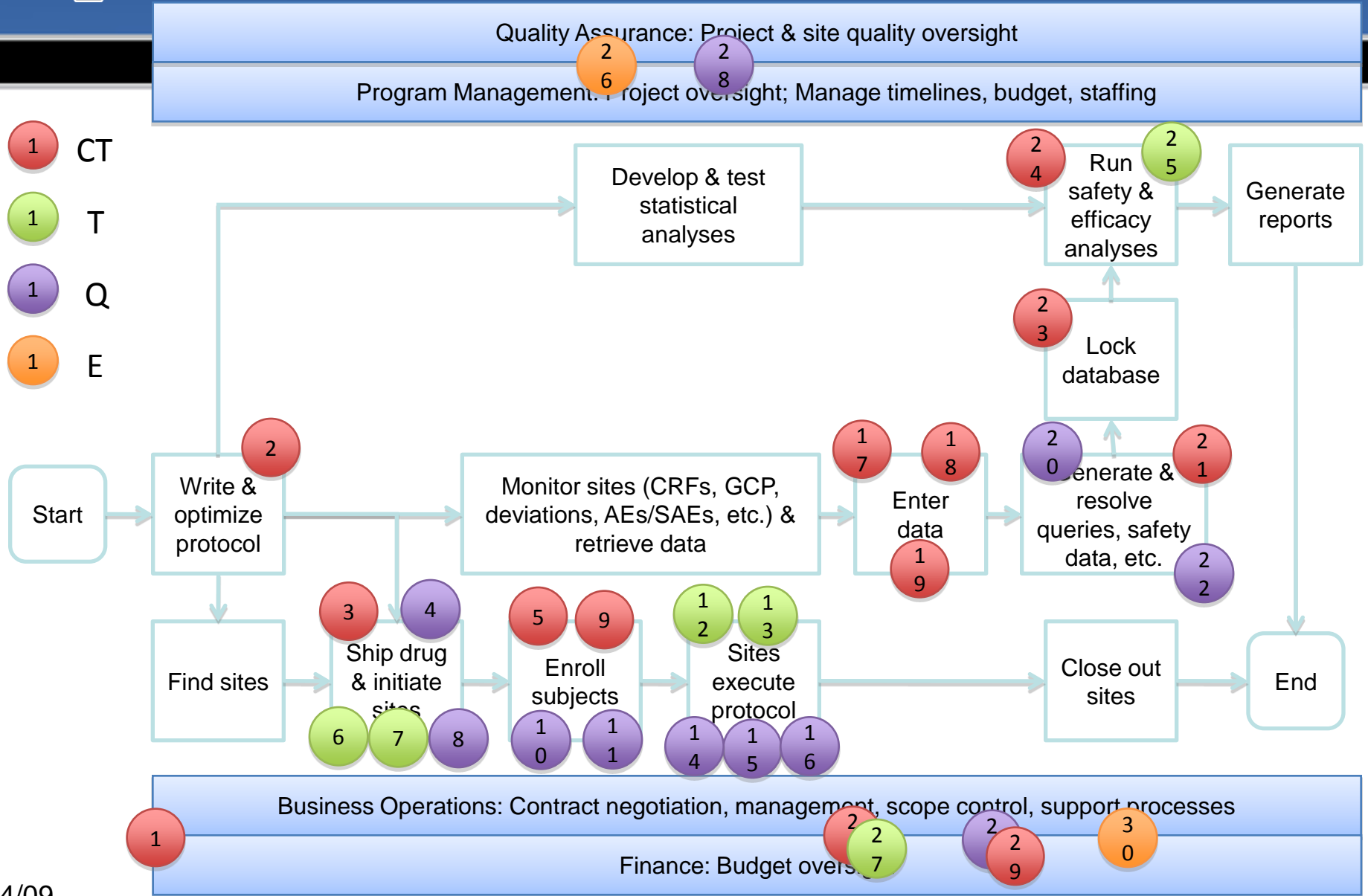
## Type of Metrics

• Cycle Time (CT)	13
• Timeliness (T)	6
• Quality (Q)	11
• Efficiency (E)	2
• Other (O)	0

Total 30\*

\* Note: Metrics 27 & 29 each have 2 metrics

# Metrics Distribution





# Clinical Trial Performance Metrics (Beta version)

Metric	Metric Title	Metric Indicator
1	Contract finalization and execution timeliness	LAGGING Indicator
2	Final Approved Protocol to Final Approved CRF	LAGGING Indicator
3	Cycle Time protocol approval to first site activated	LEADING Indicator
4	Investigator Site Reg pack approval rate	LEADING Indicator
5	Cycle time from final Protocol Approval to First Patient-First Visit (all sites)	LEADING Indicator
6	% Planned Sites Activated	LEADING Indicator
7	Drug Onsite at Initiation	LEADING Indicator
8	Drug Supply Planning	LEADING Indicator

Metric	Metric Title	Metric Indicator
9	Cycle time from Site Activation to First Patient First Visit	LAGGING Indicator
10	Site Productivity	LEADING Indicator
11	Screen Failure Rate	LEADING Indicator
12	Correct Drug Inventory & Resupply	LEADING Indicator
13	% Patients randomized	LEADING Indicator
14	Patent Retention rate	LEADING Indicator
15	% Sites Prematurely Terminated	LAGGING Indicator
16	Audit Findings	LAGGING Indicator



# Clinical Trial Performance Metrics (Beta version)

Metric	Metric Title	Metric Indicator
17	Final CRF/eCFR to Database "Go Live"	LAGGING Indicator
18	CRFs Received to Data Entry Complete - Paper	LEADING Indicator
19	Patient Visit Complete to eCRF data entered - EDC	LEADING Indicator
20	Data discrepancies generated by automated edit checks	LAGGING Indicator * *Could be LEADING Indicator if reported on a monthly basis
21	Receipt of Query Response to Database Update Time	LEADING Indicator
22	QC Rounds Required to Meet Target Error Rate	LAGGING Indicator
23	LPLV (last patient, last visit) to Database Lock	LAGGING Indicator

Metric	Metric Title	Metric Indicator
24	SAP Finalization to Final Pre-lock Blinded TLGs	LAGGING Indicator
25	TLGs delivered within target date	LAGGING Indicator
26	Determination of project progress versus planned	LEADING Indicator
27	Invoice and payment timeliness	LEADING Indicator
28	Issue identification, management and criticality	LAGGING Indicator
29	Measure of true change orders and timeliness of execution	LAGGING Indicator
30	Budget and pricing accuracy	LAGGING Indicator

LAGGING INDICATOR = End user will use metric to identify opportunities to affect change in the future study trials.

LEADING INDICATOR = End user will use metric to identify opportunities to affect change in the current trial.

# Next Steps



Please contact Guy Mascaro or Linda Sullivan at 317.848.2908 for additional information about participating in MCC activities.

[www.metricschampion.org](http://www.metricschampion.org)