



Results of the Clinical Trial Metrics Initiative — Industry Collaboration with Service Providers

Cory Gutterman
Associate Director, GPRD Outsourcing
Abbott Laboratories

Chair, Clinical Research Metrics Steering Committee
Metrics Champion Consortium

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Metrics (once upon a time)

- The need to measure
- What to measure
- Current limitations
- The role of the Metrics Champion Consortium
- How to utilize and manage the information

The need to measure

Objective:

- We want to:
- increase productivity, work smarter, make better decisions
- separate fact from fiction / myth from reality
- remove the mantra “you are only as good as your last game” approach to dealing with suppliers
- replace perception with facts
- manage and improve performance
- set and achieve realistic expectations

The need to measure

Without data

Any / all of the following are true

- _____ takes too long
- _____ costs too much
- I remember when _____
- I know a CRO that can do it _____
- The quality is _____

- Ultimately the following statement is issued: We will never work with that CRO again

The need to measure

Pros:

- If you don't measure anything you are left with "institutional memory"
- There is a natural tendency to improve what is measured
- If you measure the right things.... You have the opportunity to improve
- By repeated measurement, you can discover trends
- By the use of metrics and the identification of areas that are of concern, you create an opportunity to improve processes

The need to measure

Cons:

- Metrics take time to collect
- If you collect them, you have to analyze them
- If you analyze them, you have to take action
- If you take action, you have to continue to collect metrics to see if the action taken has positively affected the metrics
- You can become obsessed with metrics and lose sight of the "big picture"

What to Measure



What to Measure

Time

- Begin Activities
- Protocol Approved (CMR)
- First EC Approval
- First Lab Kit shipped
- First Subject Enrolled (CMR)
- First Dose to Subject (CMR)
- Last Subject Enrolled (CMR)
- Last Subject Last Visit (CMR)
- Database Lock (CMR)
- CSR sign off
- Final CRF approved
- Database ready
- First lab data load
- Time from funding to protocol
- Time to enter CRFs
- Time to execute contract

What to Measure

Cost

- Scope Changes
 - Sponsor initiated
 - Supplier initiated
- Invoice Payment Timeliness
 - Meeting payment obligations
- Costs Incurred Relative to Study Progress
 - Cash flow
 - Performance
 - Number of accessions relative to budget

What to Measure

Quality

- Data Management Metrics
 - Query rates, time queries are outstanding
 - Data loads
- Staffing Metrics
 - CRA turnover
 - Project Manager turnover
- Audit Findings
- Clinical Monitoring Metrics
 - Timeliness (trip reporting / visits according to monitoring plan)
 - Quality (queries)

What to Measure

Satisfaction

- Sponsor Satisfaction
 - Qualitative measurement
 - All quantitative measures can be “green” but team could be very dissatisfied
- Supplier Satisfaction
 - Qualitative measurement discussed at semi-annual meetings
- Voice of the Customer
 - Who is the customer

Current limitations of Metrics

- Metrics are not stored in a central database
- Participation in CMR / KMR benchmarking studies are not frequent enough to measure / affect change
- We do not capture year over year learning
- Variety of different data sources
- No one can agree on what to measure

Current limitations of Metrics

- Selecting the right metrics
- Defining the metrics and setting a target
- Establishing who is the owner of metrics? Who is ultimately responsible for gathering the information
- Determine how to use metrics correctly according to their purpose
- Avoiding overambitious timelines and unrealistic expectations for metrics
- Gaining alignment around metric definitions to achieve a streamlined system
- ... Along comes the Metrics Champion Consortium

MCC Clinical Trial Performance Metrics Development Process

Clinical Trial Metrics 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

MCC Clinical Trial Performance Work Group Participants

Abie Ekangaki	David Rodin	Joan Farrington	Lee Davis	Ned Connell
Allison Houghteling	Dawn East	Joanne Bailey	Li Ding	Nicolle Kealy
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	Diane Laumann	Joseph Giuliano	Linda Stevens	Patric Donaghue
Bonnie Beaver	Elise Kayson	Judith Chiostrì	Lisa Chen	Paty 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 Tschartland	Louise Rochon	Richard Musselman
Catherine Elliott	Eric Hiltbeitel	Kate Haratonik	Lynn Watson	Robert Holman
Charles Chesson	Eric Strait	Kathe Bainski	Magaly G. Woolard	Ronald Knickerbocker
Chili Li	Eva Kantanas	Karl Kieburz	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	

Contracting for CROs
Date: December 03, 2009

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MCC Clinical Trial Performance Metrics Development Process

Clinical Trial Metrics Work Groups

- | | |
|------------------------|------------------------|
| 1. Business Operations | 6. Data Management |
| 2. Finance | 7. Biostatistics |
| 3. Clinical Operations | 8. Medical Writing |
| 4. Project Management | 9. Quality Assurance |
| 5. Drug Supply | 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

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MCC Clinical Trial Performance Metrics Development Process

Proposed Metric - Qualities

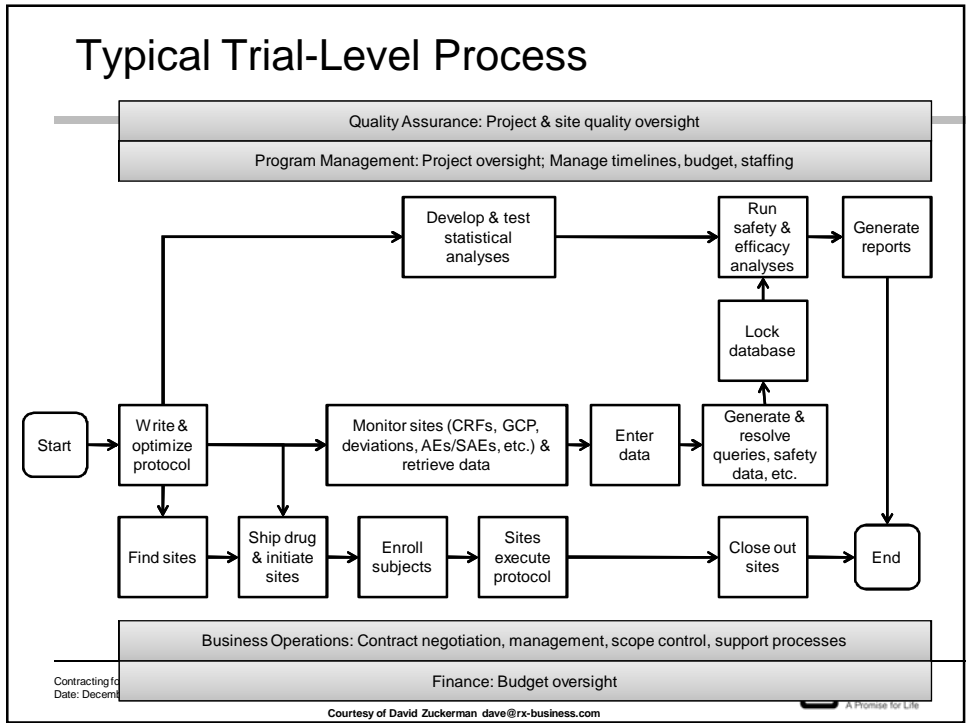
Timeliness (T)
 Cycle Time (CT)
 Efficiency / Cost (E)
 Quality (Q)
 Relationship (R)

Provide a benefit to Sponsor and Service Provider
 Add Value

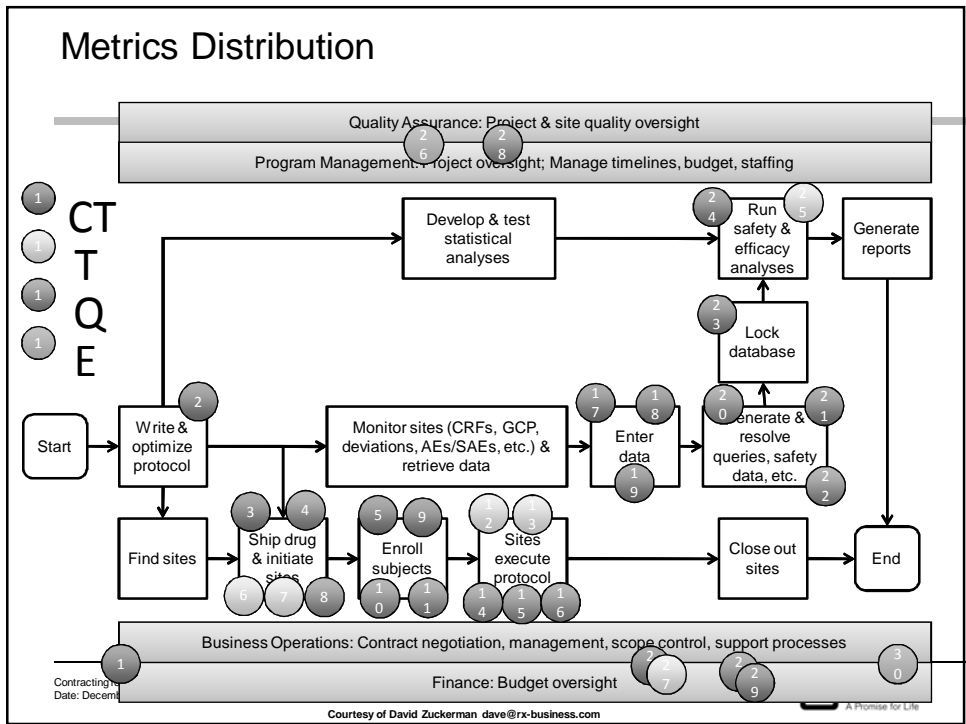
MCC Clinical Trial Performance Metrics Development Process

Metric #	Metric Type	Metric Title	Category	Metric Indicator
3	CT	Cycle Time protocol approval to first site activated	Site Selection and Activation	LEADING Indicator
		Definition	Formula / Example	Reporting Detail
		The total number of calendar days from the date the final approved protocol is released to the CRO to the date of first site activated (trial level, country level) where site activation is defined as site has been approved to begin screening patients.	Formula: X - Y, where X is Date of First Site Activated; and Y is Date of Protocol Approval Specific 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 Days/Weeks
		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 patient enrollment 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 Plus or Minus 2 weeks per contract, by geography (G); within 2-4 weeks per contract by geography (Y); >4 weeks per contract by geography (R)

Typical Trial-Level Process



Metrics Distribution



MCC Clinical Trial Performance Metrics (Beta version)

Metric	Metric Title	Metric Indicator	Metric	Metric Title	Metric Indicator
1	Contract finalization and execution timeliness	LAGGING Indicator	9	Cycle time from Site Activation to First Patient First Visit	LAGGING Indicator
2	Final Approved Protocol to Final Approved CRF	LAGGING Indicator	10	Site Productivity	LEADING Indicator
3	Cycle Time protocol approval to first site activated	LEADING Indicator	11	Screen Failure Rate	LEADING Indicator
4	Investigator Site Reg pack approval rate	LEADING Indicator	12	Correct Drug Inventory & Resupply	LEADING Indicator
5	Cycle time from final Protocol Approval to First Patient-First Visit (all sites)	LEADING Indicator	13	% Patients randomized	LEADING Indicator
6	% Planned Sites Activated	LEADING Indicator	14	Patent Retention rate	LEADING Indicator
7	Drug Onsite at Initiation	LEADING Indicator	15	% Sites Prematurely Terminated	LAGGING Indicator
8	Drug Supply Planning	LEADING Indicator	16	Audit Findings	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.

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MCC Clinical Trial Performance Metrics (Beta version)

Metric	Metric Title	Metric Indicator	Metric	Metric Title	Metric Indicator
17	Final CRF/eCFR to Database "Go Live"	LAGGING Indicator	24	SAP Finalization to Final Pre-lock Blinded TLGs	LAGGING Indicator
18	CRFs Received to Data Entry Complete - Paper	LEADING Indicator	25	TLGs delivered within target date	LAGGING Indicator
19	Patient Visit Complete to eCRF data entered - EDC	LEADING Indicator	26	Determination of project progress versus planned	LEADING Indicator
20	Data discrepancies generated by automated edit checks	LAGGING Indicator * *Could be LEADING Indicator	27	Invoice and payment timeliness	LEADING Indicator
21	Receipt of Query Response to Database Update Time	LEADING Indicator	28	Issue identification, management and criticality	LAGGING Indicator
22	QC Rounds Required to Meet Target Error Rate	LAGGING Indicator	29	Measure of true change orders and timeliness of execution	LAGGING Indicator
23	LPLV (last patient, last visit) to Database Lock	LAGGING Indicator	30	Budget and pricing accuracy	LAGGING Indicator

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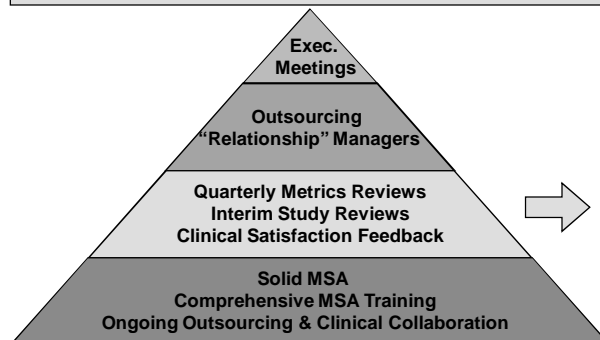
How to utilize and manage the information

- Engage in collection over regular intervals
- Review metrics individually and collectively
- Set standards and targets for improvements
- Incorporate into contracts
 - Contractual obligation to collect and provide metrics
 - Contractual terms for performance related to key metrics

Supplier Management Program

Supplier Management Objectives

- Global oversight of CRO's
- Enforce contract terms
- Review supplier performance
- One point of contact for high level issue resolution
- Detect issues before they escalate to crisis level

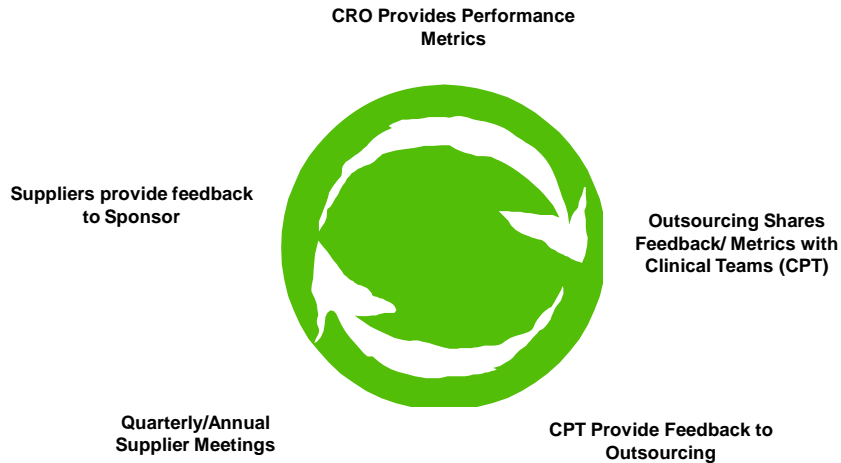


Metrics Report Key Content

- Project milestones tracking
- Enrollment
- Trip Report timeliness
- Data Clarification Field metrics
- CRO turnover
- Contract change orders
- Finance

Also blinded data shared across suppliers.

Supplier Management Program



Thank You

Cory Gutterman
Associate Director, Outsourcing
Abbott Laboratories
Cory.Gutterman@Abbott.com

