

# Sponsor-CRO Metrics

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# Lilly Medical Sourcing Office (MSO)

- Cross-functional Subject Matter Experts
- Dedicated to support of Lilly teams working on outsourced clinical projects with preferred CROs
  - Lilly-CRO relationship
  - Process enhancements
  - Metrics
  - Issue escalation
- Reporting structure: Direct to central functions, dotted line to MSO Manager
  - Do not report to development teams



# CRO Relationships

- Lilly currently has preferred relationships with several full-service CROs for clinical development services
  - Master Service Agreements
  - Preferred Pricing
  - Governance Structure
- Lilly utilizes non-preferred CROs as well
  - Niche providers (e.g., early phase, therapeutic, regional, functional)

*Lilly*

Answers That Matter.

# Managing Trials Through Metrics: Overview



- Process Optimization Group (POG) spearheading Statistical Process Control (SPC) initiative
  - Initiative started in June 2005
    - Global remit as of January 2006
  - Objective is to standardize and improve processes, ensuring consistency and quality in delivery
  - Utilize formal data collection and evaluation process to drive changes in the business
  - Utilizes SPC, Lean Sigma, and Six Sigma techniques

# Vision

- Quantitative approach to improve process understanding and evaluation, ultimately driving change within the organization
- GOALS
  - Consistent service delivery for customer
  - Consistent service delivery for Quintiles
  - Continuous support of Quintiles in goal of data-driven and metric-based decisions
  - Continuous Process Improvement

# Remit

- Global remit with focus on all divisions of the business
- No reporting structure within a specific division
- There is no “box”
  - Entrusted to be CRO innovators
  - Trying to create operational consistency within CRO
  - Think Globally; start small, scale fast

# Sponsor Partnerships

- Identify and assess potential shared process improvements
- Understand differences in the process across organizations
- Identify areas for potential alignment and efficiency gains
- Reduce variability, improve efficiency, and improve financial performance
- Create a transparent reporting structure to increase comfort level between organizations
- Ultimately standardize processes and metrics across sponsors

# Challenges

- Data collection is sometimes manual
  - Current systems do not capture required metrics or data points
  - Timeliness, accuracy, and compliance with collection
- Need to understand what accurate data should look like
- Shifting culture away from anecdotal evidence to metrics-based evidence

# POG Activities

## Metrics

*Measure and monitor what we do*

Improved Service Delivery

# POG Activities

Strategic

*Change what we do*

Tactical

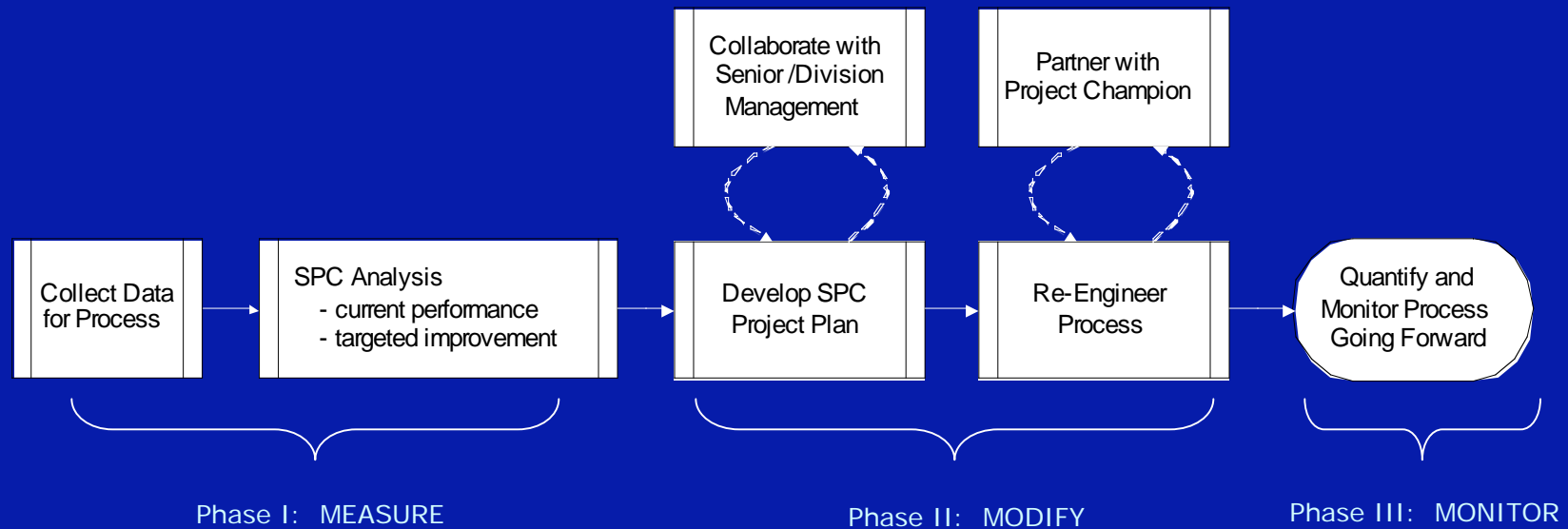
*Improve what we do*

Metrics

*Measure and monitor what we do*

Improved Service Delivery

# Tactical: Performance Analysis



# Why Metrics?

## Management

- Better understanding of organization-wide performance
- More informed decision making based off of data vs. anecdotal information

## Operations

- Outline and understand one process
- Identify inconsistent and below target performance
- Prioritize areas and processes for re-engineering
- Pinpoint areas that will impact company and financial performance

## Customer

- Transparent processes and expectations
- Better relationship management
- Contained costs and higher efficiencies

## Regulatory

- Increased patient safety
- Less ambiguity in process understanding and execution
- Increased transparency in data collection and reporting

# Metrics as a Business Requirement



- It is a part of our organization's life
  - Top-down understanding and support
  - Metrics are used to have a better understanding of our delivery
  - Moving away from business being driven by outliers – use data to drive business
- Better understanding of what we do
  - Know process well enough to either change less and manage scope creep better
  - Need to recognize deviation from the norm

# Process Optimization and Lilly

- Lilly and Quintiles mapped their internal processes for various functions
  - Site Start Up
  - Change Orders
  - Contract / Payments Management
- Processes compared across organizations and metrics identified to assess performance
  - Baseline metrics established
  - Upper and Lower control limits identified
  - Ongoing metrics collected to understand how well we are doing against our standards
  - Adjust process / expectation based on metrics collection

# How does Lilly select a CRO partner?

- Requests for Proposals sent to pCROs
  - May send to niche provider depending upon circumstance
  - Face-to-Face bid defenses no longer routinely held
    - Relationships have evolved to where no longer necessary
      - Mutual understanding of needs and capabilities
  - Necessary clarification managed through other methods (e.g., teleconference, webconference, etc.)
  - Bids reviewed and evaluated internally with facilitation by Sourcing Office and Procurement
- Certain events may trigger non-receipt of RFP
  - Significant audit findings, e.g.
  - Clear and obvious gap in capabilities

*Lilly*

Answers That Matter.

# Performance Metrics

- Lilly historically has had no standardized performance metrics with our CRO partners
  - Each Lilly team working with a CRO develops individual metrics and tracking tools: many similarities in what/how collected and reported
  - Current practice is inefficient, especially for CRO: have to “please” too many customers who all want something different
  - Internal Lilly customers confused by different metrics and formats
- Momentum: April 2006 Lilly-Quintiles Steering Committee requests from Senior Leaders of both companies
  - Standardized processes across Lilly and Quintiles projects
  - Standardized metrics across all Lilly and Quintiles projects
  - Revamped and more efficient Governance Committees
- Plan to enhance and replicate with other CRO partners

The Lilly logo is a stylized, cursive script of the word "Lilly" in white, positioned in the bottom right corner of the slide.

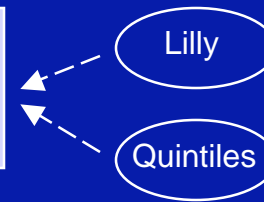
Answers That Matter.

# Lilly-Quintiles Performance Metrics

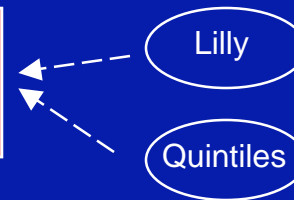


Joint Lilly-Quintiles

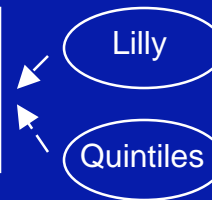
**Oversight Committee**  
7-8 Key measures



**Operations Committee**  
12-14 Key measures



**Lilly-Quintiles Project Team**  
18-20 Key measures



Internal Quintiles

**Quintiles Metrics**  
38-40 Key measures



Key measures roll up to higher levels of oversight

Dual source of joint Lilly-Quintiles Metrics



Answers That Matter.

# Lilly-Quintiles Performance Metrics



Detailed  Summarized

Category	Quintiles Metrics	Lilly-Quintiles Project Team	Operations Committee	Oversight Committee
Site Readiness	Y	Y		
Patient Enrollment	Y	Y		
Data Management	Y	Y		
Major Project Milestones	Y	Y	Y	Y
Cycle Time	Y	Y	Y	
Quality	Y	Y	Y	Y
Change Orders	Y	Y		
Financial	Y	Y	Y	Y
Team Health	Y	Y	Y	Y



Answers That Matter.

# Metrics Development

- Identified 4 key areas:
  - Quality
  - Operational
  - Team Health
  - Financial
- Partnership between Lilly MSO and Quintiles Global Process Optimization Group
- Brainstormed with Clinical Staffs (identified areas where we are lagging, reviewed leading metrics)
  - What is currently collected?
  - What does it make sense to continue to collect?
  - What should we stop collecting—meaningless metrics?
  - What is missing?
  - Push Quintiles metrics down to Quintiles—discourage Lilly micro-management of Quintiles

# Metrics Development

- Developed Metrics Collection Plan
  - Operational definitions
  - What is the source?
  - Who will collect?
  - How will it be collected?
  - How often?
  - How will we use it? (e.g., Risk Management, Contingency Planning, etc.)
- Checked for alignment with Quintiles and Lilly clinical groups during multiple iterations of collection plan
- Requests for changes to standardized metrics panel will be managed through formal change control process

# Operations Committee Example

## Metrics Collection Plan

What ?				Who ?	How ?	When ?	How will it be used?	Intervention Action
Category	Performance Measure	Operational Definition	Data Source and Location	Who will collect data?	How will data be collected?	Project Phase / Frequency	How will it be used?	
Quality	% of Protocol Amendments	Total No. of protocol amendments / total No. of ongoing protocols; will track root cause. Ongoing protocol = protocol has been approved by Lilly and LPV has not occurred.	Lilly Impact Database	Lilly CRO CCO Lead Team	Lead Team will solicit data from Lilly SDP Process Owner	Duration of Projects / Quarterly	Risk Mitigation	
	% Review cycles to plan	No. of total review cycles / No. of review cycles as defined in the Work Plan. This is expressed as a total of all deliverables (e.g. CRFs, protocols, study reports, etc.) Root causes will be tracked	To be developed: review cycle tracking tool	Lilly CDA and Quintiles Project Manager	Manual tracking tool - to be developed.	Duration of Project	Risk Mitigation	

# Challenges Remain

- Existing team metrics—don't necessarily want to change if meeting the team's needs
- Easiest to implement governance level metrics
- Very manual to collect
  - Need to prioritize IT development work
  - Goal is “one pager” scorecard
  - Data coming from multiple databases
  - Continued challenges with partners' transfer of trial management and other critical data to Lilly systems
- Organizational inclination to develop team-specific metrics

# Making Progress

- Leadership acceptance of value of standardized metrics
- Teams recognize value of *governance* level metrics
- Data readily provided for collation in manual process
- IT Business Case developed for scorecard development
- Pursuit of aligned format for existing project level metrics
- Enhanced relationship between Lilly and Quintiles during metrics development
  - Deeper understanding of each other's internal processes and challenges

# Current Status

- Have initiated Metrics reviews at 2 most recent quarterly Joint Operations Committee meetings
- Some of our projects are “hybrid”; there are some activities and responsibilities that Lilly retains
  - Integration of these projects shines the spotlight on the successes and challenges for both partners
- Aggregated metrics review has highlighted areas of concern and identified targets for process improvement projects

# Key Success Factors

- High Executive commitment from both parties
- Strong communication between both parties and between business areas
- Resource commitment to understand the underlying process dynamics
- Need to have a vision of what product will look like – “end in mind”
- Embrace idea that manual data collection and aggregation may be necessary

# Key Success Factors

- Share data to ensure clear expectations
  - Hybrid studies
  - Fully outsourced studies
- Open relationship, no consequences
- Recognize low-value metrics and discontinue collection
- Operate as equals for mutual benefit – true partners

# Benefits

- Increased ability of Governance committees to look across the portfolio “book of work” and identify constraints
- Lilly and Quintiles can pinpoint internal areas of concern and adjust accordingly
  - Resource allocation
  - Process improvement
- Development of comprehensive portfolio risk plan
- “One Stop Shopping” for performance metrics
  - Critical from a functional perspective to monitor business performance
- Identification of process bottlenecks
  - Invoice processing
  - Change Orders
- Staff Motivation
  - Increased productivity
  - Recognition of performance and process improvements

# Blue Sky?

- Mutual understanding of processes and process constraints will reduce (or eliminate?) change orders
  - Expectations clear from project launch
  - Mitigate pinch points
- Streamlined work plan and contract process
- Standardized metrics across sponsors and CROs
  - Seamless partnerships
  - Even the playing field
    - Sourcing decisions are evaluated against capabilities to deliver, not who has the snazziest metrics scorecard

# What We Need

- Standardized metrics across the industry
  - CROs and Sponsors
- Set realistic metrics goals
  - What does it take to get the job done?
- Debunk perception of:
  - volume + complex = excellent
  - key + simple = inadequate
- Help standardize definitions
- Promote efficient clinical trials through understanding of metrics
  - >30% efficiencies through focused clinical trials