Metrics Review Process
for
MCC CRO Metrics Teams

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Differences Between CRO Metrics and Other Metric Types

- Not strictly supplier-customer
  - Success of both parties required
  - Team-based
  - Relationship-based
- Decision driven vs. transactional
  - Lots of interim decisions that affect the project direction
- Each project is unique to some extent
  - Not “cookie cutter”

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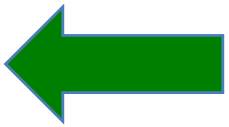
What Types of Metrics are Appropriate (1 of 2)?

- Measure performance 
  - Timeliness, Cycle Time, Quality, Efficiency
- Measure the relationship ?
  - Pharma satisfaction, CRO satisfaction
  - Financial stability
  - Organizational cohesiveness & stability (both parties)
  - Cutting edge technologies

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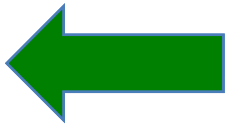
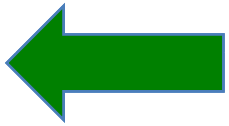
What Types of Metrics are Appropriate (2 of 2)?

- Retrospective metrics 
  - Measure what's already happened
    - Ex: Cost per clean data point
  - Good for project-over-project improvement
- Prospective metrics 
  - Predict future performance
    - Ex: On-time site initiation
  - Good for avoiding/mitigating problems on the current project

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Types of Performance Metrics

Timeliness (T)

Measures whether a milestone was achieved on-time

Cycle Time (CT)

Measures how long it takes to complete a task

Quality (Q)

Measures the number of errors in completing a task

Efficiency (E)

Measures the resources required to complete a task

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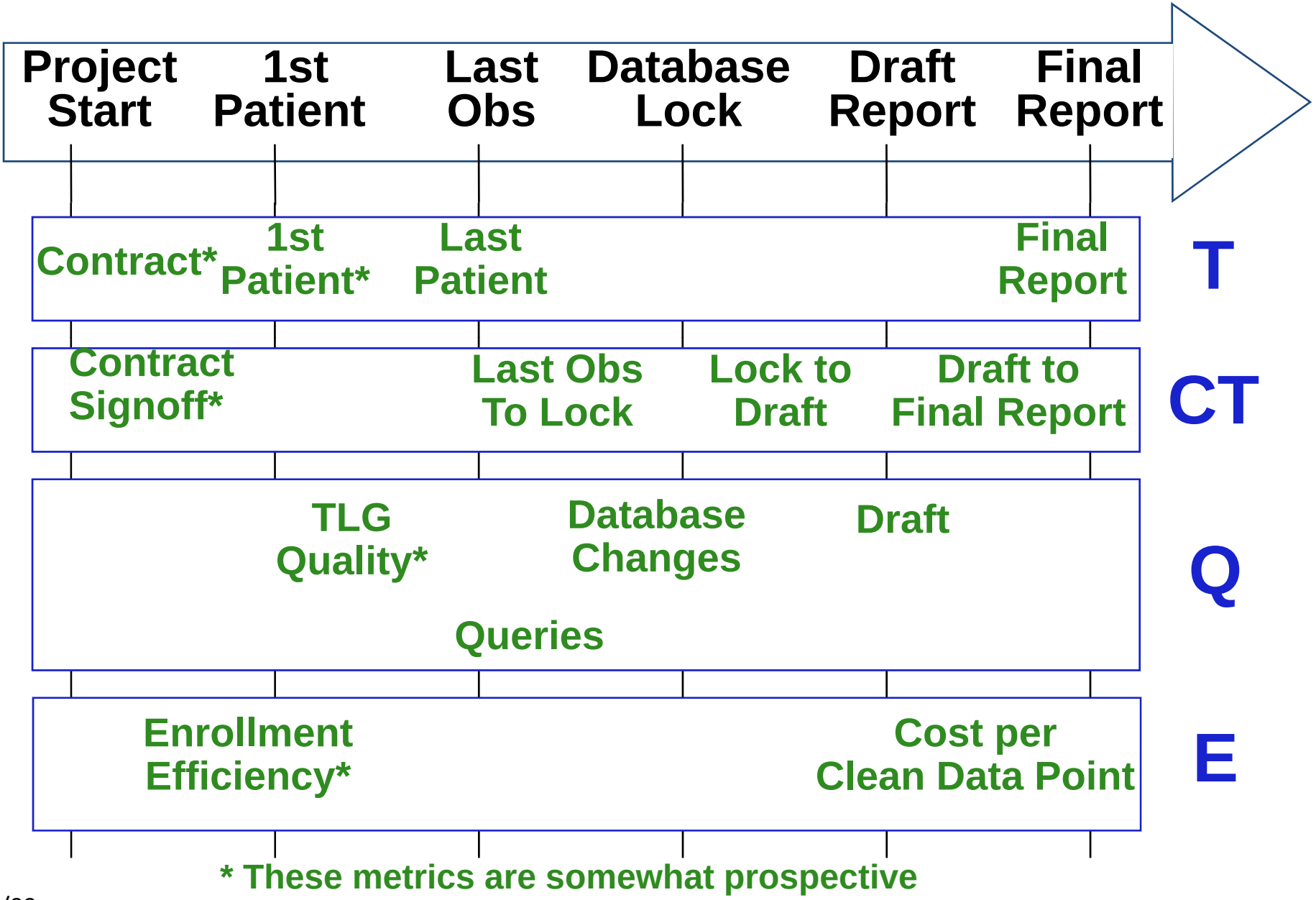
Example: Searle-CRO Metrics Set



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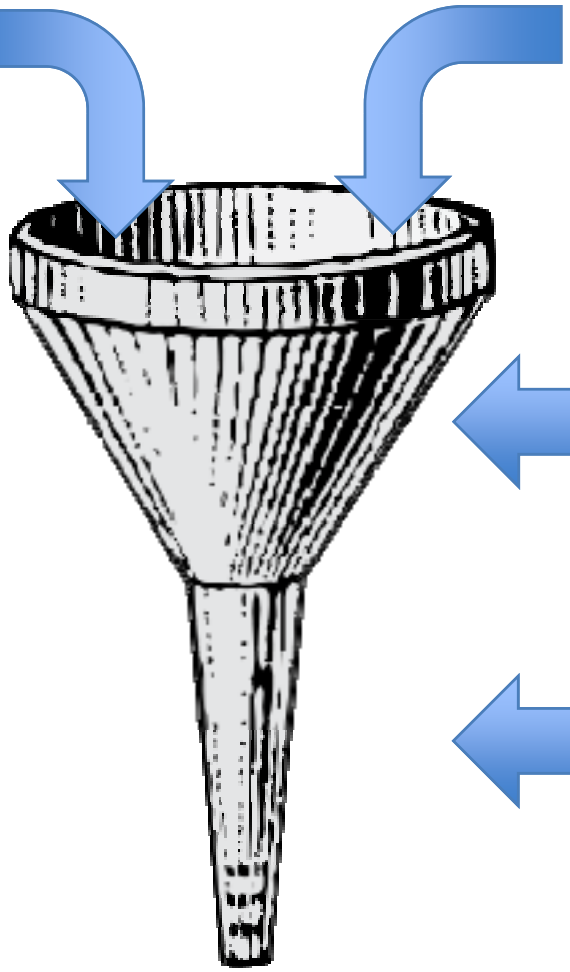
MCC metrics selection approach

1 Brainstorm Metrics Lists

Existing Metrics Lists — **DONE**



2 Process Mapping Screening — **DONE**

3 Review and Ranking — **TODAY**

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MCC CRO metrics list screening approach

1. Define the process
2. Identify problems in the process
3. Measure the process
   - T, CT, Q, E
   - Long-term improvement (multiple projects)
   - Short-term success (on time & on budget)

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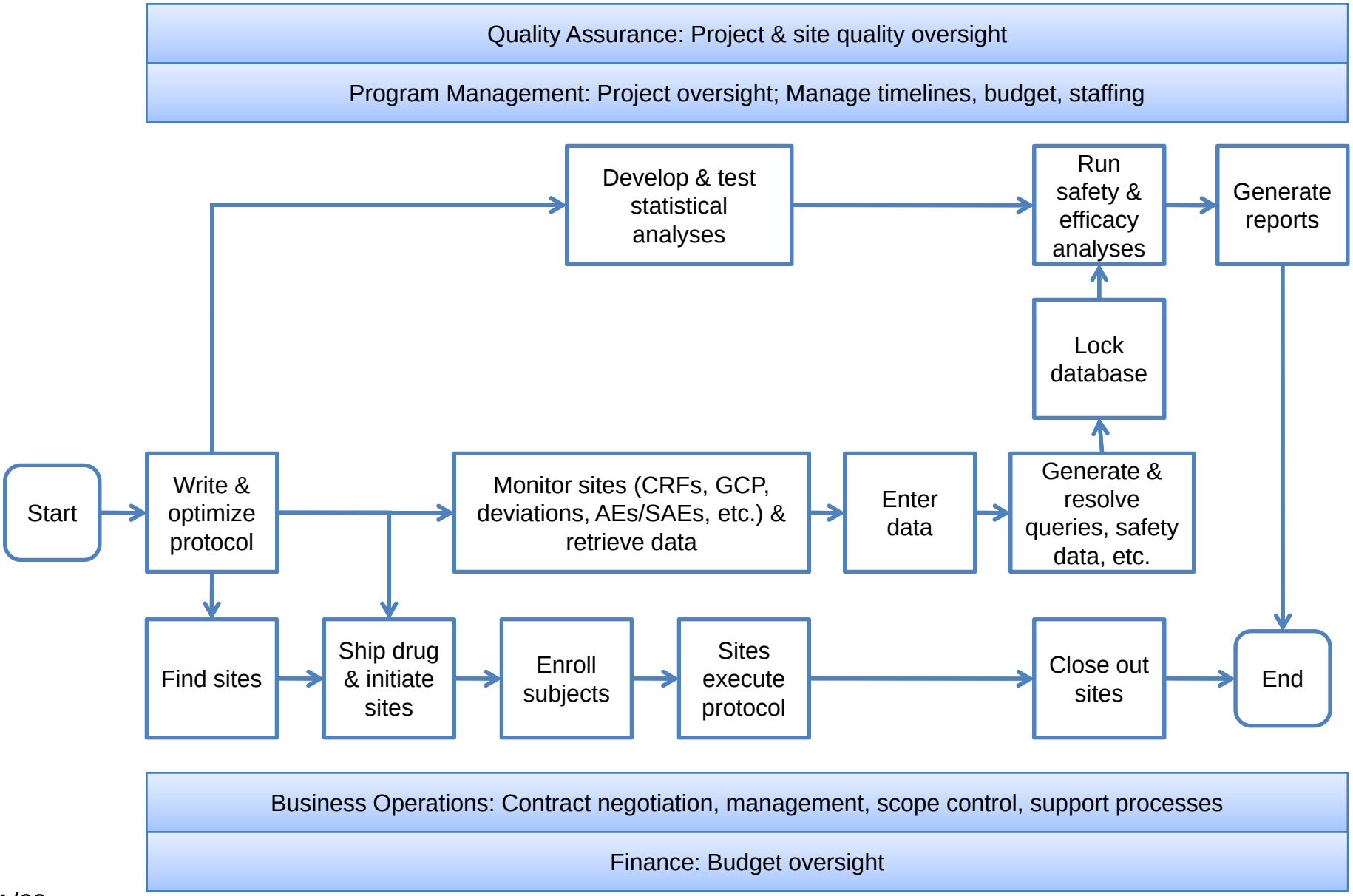
Typical Trial-Level Process



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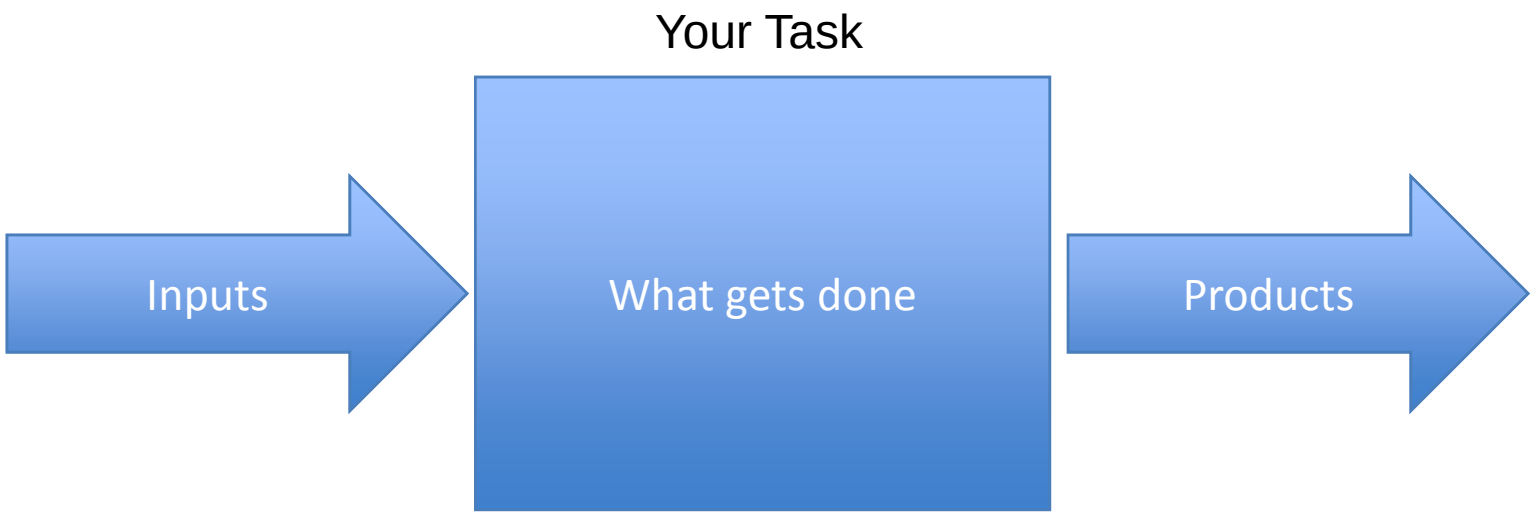
Analyzing the Process



Input Problems

Task Problems

Output Problems

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Process/Task Definition Form

Process/Task Name:

Is task being performed by CRO or pharma?

Process/Task Objective:

Pharma Inputs **Suppliers**

Supplier Issues

CRO Inputs **Suppliers**

Supplier Issues

Subtasks in This Process/Task

Beginning Boundary:

Subtasks

Factors that drive cost/cycle time

Ending Boundary:

Products **Customers**

1.

2.

Metrics (T, CT, Q, E)

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Definitions

Process/Task Name: *MCC Team Name*

Process/Task Objective: *What work is accomplished during these tasks*

Is task being performed by CRO or pharma?
Are you assuming that the pharma or CRO is doing this work?

Pharma Inputs **Suppliers**

What inputs are required from the pharma and which functions/groups supply them?

Supplier Issues

What are the typical problems encountered with these inputs? Are they late, of poor quality, misunderstand the requirements, etc?

CRO Inputs **Suppliers**

What inputs are required from the CRO and which functions/groups supply them?

Supplier Issues

What are the typical problems encountered with these inputs? Are they late, of poor quality, misunderstand the requirements, etc?

Subtasks in This Process/Task

Beginning Boundary:

What tasks triggers the start of this work?

Subtasks

What specific steps are required to perform this work and produce the products at left?

Factors that drive cost/cycle time

What are the typical problems encountered when performing this work? What tends to cause delays, extra work/cost, errors, rework?

Ending Boundary:

What tasks triggers the completion of this work?

Products **Customers**

1. *What are the one or two key products that result from this work and who*
2. *receives these products?*

Metrics (T, CT, Q, E)

What metrics can you think of that will help you measure and improve on the:
- *Supplier Issues*
- *Cost/Cycle Time of your work*
- *Products you provide to customers*

Try to focus on metrics that can be used to avoid problems in the future rather than simply cataloging problems of the past.

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CRO Performance Metrics Initiative – Process/Task Definition Worksheet

Process/Task Name:

Final Contract Execution

Is task being performed by CRO or pharma?

CRO

Process/Task Objective:

Finalize SOW, budget, payment schedule, timeline and contract terms for a new project

Pharma Inputs
Protocol/synopsis
Scope of Work (SOW)
Contract template
RFP
Responsibility Matrix
Timeline

Suppliers
Line functions
TA Groups
Contract Mgmt
Legal
R&D Finance
Procurement
Country representatives
Business Development

Supplier Issues
Lengthy/late review of scope/contract documents by legal and line function
Resources
Changing scope

CRO Inputs
Proposal
Assumptions
Contract template
Resources/experience
Rates/cost
Unclear/missing info scope/timelines

Suppliers
Contract and proposal group
Line functions
Country representatives

Supplier Issues
Lengthy/late review of scope/contract documents by legal and line function

Subtasks in This Process/Task

Beginning Boundary:
Written authorization from pharma to CRO to start work

Subtasks
Agree on:
- Scope and timelines
- Deliverables
- Rates
- Budget and payment schedule
- Milestones
- Contract wording
- Resource assignments/experience

Joint SOW review process
Internal process for review of proposal/ RFP/SOW/Contract

Factors that drive cost/cycle time
Calculation errors
Lack of clarity in protocol/SOW
Delays in review by parties that require review/input/approval
Unrealistic timelines
Changing scope

Ending Boundary:
Fully executed contract (agreement, scope, budget

Products
Clear SOW
Timeline
Budget
Contract terms
Payment schedule

Customers
Project teams
Finance

Metrics (T, CT, Q, E)

1. # calendar days from written authorization of work to full execution of contract (no MSA in place) (T)
2. # of calendar days from written authorization of work to full execution of work order (MSA in place) (T)
3. # of changes to initial SOW (clarity of SOW) (Q)
4. # of review cycles for (CT):
   - contract terms
   - SOW finalization
   - budget

Courtesy of David Zuckerman dave@rx-business.com

Key Attributes of a Good Metric

1. Fit for Purpose (Utility)
2. Collectable Data
3. Quality Definition

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Fit for Purpose - Utility

- Prospective
  - Metrics that look forward offer more value than those that look backward
  - A “risk” metric vs an “errors” metric
- Assesses the relationship
  - On-schedule performance is good
  - On-time, high-quality deliverable is better
  - Satisfied pharma & CRO is best
- Passes the “so what” test
  - We know whether increasing the metric value is “good” or “bad”
  - We can derive root cause data
- Promotes desired improvement/behavior
  - No unintended consequences
- Will you use it?

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Collectable

- Data is actually available
  - CROs and pharmas are actually collecting this data now
  - It is clear that this data can be collected
- Data is of high quality
  - The data being collected is consistent across time and between organizations
- Data collection cost is reasonable

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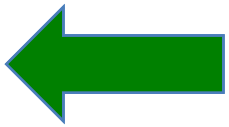
Quality Definition

- You easily understand the definition 
  - It is clear as written
  - Careful explanation is not required to understand it
- Everyone else understands the definition the way you do

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Questions/Comments/Discussion

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