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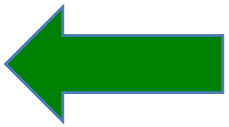
What Types of Metrics are Appropriate (1 of 2)?

- 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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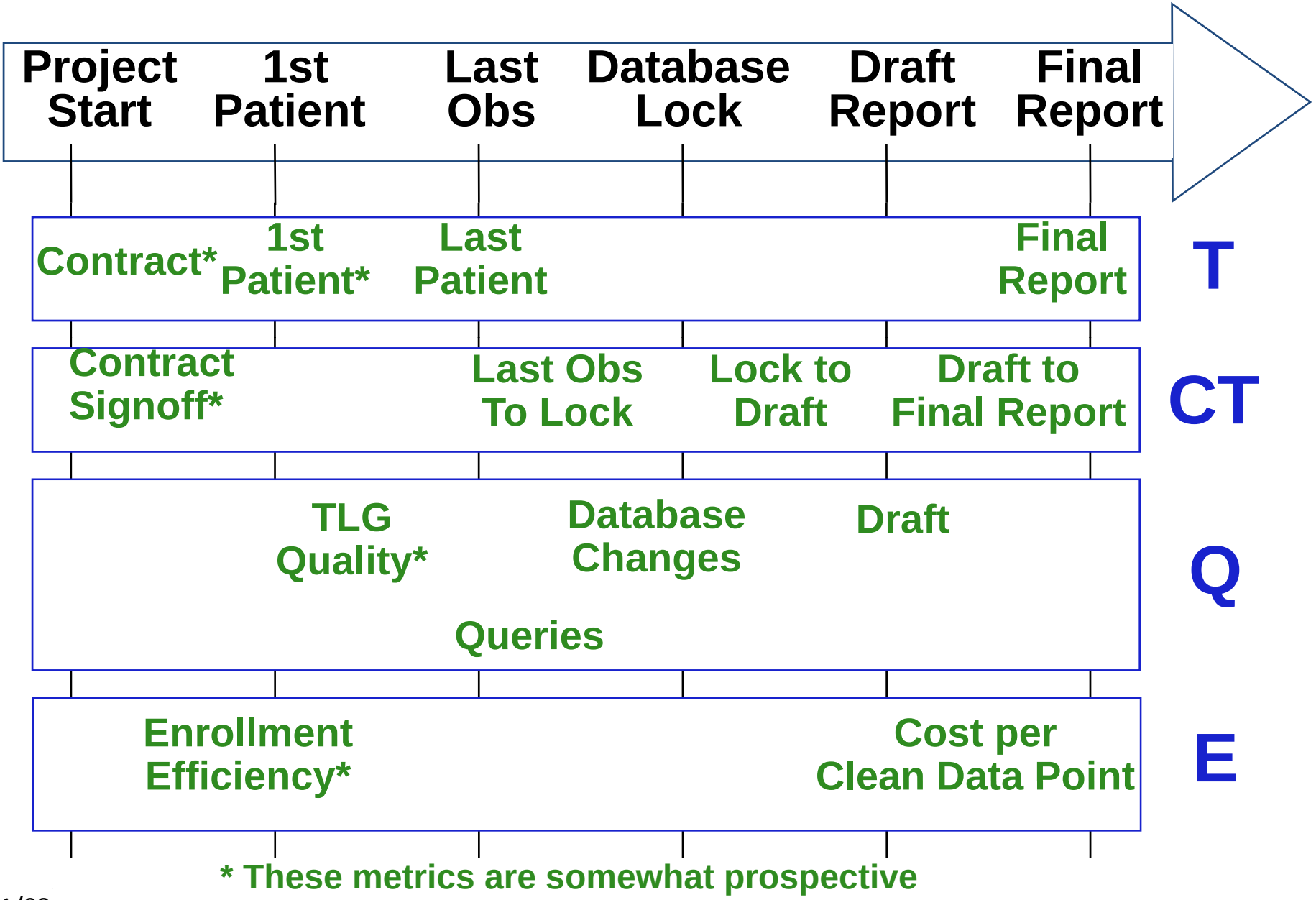
Example: Searle-CRO Metrics Set



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MCC CRO metrics 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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Approach Details

1. Determine where your work fits in the clinical trial process (see process map)
2. Identify who supplies inputs and who receives your outputs
3. Fill out the Task Definition Form for your work
   - See completed TDFs for examples
4. Identify metrics (T, CT, Q, E) that will measure progress in improving performance
   - Will improve products, fix supplier issues, help reduce cost or cycle time issues
   - Are predictive whenever possible

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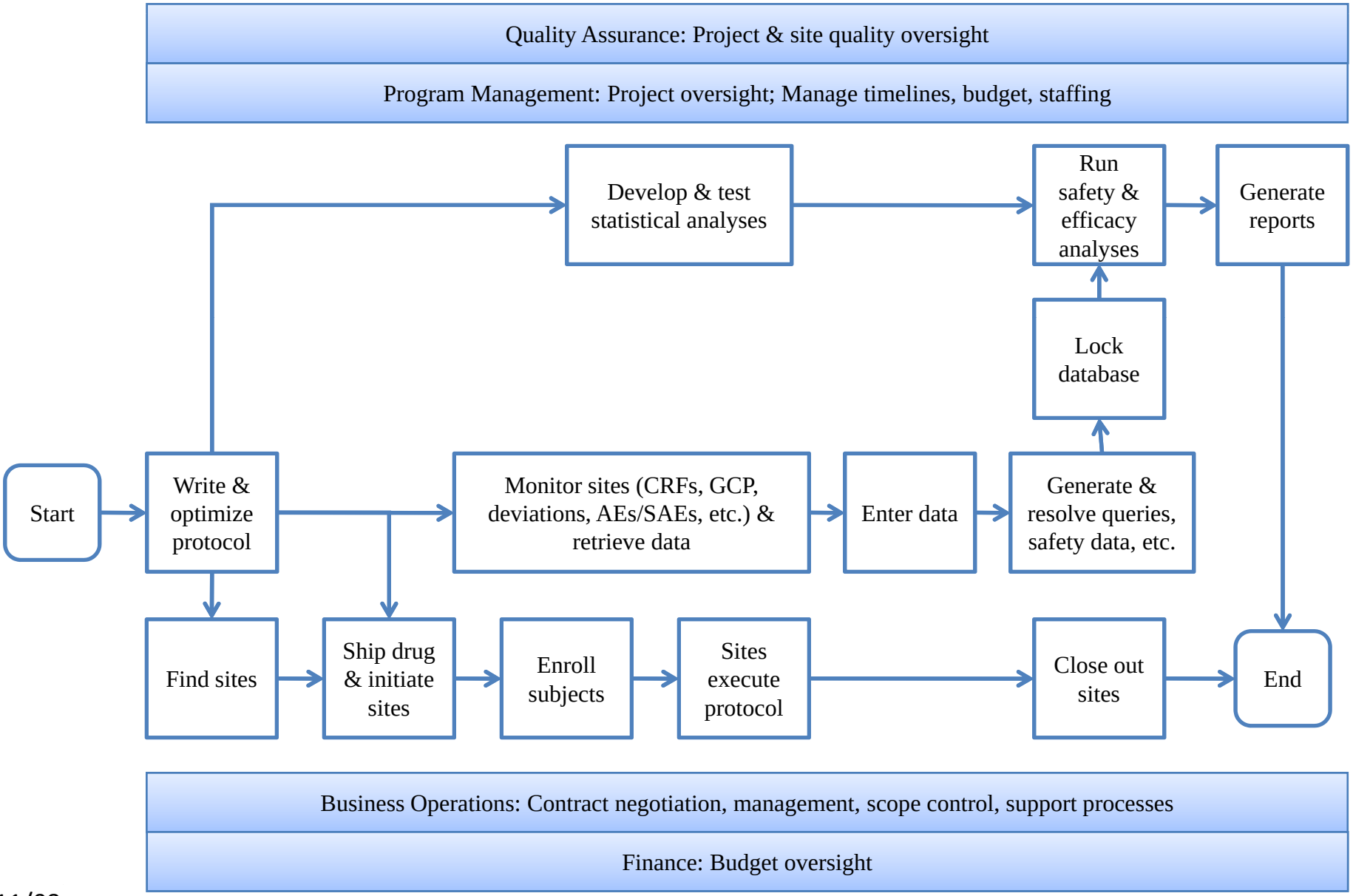
Typical Trial-Level Process



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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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Complete the Form in This Order…

Process/Task Name: 1

Process/Task Objective: 2

Is task being performed by CRO or pharma? 3

Pharma Inputs **Suppliers** 4

Supplier Issues 5

CRO Inputs **Suppliers** 6

Supplier Issues 7

Subtasks in This Process/Task

Beginning Boundary: 8

Subtasks 9

Factors that drive cost/cycle time

Ending Boundary: 10

Products **Customers**

1.

2. 11

Metrics (T, CT, Q, E) 12

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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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Example 1 Process/Task Definition Form

Process/Task Name: *Data Management Edit Check Development*

Process/Task Objective: *Develop Edit Checks for a protocol & CRF*

Is task being performed by CRO or pharma?

CRO

Pharma Inputs
Protocol
CRF

Suppliers
MW
CRF designer

Supplier Issues
Supplied late

CRO Inputs
Stats analysis rqmts

Suppliers
Biostats

Supplier Issues
Supplied late

Subtasks in This Process/Task

Beginning Boundary:
Receive protocol & CRF

Subtasks
Define edit check rqmts
Construct edit checks
Review & scrub edit checks
Program edit checks
Validate/test edit checks
Modify as required

Factors that drive cost/cycle time
Inadequate edit check review/scrub
Inadequate test/validation

Ending Boundary:
Production started

Products
1. *Edit checks*
2. -

Customers
Data analysts
CRAs

Metrics (T, CT, Q, E)
On-time protocol & CRF (T)

% participation in edit check review (Q)

Comprehensiveness of test/validation data set (Q)

Number of edit check changes after sign-off (Q)

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Example 2 Process/Task Definition Form

Process/Task Name: *Site selection*

Process/Task Objective: *Identify appropriate sites for a specific protocol*

Is task being performed by CRO or pharma?

CRO

Pharma Inputs	**Suppliers**
Protocol	*Pharma*
Required site list	*Pharma*

Supplier Issues
Protocol supplied late
Protocol amended
Required site list too long

CRO Inputs	**Suppliers**
CRF	*CRF designer*
Site selection criteria	*Project team*
Enrollment forecast	*Project team*

Supplier Issues
CRF supplied late
Site selection criteria are vague
Enrollment forecast is too optimistic

Subtasks in This Process/Task

Beginning Boundary:
Receive protocol & CRF

Subtasks
Verify enrollment forecast
Refine site selection criteria
Identify sites that match criteria
Determine individual site capabilities & interest
Rank sites by enrollment potential & interest

Factors that drive cost/cycle time
Can't get good enrollment forecast (so have to identify extra sites)
Can't get crystal clear site selection criteria (so end up with low enrolling sites)

Ending Boundary:
Send ranked site list to CRAs for site initiation

Products	**Customers**
1. *Enrollment success criteria*	*CRAs*
2. *Ranked site list*	*CRAs*
	Project team

Metrics (T, CT, Q, E)
On-time protocol & CRF (T)

# of protocol amendments (Q)

Accuracy of enrollment forecast (Q)

Time to next site initiated vs forecast (CT)

Quality of next site initiated (Q)

% of sites enrolling ≥ forecast (Q)

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CRO metrics champion

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

Questions/Comments/Discussion

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