



RH Bouchard & Associates

**RH Bouchard & Associates,
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Process Improvement Expectations

- ◆ Long term relationships will result in efficiencies
- ◆ Efficiencies will result in cost savings
- ◆ Process improvement can be planned
- ◆ Process improvement can be measured



Metrics: Key Performance Indicators (KPI)

- ◆ Set goals for performance
- ◆ Measured for each study
- ◆ Correlated across studies
- ◆ KPI's measure:
 - Cycle time improvement
 - Quality improvement
 - Relationship satisfaction



Objective of KPIs

- ◆ Set expectations (long and short term)
- ◆ Framework to measure improvement
- ◆ Common language for discussions of performance
- ◆ Standardized approach to managing performance
- ◆ Early warning system



What KPIs are NOT

- ◆ A way to criticize CRO performance
- ◆ A tool for pointing fingers
- ◆ A method for collecting minutia



KPIs must be...

- ◆ Applicable to both parties
- ◆ Readily available
- ◆ Easy to collect
- ◆ Objectively measured



KPI Examples

◆ Project Metrics

■ Cycle Time

- # of days to initiate sites
- # days LPO to database lock
- # days from award to final contract
- # days for notification of Change Order to signed modification



KPI Examples

- ◆ Quality
 - # queries per CRF page
 - Database audit error rate
 - # versions of Stat plan
 - # of database changes between close and lock



KPI Examples

- ◆ Relationship
 - Reasons for change orders
 - Projected pass-throughs to actuals
 - Satisfaction surveys
 - Staff turnover rates
 - Lessons learned meetings



Manage Performance through KPIs

- ◆ Set targets in the contract
- ◆ Know status of key metrics, quality measures, and deliverables
- ◆ Give and receive feedback
- ◆ Establish accountability
- ◆ Be fair and balanced but set expectations



Exercise #1

Handouts



Guidelines for Negotiation

- Think about closure from the beginning
- Determine not only your interests, options and alternatives but also those of your counterpart
- Include your counterpart in the brainstorming process
- Identify issues that may need to be dealt with and possible ways to resolve issues
- Think about what it might take to persuade the other side – and you – to accept a proposed agreement
- Develop a “framework agreement”: outline each term to be resolved in the negotiations



Goals of Successful Negotiation

- Interests – not positions
- Options – expand the pie
- Standards – external and fair
- Alternatives – Find the best alternative for both sides



Exercise #1: Role Play

- ◆ Negotiation Skills
- ◆ ½ CROs, ½ Sponsors
- ◆ Divide into 5 groups
- ◆ Purpose: To determine, based on your contract, if a change order is needed, and if performance expectations were met



Questions & Answers

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