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## Performance Metrics in Contracts

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**Incorporating Performance Metrics into Proposals and Contracting**  
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## Rationale for Participation in MCC

- Historical perspective
  - Metrics: Frequently requested, seldom consistent, often confusing, mostly misinterpreted and not understood
- MCC Standardization approach
  - Facilitates collection and reporting
  - Well defined
  - Interpretable across participants
  - Relevant to work and performance

## Rationale for Adopting in Contracts



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- May be defined once in MSAs
- Discussed in governance (regular discussion promotes better understanding)
- Adopted in working practices (process improvements)
- Adjunct to internal KPIs (more focused)
- Assists with alignment of resources and goals
  - Timelines, quality gates, costs and reduces COs



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## Metrics in the Outsourcing Continuum

**RFI ⇒ Proposal ⇒ Contract**

## BD Continuum: Metrics in RFIs



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- Distinguish operations based on industry standards for timeliness and quality
  - Present tangible benefits to working with your CRO
- Set expectations for future engagements based on benchmarks
  - Reinforces marketing messaging with objective measures


## BD Continuum: Metrics in Contracts



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- Target Metrics add definition to scope
  - Cycles and turnaround times
  - Quality gates and rejection rates
- Better comprehension of deliverables expectations
  - Yields more accurate costs
  - Fewer out of scopes and over budget situations
- Defines expectations for reporting and reviewing output

## Metrics Contracting Objectives




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- Commit to **essential** metrics
- Reduce ambiguity in contracting objectives and incentives
- Promote relationship management through metrics maintenance in governance
  - Standardization of reporting and performance appraisal leads to open dialog and process improvement

## Metrics in Operations




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- Helps identify where process change is needed to improve outcome

**Time**




Task execution  
Metric creation  
Reporting

**Cost**



Resource use  
B-I-C process  
B-I-C tools

**Quality**



Tolerance  
TAT  
Risk Management

## Desired Outcomes



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- **Documented** solid performance encourages repeat performances
- Governance promotes awareness
- Benchmarking helps **everyone** do better
- Non-fit risks may be identified early
- Industry-wide definitions make reporting simpler and more efficient

## Benchmarking



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- Requirements for achieving strong performance are well defined
- Should include both parties to evaluate process improvement opportunities
- Benchmark metrics can be used to score clients
  - Turn around or response times
  - DSOs
  - Helps identify potentially unrealistic expectations in evaluation of contracting risks

## Relationship Management



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### **Use industry-wide metrics to answer RFIs or drive behavior change:**

#### **Sponsor RFI Questionnaire:**


- “Based upon your expertise, comment on what works well with/for other clients, but has not worked/been implemented with us. Where do you feel we can improve / realize efficiencies?”

## Governance & Metrics




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- Serves as foundation for operations-level win-win reviews
- Promotes constructive dialog leading to performance improvement
  - Partner vs. provider
  - Mutually agreed practices or revised and updated SOPs
- Consideration of targets leads to better risk management strategies

  
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# Case Study #1

## Labs Metrics: Getting Started


Getting Started   
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- Identify essential metrics from MCC list
- Establish mutually-agreed definitions
- Test sources of data
- Define reports, frequencies for delivery
- Plan for meetings to discuss results
- Establish contracted obligation
- Iterative process so expect and accept change
- Be alert for divergence

## Identify Essential Metrics




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### MCC Central Lab Metrics v 1.1

Metric	Category	Metric Title	Definition <sup>a</sup>	Reason for changes in v1.1
4	Data Cleaning	Percentage of queries from central laboratory to site based upon requisitions received	<p><b>Minimum:</b> The number of queries generated between the central laboratory and the sites, compared to the number of requisitions received by a central laboratory.</p> <p><b>Additional analysis on a "for cause" basis:</b></p> <p>a. The number of queries generated between the central laboratory and the site, compared to the number of requisitions received for a site, protocol, sponsor, and central laboratory by business unit.</p> <p>b. The reasons which resulted in these calls by central laboratory defined by site, protocol, sponsor, and central laboratory by business unit.</p>	This metric was refined to reflect the organization's overall ability and track record in query levels across all their studies. Sponsor level and study level are optional additional metrics.
5	Data Cleaning	Average turnaround for resolution of queries from central laboratory to site	<p><b>Minimum:</b> Average time required for resolution of queries from central laboratory to site based on the requisitions received by a central laboratory.</p> <p><b>Additional analysis on a "for cause" basis:</b></p> <p>The amount of time required to resolve these queries by reason for a site, protocol, sponsor, and central laboratory by business unit.</p>	This metric captures the time to resolve the queries by the lab across all their studies. Sponsor level and study level are optional additional metrics.
6	Site Support Services	Percentage of queries from site to central laboratory based upon requisitions received with average turnaround time	<p><b>Minimum:</b> The number of queries generated between the site and the central laboratory, compared to the number of requisitions received for a sponsor and central laboratory, and the average time to resolution</p> <p><b>Additional analysis on a "for cause" basis:</b> The number and type of queries generated between the site and the central laboratory, compared to the number of requisitions received by protocol.</p>	Type of query was added to this metric as a clarifier for the reasons why the queries are occurring. Title, formula, and target were clarified to match the benefit statement.

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## Redefinition

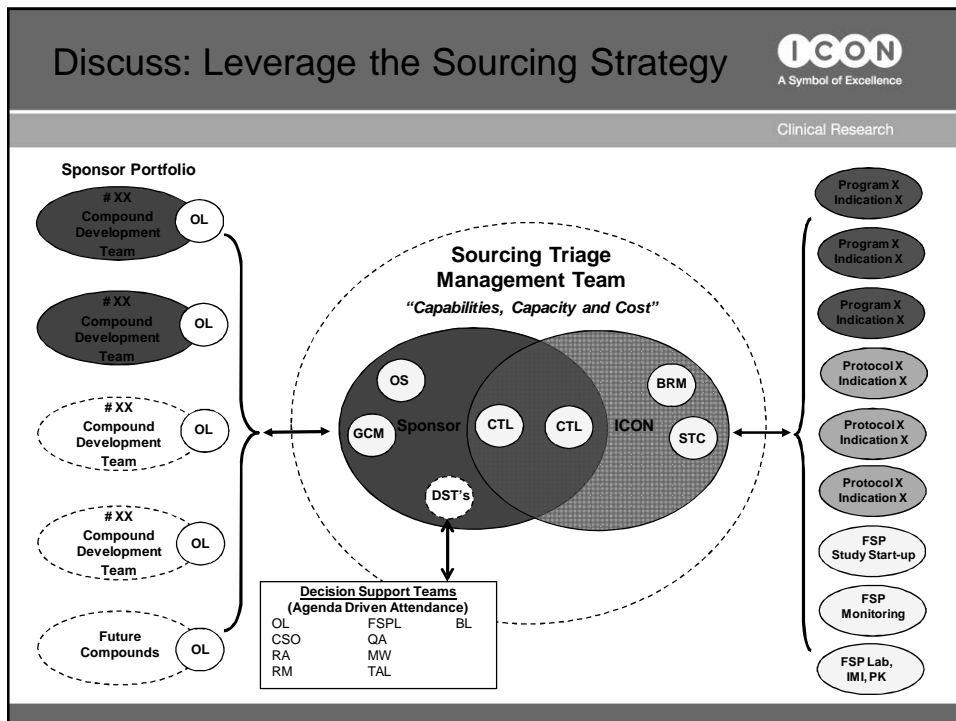
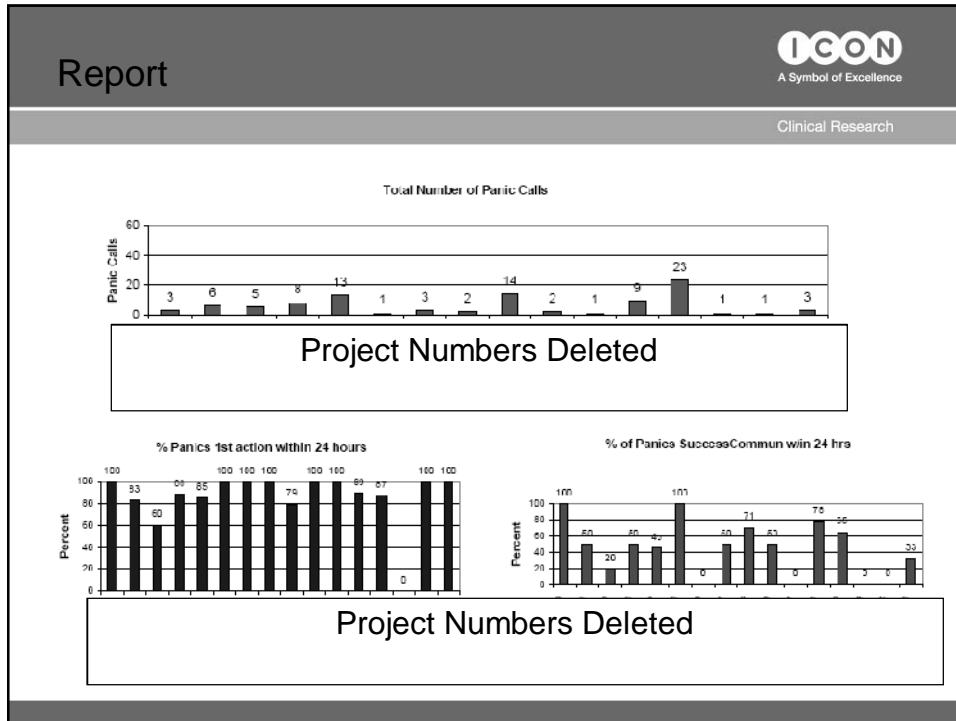


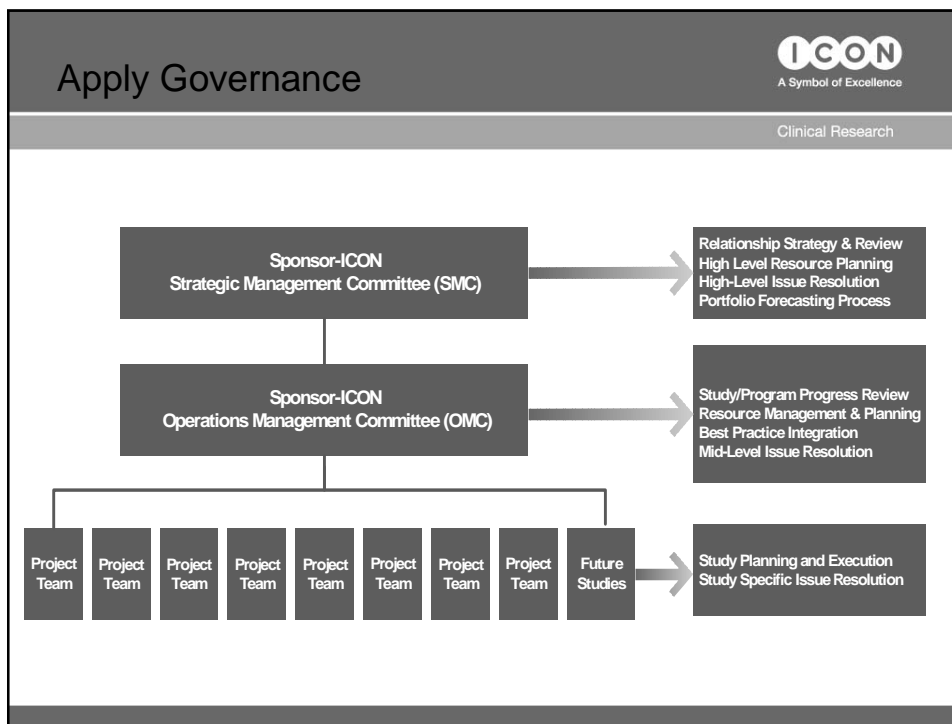
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8	Safety	Percentage of panics successfully communicated to the sites within the defined turnaround time	<p><b>Minimum:</b> Percentage of panics successfully communicated to sites within the defined turnaround time - overall by sponsor and central laboratory.</p> <p><b>Additional analysis on a "for cause" basis:</b> Percentage of panics not successfully provided within the defined turnaround time for a site, protocol, sponsor, and central laboratory by business unit.</p> <p><b>Note:</b> "Successfully" could be defined per Standard Operating Procedure or specific requests per sponsor</p>	<p><b>Formula:</b> (Total N panics which were successfully communicated / Total N panics) x 100</p> <p><b>Specific Example:</b> 100 panics successfully communicated; 120 total panics Result: 100/120 = 83% successfully communicated panics</p>
8	Safety	Percentage of panics that had both 1 <sup>st</sup> attempt made and were successfully communicated to the sites within the defined turn around times	<p><b>Minimum:</b> Percentage of panics that had both 1<sup>st</sup> attempt made and were successfully communicated to the sites within the defined turn around times- overall by sponsor and central laboratory.</p> <p><b>Additional analysis on a "for cause" basis:</b> Percentage of panics not successfully attempted nor successfully provided within the defined turn around time for a site, protocol, sponsor and central laboratory by business unit.</p> <p><b>Note:</b> "Attempts" and "Successfully" could be defined per Standard Operating Procedures or specific requests per sponsor.</p>	<p><b>Formula:</b> (Total N panics which had 1<sup>st</sup> attempt / Total N panics) X 100 and (Total N panics which were successfully communicated/ Total N panics) X 100.</p> <p><b>Specific Example:</b> 100 panics successfully communicated; 10 panics with 1<sup>st</sup> attempt made; 120 total panics Result: 110/120 = 92% attempted and communicated panics</p>


Metrics Definition of Deliverable			 A Symbol of Excellence	
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Total N and Percentage	Quarterly	>95%	<p>You will be informed regarding the service provider's delivery of panics to the sites so that you can evaluate and ensure that patient care is being maintained. In addition, timely, successful communication of alerts to the sites promotes site confidence in provider and sponsor.</p>	<p>Specifically, you can evaluate:</p> <ul style="list-style-type: none"> <li>• Panic turnaround delivery per protocol</li> <li>• Panic turnaround deliver per sponsor</li> <li>• Panic turnaround delivery per geography</li> </ul>
Total N and Percentage	Quarterly	>95%	<p>You will be informed regarding the service provider's delivery of panics to the sites so that you can evaluate and ensure that patient care is being maintained. In addition, timely, successful communication of alerts to the sites promotes site confidence in provider and sponsor.</p>	<p>Specifically, you can evaluate:</p> <ul style="list-style-type: none"> <li>• Panic turnaround delivery per protocol</li> <li>• Panic turnaround deliver per sponsor</li> <li>• Panic turnaround delivery per geography</li> </ul>

Metrics Reporting		 A Symbol of Excellence			
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<b>ICON Central Laboratories METRICS</b>					
Print Date:	ICON Central Laboratories (ICL) have begun the initiative of providing quarterly metrics based on Central Laboratory Metrics Consortium's guidelines. We, in partnership with our Clients, are now providing the 5 most important of the Standard MCC Metrics to evaluate study success.				
Report Description:	ICL has committed to continuing to deliver those Standard MCC Metrics that are deemed useful for your use in the future.				
<b>2009-Q1</b>					
Metrics Report for		<b>Sponsor A</b>	<b>2009-Q1</b>		
Metric	Category	Laboratory Metrics Champions Definition (v2.0)	ICL Definition (per study/per Quarter)	Unit of Measure	Target
4	Data Cleaning	The number of queries generated between the central laboratory and the sites, compared to the number of requisitions received by a central laboratory.	The number of visits that needed an outgoing query to sites, compared to the number of total visits received by ICL.	Total N and Percentage	<20%
6	Site Support Services	The number of queries generated between the sites and central laboratory, compared to the number of requisitions received for a sponsor and a central laboratory.	The number of incoming queries generated by sites, compared to the number of total visits received by ICL.	Total N and Percentage	>95%
8	Safety	Percentage of panics that had both 1st attempt made and were successfully communicated to the sites within the defined turnaround times-overall by sponsor and central laboratory.	Percentage of call lists that contained at least one panic value that had an action and have been successfully communicated to the site. Successful communication is defined by either an email reply, signed fax, or repeated value telephone confirmation. (Note that values are not limited to business days or hours and therefore Sunday data is represented in totals)	Total N and Percentage	>95%





## Learnings



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- Not all metrics can be reported without systematic or programmatic change
  - Assess cost/benefit
  - Accept? redefinition → divergence
- Understand the root causes for failures when considering performance
  - E.g., ACP definition for completed lab contact for panic value is different from industry
- Use program to improve process
  - We have instituted Sunday staffing in ICL for panic reports
  - Does not improve metric but improves outcome for patient

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## Case Study #2

### Contracted Metrics Driven Process Improvement

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### Identify Relevant Processes

#### Factor Most Often Causing Study Delays United States

Factor	Percentage
Contract and budget negotiation & approval	52%
Patient recruitment & enrollment	45%
Protocol amendment and refinement	37%
IRB review & approval	35%
Review & approval of consent forms	28%

Source: Thomson CenterWatch 2005 Survey of 612 Investigative Sites in the U.S.

**Case Study: Reg Docs Approval**

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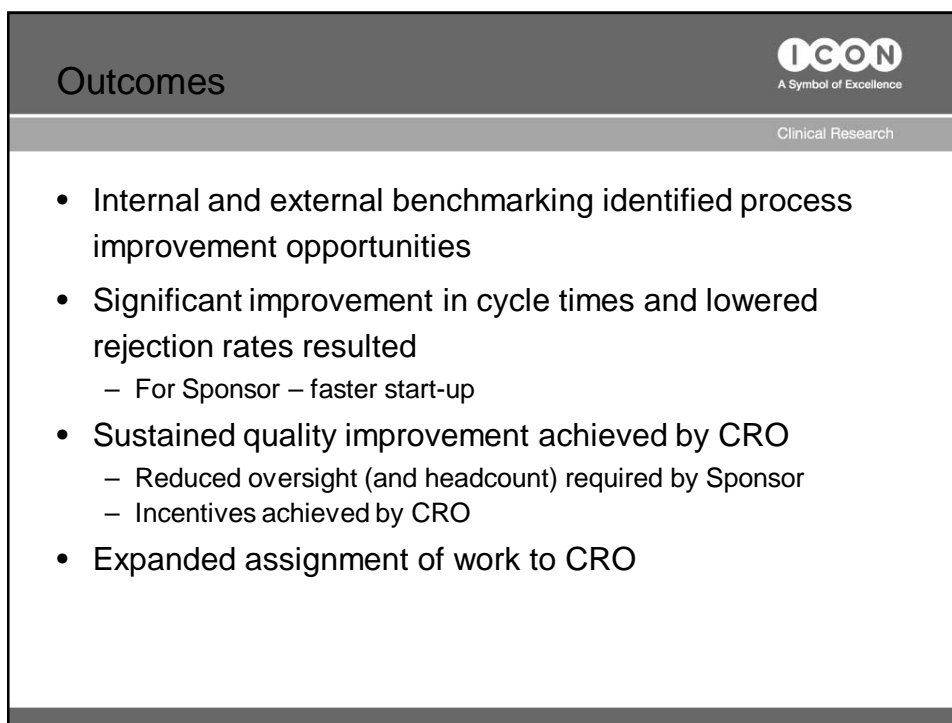
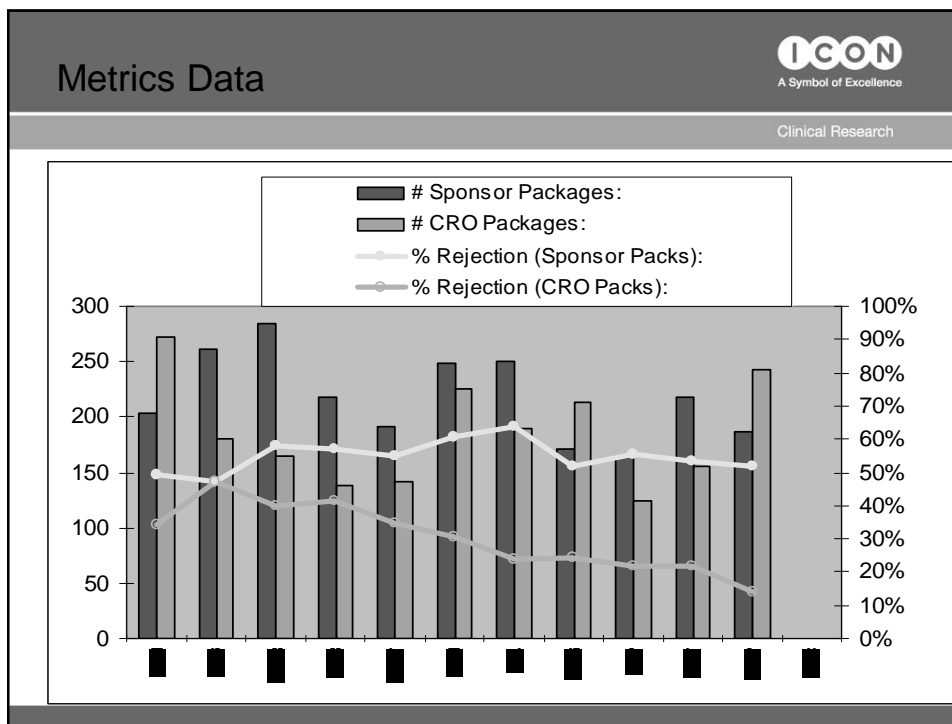
- Observation
  - Regulatory packages approval rate limiting to start-up
- Contracted Essential Metrics
  - Cycle time for approval
  - Rejection rate

**Contract model**


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- Functional Services
- Approval rate target
- Turnaround target
- Continuous improvement incentive
- Monthly metrics reporting
- Governance Board
  - Monthly functional review
  - Quarterly management review




**Concerns**



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- Data access
- Ranking
- Divergence



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**Questions?**