OUTSOURCING OF ANCILLARY SERVICES

- Introduction
  - Overview
  - Operational Considerations
  - Industry Best Practices-Supplier Management Profile
- Rationale & Value Proposition
  - Current Contracting Landscape
  - Category Classification
  - Projected Return on Investment (ROI)-Shifting Resources
  - Governance and Supplier Management

INTRODUCTION:
OVERVIEW

Problem Statement

The current Clinical Outsourcing environment to support the execution of contracting for clinical studies is not conducive to effectively managing costs and risks across a large supplier base in an increasingly complex business

Current State

- 1 Service Category=1 Contract
- 2 FTEs addressing Service Categories which are more commodity based
- Limited ability to effectively manage suppliers to drive performance and address risk.
- Limited ability to address unmet needs and opportunities.

Proposal

- Develop and implement a process resulting in a step wise approach to:
  - Identify lower risk/commodity service categories and suppliers to be managed and contracted by a Clinical Research Organization (CRO)
  - Ensure CRO has proper oversight in place for supplier management
  - Define how transition and implementation process from Sponsor to CRO
  - Monitor and adapt

Benefits

- Reduced risk
- Re-assign resources to more strategic/higher risk categories
- Improved Supplier Management
- Move from Tactical to Strategic=Increased Savings($)

INTRODUCTION:
OPERATIONAL CONSIDERATIONS

- Ideally this proposal will yield numerous benefits across multiple departments; however, there are some challenges we must acknowledge:
  - Direct contact control will be shifted to the CRO– could impact issue escalation / resolution. Conversely, issue escalation / resolution is managed with no/little input from Sponsor.
  - Reduced transparency into cost
  - Reduced leverage of relationship with Ancillary suppliers. Conversely, CROs often have greater leverage over suppliers than Sponsor.
  - Limited information on Quality Audits of Ancillary suppliers being contracted and managed by the CRO
  - Additional focus/process to ensure “Inspection Readiness”

- With any challenge there is an opportunity to mitigate risk. This will be will be a core focus of the developed process.

INTRODUCTION:

INDUSTRY BEST PRACTICES-SUPPLIER MANAGEMENT PROFILE* - UPDATE FOR BIOTECHS

ICON Sub Contracting on Behalf of Sponsor - Models

A. Tactical Only	Sponsor Chosen	Sponsor - MSA Held	Sponsor - Vendor Development	ICON - Operations Management	ICON Client Engagement
Sponsor responsible for selection, supplier contracting and audit					Standard Global Pharma Organizations engage utilizing Model A tactical option.
Operational day to day management by ICON aligned to Sponsors SOP's					
Entered on ICON Global Supplier Listing (GSL) per ICON SOP					
Alignment with agreed Sponsor operation guidelines/SOP's. Available for Sponsor Audit					

B. Hybrid Model	Sponsor Chosen	ICON - MSA Held	ICON - Vendor Development	ICON - Operations Management	ICON Client Engagement
ICON responsible for supplier contracting and audit					Two major global Pharma organization's currently utilize Model B Hybrid outsource option.
Operational day to day management & Strategic Supplier Management/Development by ICON to ICON SOP					
ICON submit and obtain sub-contractor approval from Sponsor and register per ICON SOP					
Alignment with agreed Sponsor operation guidelines/SOP's. Available for Sponsor Audit					

C. Full Outsource	ICON Chosen	ICON - MSA Held	ICON - Vendor Development	ICON - Operations Management	ICON Client Engagement
ICON identify and qualify supplier, ICON responsible for vendor contracting and audit per ICON SOP					One major global Pharma organization's currently utilize Model C Full outsource option.
Operational day to day management & Strategic Supplier Management/Development by ICON to ICON SOP					
ICON submit and obtain sub-contractor approval from Sponsor					
Full alignment & responsibility to ICON's operating requirements /SOP's and available for Sponsor Audit					

RESOURCE ALLOCATION

Clinical Outsourcing resource allocation

1 - Manager

15% Administrative
(training, reporting, dept meetings, other)

10% Functional Management
(Business Improvements)

75% Contract & Vendor Management
(RFx, MSA, work orders, amendments, new suppliers, supplier/category/issue management, functional outsourcing)

opportunity

1 - Associate Director

15% Administrative
(training, reporting, dept meetings, other)

15% Functional Management
(Business improvements)

10% Staff Management

60% Contract Management
(RFx, MSA, work orders, amendments, new suppliers, supplier/category/issue management, functional outsourcing)

RATIONALE AND VALUE PROPOSITION

CURRENT CONTRACTING LANDSCAPE

Current Study Level Workload Estimate

Clinical Research Organizations
Clinical Research Units
Patient Recruitment
Central Labs
Specialty Labs
Electrocardiogram
Electronic Clinical Outcome Assessments
Interactive Voice Technology
Clinical Logistics
Data Management
Medical Writing
PV & Risk Management

Per study average 7-10 suppliers 25 contracts (includes MSAs, work orders, change orders)

~60 Active Studies

Life cycle Protocol concept to Reconciliation 2.5yrs

1500 open contracts

~600 contracts/year

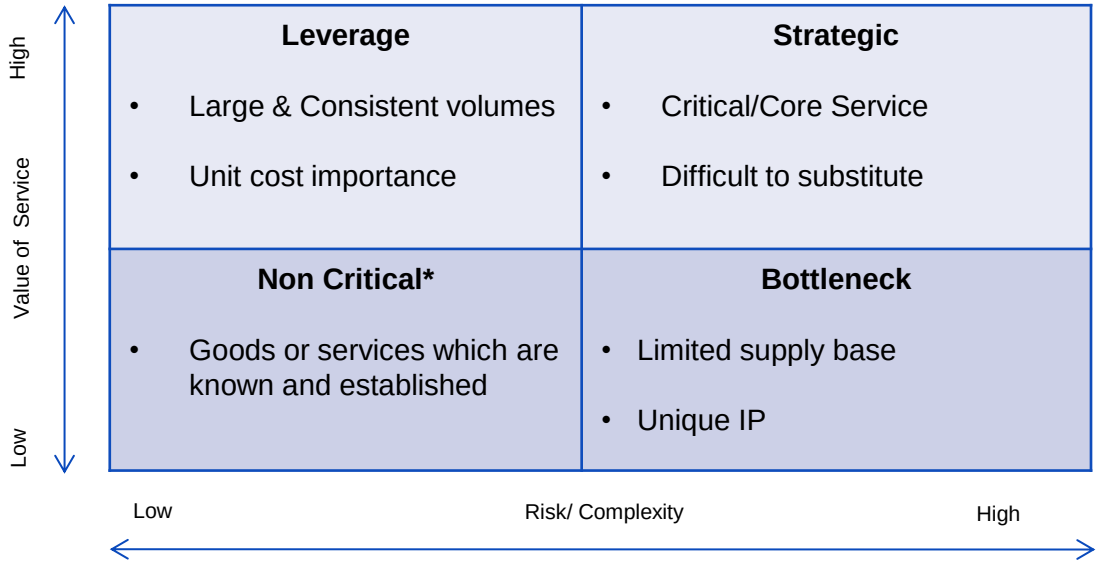
~50 contracts/month

RATIONALE AND VALUE PROPOSITION:
CATEGORY CLASSIFICATION

- In the following slide, an overview of how the sourcing of clinical study services are classified from a business perspective. The positioning is based on two key factors will be presented :
  - Value of Service
  - Risk and Complexity

What is a "Classification Matrix"

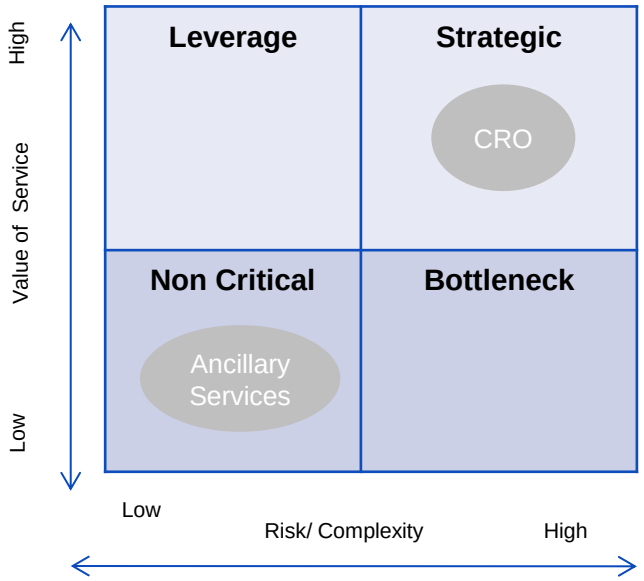
- A systematic approach to classify service categories based on Risk and value
- Output will support the development of the sourcing approaches
- Refined approaches results in mitigation of risk, increased security, and cost optimization, and better utilization of resources.
- ***Note-Non Critical*** Although one may infer goods or services in this quadrant are *not important* to the business, this is not the intent. The intent is to show complexity and value and where resources should be deployed to manage value and risk



*

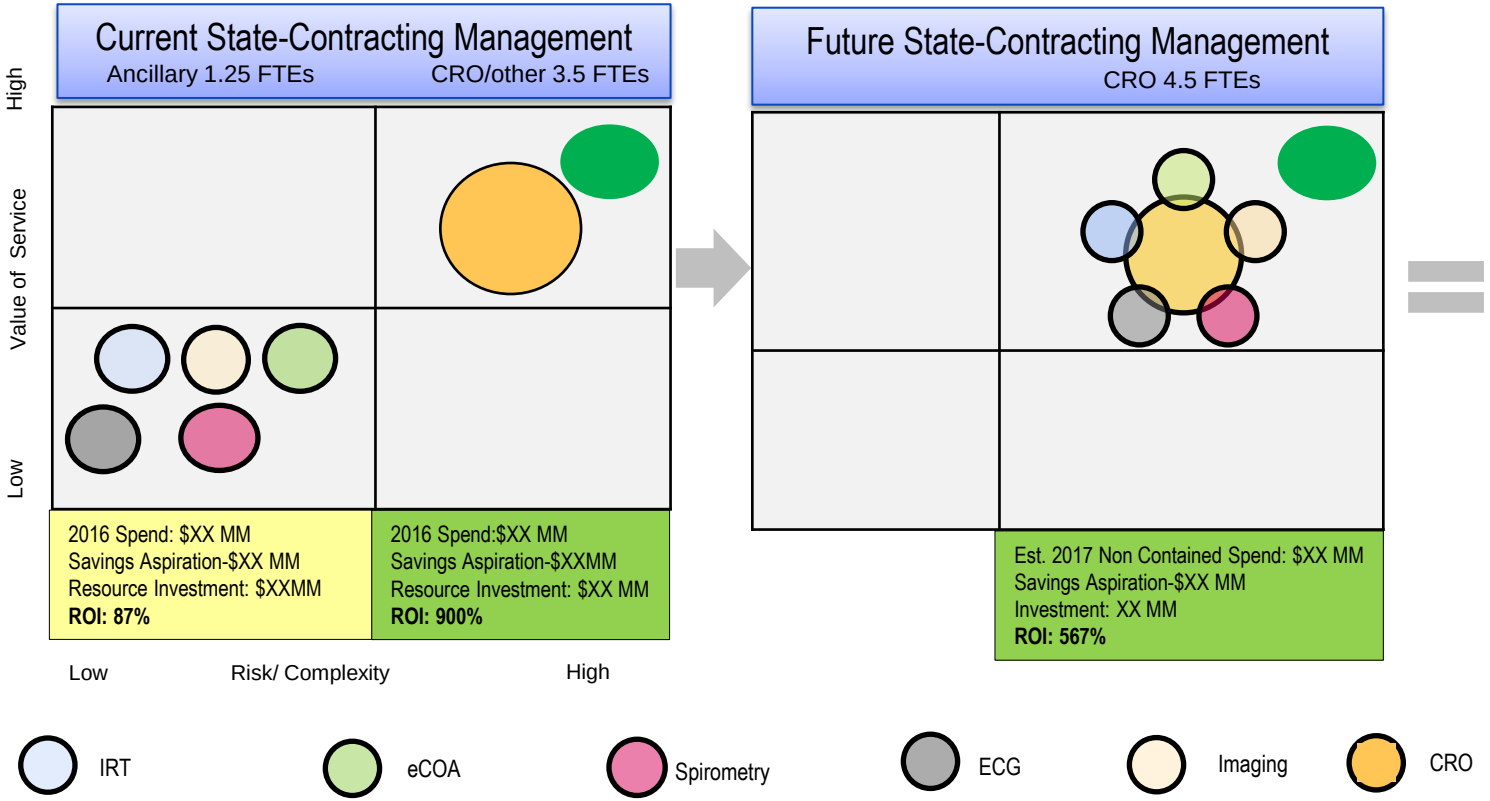
RATIONALE AND VALUE PROPOSITION:
CATEGORY CLASSIFICATION (CRO & ANCILLARY)

Service Category	Sourcing Staff (FTEs)*	Attributes
CRO Full Service-Clinical Core Functions	5	• Variable specification and unique demands on a study by study level basis • CRO engaged early in planning process which could impact operational components of the study-offers industry insight • Spend • Higher risk activities which are transferred from Sponsor responsibility to the CRO
Ancillary Services IRT eCOA ECG Spirometry Imaging	2.5	• Required Service and important to success of a Sponsor Clinical Study • Combined spend of in scope categories was about $XXMM and a growth rate much lower than CRO • Service is more commodity driven with industry and Sponsor standards established for study needs • Standard governance with a small Sponsor population involved



RATIONALE AND VALUE PROPOSITION :

PROJECTED RETURN ON INVESTMENT (ROI)-SHIFTING RESOURCES - ILLUSTRATIVE PURPOSES



Benefits

- 1.25 Additional FTEs to support critical CRO Category and Emerging Business (Unmet Category Needs)
- Estimated increase in Savings of $ XX MM against unmet category needs
- Increase in ROI by shifting two FTEs could result in a 480% increase in ROI

0.25 FTE allocated to account for increased CRO SoW and low level cat man activities

IRT | eCOA | Spirometry | ECG | Imaging | CRO | Unmet Category Needs

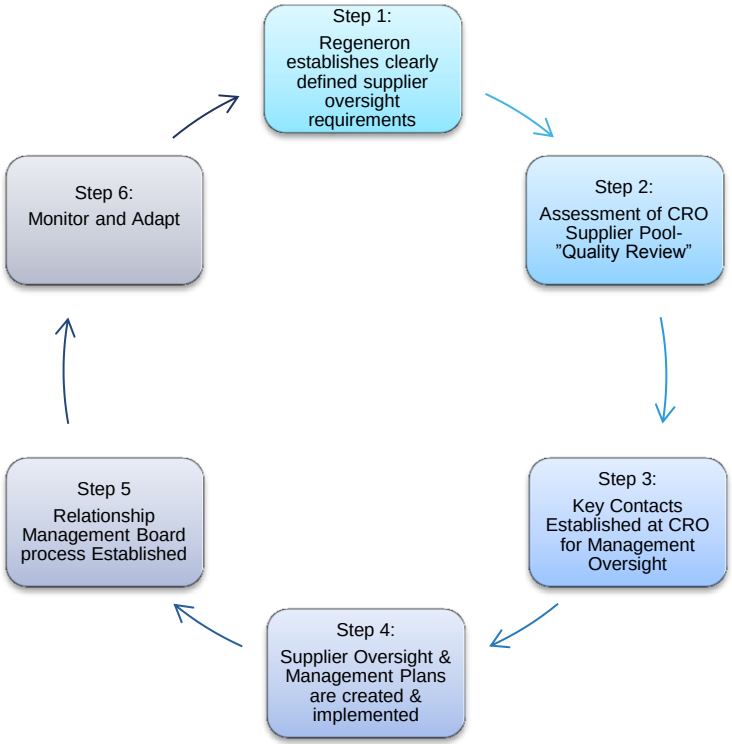
RATIONALE AND VALUE PROPOSITION :
GOVERNANCE AND SUPPLIER MANAGEMENT

- FDA regulations and ICH-GCP Guidelines require sponsor oversight of all clinical research activities where transfer of regulatory obligations occurs with external Suppliers.

- Based on current resource levels, the current environment does not allow allow for a conducive environment to effectively manage suppliers in a proactive manner
  - Formal oversight of Ancillary suppliers is occurring in some aspects but limited
  - Formalized Governance plans are lacking and resources to administer oversight is limited

- Ongoing efforts to assess supplier oversight is in progress. Any change in approach to contracting with ancillary vendors would seek to complement Sponsor's approach to supplier governance and oversight

- Formal approach to minimize risk exposure would be addressed in a contractual arrangement with the CRO

RATIONALE AND VALUE PROPOSITION :
GOVERNANCE AND SUPPLIER MANAGEMENT

- Oversight & compliance of the subcontractor management activities defined in the Service Level Agreement (SLA) between Sponsor and CRO
- Key stakeholders (Sponsor & CRO) identified upfront
- Review approvals where required for use of relevant suppliers
- Escalation path for QA or performance issue resolution and remediation
- Agreed periodic two way Strategic Business review of supplier initiatives within SLA that covers but not limited to:
  - Agreed Process Improvement
  - Agreed Cost Reduction / Supplier consolidation
  - Corrective Action progress where initiated
  - Two way review of emerging improvement opportunities