

Mastering Clinical Provider Selection Qualification and RFP Process

Leveraging Technology to
Strengthen Selection, Retain Knowledge, and
Modernize Outsourcing



Agenda

- Technology Introduction
- Qualification/RFI Process
- Study Selection/RFP Process
- Award to Contract Process
- Case Studies

Instructor

- Anca Maria Copaescu
- Chief Executive Officer, Strategikon Pharma
- Former Head of Outsourcing, BioMarin Pharmaceuticals
- Former M&A Lead (Icon Clinical Research, PharmaNet Development Group)
- Domain expertise: Clinical Finance, Outsourcing, Alliance Management
- Master of Science in Corporate Finance, Masters of Business Administration, Bachelor of Science in Economics



Course Goals

1. LEARN best practices for clinical service provider qualification and selection
2. LEARN how to develop a qualification library using modern tools
3. LEARN how to use technology to develop Requests for Information (RFIs) and Requests for Proposals (RFPs)
4. MASTER how to conduct “deeper” due diligence for qualification and selection
5. PREPARE for the RFP: how budget benchmarking drives savings
6. UNDERSTAND the importance of vendor category management in strategic sourcing

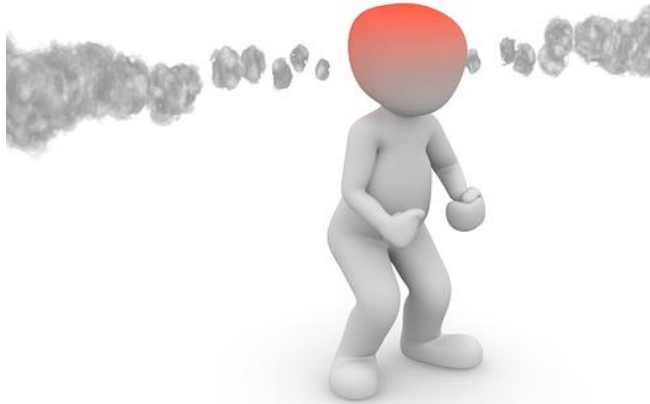




Technology Introduction

Pain Points in Clinical
Outsourcing and Strategic
Category Management

Pain Points in Clinical Outsourcing and Strategic Category Management



Resource and Time Intensive

- Manual collection of requirements, RFP/RFI creation, bid management and due diligence
- Inconsistencies in qualification/selection processes

Dependent on Office tool set

- Word/Excel templates make analytics challenging
- Document management vs. “database” management

Lacking Transparency

- Difficult to compare qualification/selection processes across studies, vendors and categories
- Lack of fair market value to drive cost due diligence



Step into the Future: Technology is the Answer



Cost and Time Savings

- >75% time saved
- RFPs and proposals exchanged via system
- Market data for cost benchmarking



Technology Driven

- RFI/RFP database
- Eliminate manual document management
- Easy to learn: apply your existing skill set



Reports and Analytics

- Traceability from RFP to Award
- Outsourcing department management
- Visibility via reporting and bid analytics



LEAD™

Budget Tracking and Accrual Reporting



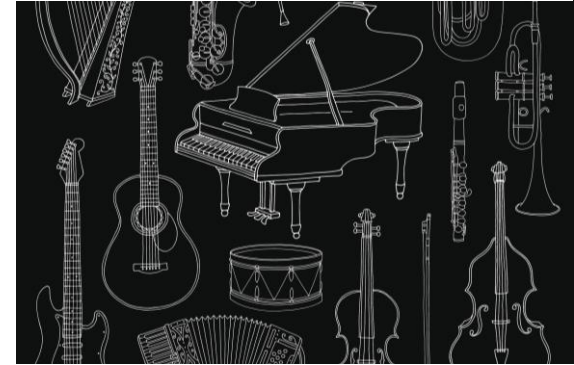
VISION™

Alliance Management



SOURCE™

RFP and Bidding



PORTOFOLIO™

Clinical Planning and Budgeting



Four Modules
One Platform

Clinical Maestro SOURCE™

Manage service provider profiles

Keep best practice library of qualification questions, requirements and selection criteria

Configure preferred RFP/RFI templates

Initiate outsourcing projects in minutes and send RFP/RFIs via system

Manage end to end RFP and bid history

Compare vendor responses over time, across sourcing projects and studies

Empower outsourcing teams with powerful reports and analytics





Core Concepts

Team Structure

Outsourcing Strategies

Roles and Responsibilities

Vendor Selection Team Structure



Procurement

Vets vendor qualifications, e.g. financial background, ability to provide intended service

Conducts “general” Requests for Information (RFIs)

Approves vendor at corporate level



Clinical Outsourcing

Assesses vendor fit to perform service as per clinical study protocol, service needs and outsourcing strategy

Conducts operational due diligence

Conducts operational RFPs and RFPs



Vendor Management

Provides input into vendor selection strategy based on historical performance

Manages vendor preference, tier, risk, performance



Clinical Operations

Sets the requirements for operational requirements at study / program level

Participates/
Leads vendor selection process at specific study level



Finance

Confirms budget availability and spending capacity
Conducts financial due diligence

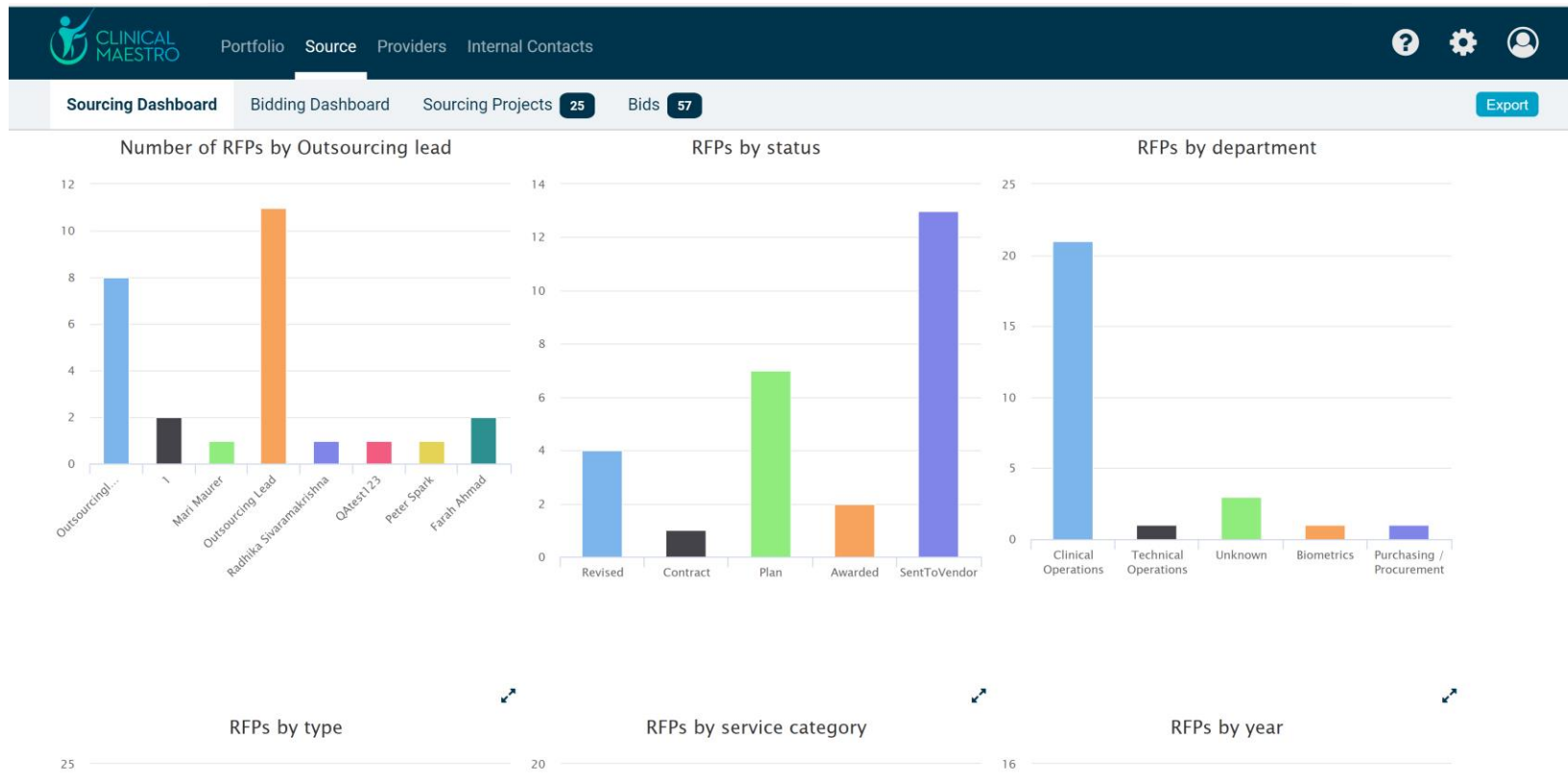


SMEs (Subject Matter Experts)


Provides specific requirements at the service level, e.g. IT may provide requirements for “systems”



Outsourcing Management: Sourcing Dashboard



Sourcing Dashboard: Comprehensive Tracking

CLINICAL
MAESTRO

PortfolioSourceContractsProvidersInternal Contacts

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Sourcing DashboardBidding DashboardSourcing Projects (23)Bids (50)Change Orders (0)

🔍 Search Sourcing Projects

New Sourcing Project

Type:Study:Requested ServicesLead:Status:Created From:To:

AllAllAllAllAllSelectSelect

<input type="checkbox"/> Sourcing Project	Project Type	Study	Lead	Requested Services	Proposal Due	Responses	Created	Last Edit
<input type="checkbox"/> Medical Imaging 2 Plan	Non Study Specific RFP	-	Bert M.	View (2)	06/05/2020	-	03/01/2020 by Bert M.	03/01/2020 by Bert M.
<input type="checkbox"/> MD RFP Plan	RFP	ONC-273	Bert M.	View (2)	06/05/2020	-	02/01/2019 by Bert M.	04/01/2019 by Bert M.
<input type="checkbox"/> CRO Selection 273 In Progress	RFP	ONC-272	Bert M.	View (3)	02/06/2020	Open: 3 - Total: 11	12/01/2019 by Bert M.	03/02/2020 by Bert M.
<input type="checkbox"/> Feasibility AG280 Completed	RFI	P222-004	Claudia D.	-	08/15/2019	Open: 0 - Total: 6	07/01/2019 by Bert M.	08/01/2019 by Claudia D.
<input type="checkbox"/> Medical Imaging Completed	RFP	P222-003	Bert M.	View (2)	06/05/2019	Open: 0 - Total: 5	04/02/2019 by Bert M.	05/20/2019 by Bert M.
<input type="checkbox"/> Neuro-Oncology Completed	RFP	ONC-272	Bert M.	View (2)	06/05/2019	Open: 0 - Total: 5	04/02/2019 by Bert M.	05/20/2019 by Bert M.
<input type="checkbox"/> CRO Selection 271 Completed	RFP	ONC-271	Bert M.	View (3)	04/06/2019	Open: 0 - Total:	01/01/2019 by Bert M.	03/02/2019 by Bert M.

Outsourcing Strategy Responsibility Matrix (RACI)

Outsourcing strategy implies RACI matrix tracking at both study and portfolio level: who is Responsible, Approving, Consulting and Informed




Essential to maintain RACI visibility for optimal resource allocation

Who is responsible for what	Hybrid tasks (dual responsibility)	TORO (Transfer of Regulatory Obligations)	Vendor and internal communication	Portfolio level considerations
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RACI Dashboard: Responsibilities Tracking



PortfolioSourceProvidersInternal Contacts

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Sourcing Projects > Andrei Test

OverviewProject TimelinesStudy Profile**Study Assumptions**QuestionsRequestsCriteria

Send to VendorPrint View

PatientsSitesTimelinesCentral Assumptions**Services**Alerts

StudyEdit

Service Categories

▶ Biostats and ProgrammingEdit

▶ Clinical Study ManagementEdit

▼ Regulatory ServicesEdit

Services

Study Start-UpEdit

Regulatory PlanningEdit

Regulatory AffairsEdit

Project ManagementEdit

▶ SystemsEdit

Task List & Responsibilities

Service Assumptions

Costs

Resources

New Task

Regulatory PlanningEdit

	Sponsor Responsibilities	Provider Responsibilities	Sponsor Comments	Sponsor Allocation
Develop Regulatory Plan	R A	I	Sponsor to develop, inform CRO	
Regulatory Research	R A	R	Dual responsibility	USA
Develop Gap Analyses	R A	R	CRO to develop, Sponsor to review and approve	Review
Develop Protocol Assessment	R A	R	CRO to develop, Sponsor to review and approve	Review
Regulatory Authority Meeting	R A	C	Sponsor to conduct, consult CRO on strategy	

EudraVigilanceEdit

	Sponsor Responsibilities	Provider Responsibilities	Sponsor Comments	Sponsor Allocation
Eudra Vigilance Registration	A	R		
Eudra Vigilance Representative	A	R		





Digital Transformation Benefits

Standardization

RACI Tracking

Outsourcing Strategy

Stakeholder Management

Communication and Transparency



Requests for Information (RFIs)

Implement category
management best practice
in service provider
qualification



Vendor Qualification Process



Request for Information (RFI)

Question and Answer based survey intended to assess vendor qualification and fit to perform intended services

- Capabilities survey- service and corporate level
- Cost: non-study specific, e.g. resource rate card
- Differentiating factors

Non-study specific, but may be combined with RFP

- RFI/RFP process expedites qualification/award under tight timelines

May be conducted by “Procurement” or “Clinical Outsourcing” functions

Part of overall Quality Management process

- Qualification Criteria decided *prior* to qualification process/RFI
- Scoring/Evaluation mechanism *post* RFI
- Survey repeated annually or determined frequency to ensure “qualified” status is maintained

End Goal: Vendor “added” to Portfolio

- Ensures adequate vetting at corporate level



Step by Step Traditional RFI Build



Design: unstandardized

Word – easy to respond (text editor), but difficult to compare answers

Excel – difficult to respond (no text editor), but easy to compare answers



Rules of engagement

Define expectations and instructions, e.g. are questions allowed?

Define timelines, e.g. when is the response due?

Define roles: who is leading the RFI process



Evaluation criteria

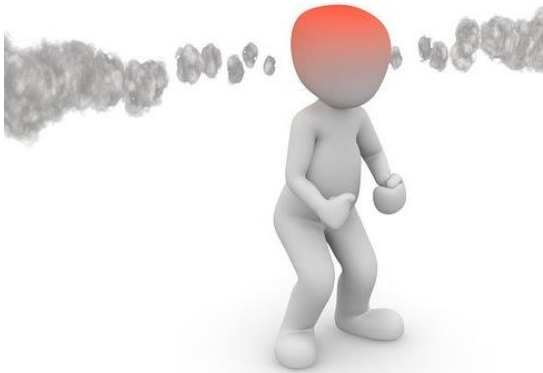
Define the methods/criteria to establish qualification

Define evaluation stakeholders/SMEs

Design survey questions and “asks” to match criteria



Pain Points in Traditional RFI Management



Manual, Unstandardized

- Excel or Word, not conducive to dynamic comparisons and trending

User unfriendly

- Difficult to analyze, compare side by side

Static document management:

- RFI/Answers library in multiple folders with limited search capabilities

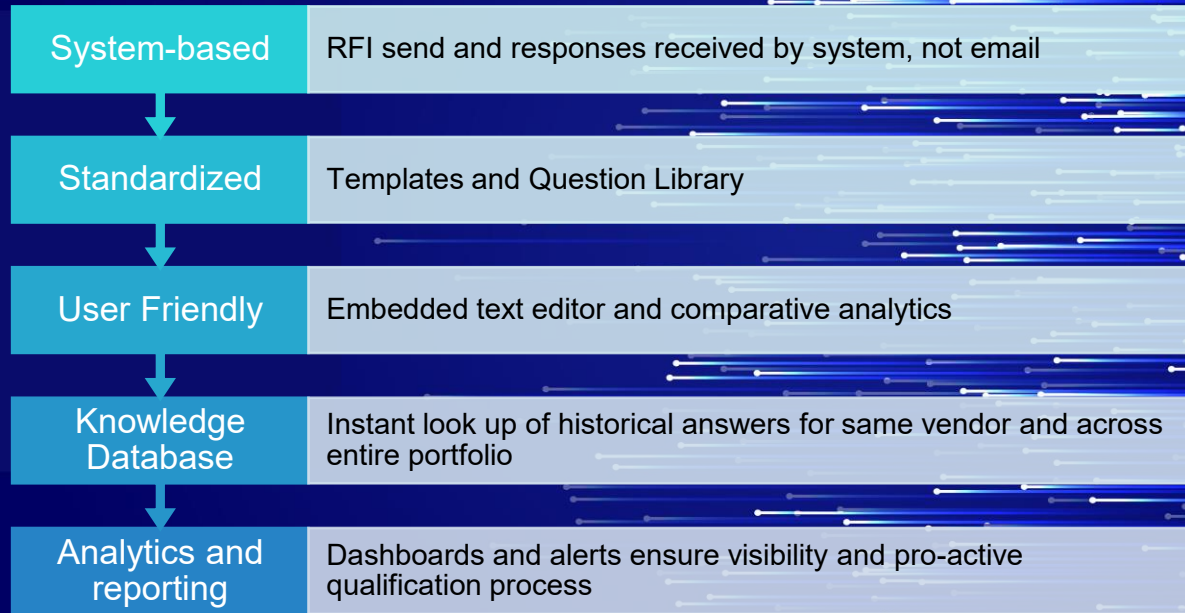
Difficult to compare answers across providers and over time

- Challenging to answer even simple questions, e.g. what is RFI answer question of Vendor1? How did Vendor1 answer compare to Vendor 2 answer for same question?





Difficult to evaluate and score

- Scoring done verbally or via trackers maintained in disparate documents

Modern RFI: Technology Driven



Modern RFI: Standard Configurable Templates

 [Portfolio](#) [Source](#) [Providers](#) [Internal Contacts](#)   

[Sourcing Projects](#) > EDC Selection

[Overview](#) [Project Timelines](#) [Services](#) [Questions](#) [Requests](#) [Criteria](#) [Send to Vendor](#) [Print View](#) [Edit](#)

Sourcing Project Name: EDC Selection	Requesting Department: Biometrics	Request for Service Type: R F I	Status: Plan
Team Lead: Outsourcing Lead	Approver Name: Executive Member	Members: Selection Team	
Description: This is my standard text for system RFIs.			
Instructions: These are my instructions for systems RFIs.			
Attachments:		Links:	



Modern RFI: Qualification Question Library

The screenshot displays the 'Clinical Maestro' web application interface for managing a qualification question library. The top navigation bar includes links for Portfolio, Source, Providers, and Internal Contacts, along with utility icons for help, settings, and user profile. The breadcrumb trail indicates the current location is 'Sourcing Projects > EDC Selection'. Below this, a secondary navigation bar offers tabs for Overview, Project Timelines, Services, Questions (which is active), Requests, and Criteria. Action buttons for 'Send to Vendor', 'Print View', and 'Edit' are positioned on the right. The main content area is divided into two tabs: 'Qualitative Questions' and 'Quantitative Questions'. On the left, a sidebar provides a hierarchical view of the library, showing counts for Study (3), Service Categories, Systems (0), and Services, with 'EDC System' currently selected, showing 172 questions. The central panel features a search bar and a dropdown menu set to 'Capabilities'. A list of 10 qualification questions is displayed, each preceded by a checkmark icon. To the right of the questions, a vertical list of topics is visible, including Architecture and Code, General, Process, and Data Transfers.

CLINICAL MAESTRO Portfolio Source Providers Internal Contacts

Sourcing Projects > EDC Selection

Overview Project Timelines Services **Questions** Requests Criteria

Send to Vendor Print View Edit

Qualitative Questions Quantitative Questions

Study 3

Service Categories

▼ Systems 0

Services

EDC System 172

Q Search Questions Create New Question


Topic: x All x ▼

Capabilities

Question	Topic
✓ Is customer allowed to write code on your platform? Describe custom code policy.	Architecture and Code
✓ Speed: How does your organization recognize and implement change quickly?	General
✓ Accountability: How does your organization demonstrate accountability for its performance and deliverables?	General
✓ Are all environments automatically upgraded if applicable (test, training, etc.)?	Process
✓ Are code reviews performed?	Architecture and Code
✓ Are development and testing environments for applications kept separate from production environment?	Architecture and Code
✓ Are study exports performed asynchronously and saved to a secure location?	Data Transfers
✓ Are system alerts pushed directly to users, e.g. via email?	Reports and Metrics
✓ Are upgrades mandatory?	Process
✓ Are your clients provided with UAT materials for upgrades?	Process



Modern RFI: Selection Criteria

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MAESTRO

PortfolioSourceProvidersInternal Contacts

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Sourcing Projects > EDC Selection

OverviewProject TimelinesServicesQuestionsRequestsCriteria

Send to VendorPrint ViewEdit

Q Search Criteria

Create New Criteria

Topic:


Priority:

General

Criteria	Explanation	Topic	Priority
✓ Ability to meet timelines	Availability to meet Sponsor expectations on timelines	Capabilities	High
✓ Continuity	Number of years in business	Capabilities	High
Equipment supply	Provider can supply necessary equipment to sites.	Capabilities	High
✓ Execution plan	Overall quality of execution/project plan as described in proposal and/or bid defense.	Capabilities	High
Geography	Provider ability and breadth of resources to execute services in required geography	Capabilities	High
✓ Long term fit	Assessment of Provider's long term relationship potential (based on cultural fit, communication, etc.)	Capabilities	High
Overall ability to execute project	Assessment of Providers ability to execute the project	Capabilities	High
✓ Proposal	Overall quality of Provider proposal, including timeliness of response, completeness, research quality, presentation quality.	Capabilities	High
✓ Qualifications and experience of proposed staff		-	High




Modern RFI: Answer Comparisons

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PortfolioSourceProvidersInternal Contacts

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Back

TimelinesPatientsSitesAdverse EventsBudgetServices AssumptionsQuestionsAdditional InformationTermsScoreBid Options

Export

Qualitative QuestionsQuantitative Questions

Select Question:

List All Questions

Customer Connectivity: How does your organization build enduring relationships with clients?

Bid 1 (Vendor1)

Answer:

We do this through our Service Excellence philosophy of working closely with the clients to ensure that issues are addressed as they happen.

Bid 1 (Vendor2)

Answer:

We do this through appropriate risk sharing, ensuring cultural fit and ensuring we are listening to the clients needs at all times.

What percentage of your key staff, if any, will be dedicated to the study(s)?

Bid 1 (Vendor1)

Answer:

We will have a dedicated PD and regional PMs as well as dedicated CRAs in Europe.

Bid 1 (Vendor2)

Answer:

All key personnel will be dedicated to the project.



The background of the slide features a glowing digital globe with various data visualizations overlaid on it, including bar charts and network diagrams. In the foreground, a portion of a computer keyboard is visible, with keys like 'E', 'R', 'T', 'Y', 'U', 'I', 'O', 'P', 'D', 'F', 'G', 'H', 'J', 'K', 'L', 'S', 'A', 'D', 'C', 'V', 'B', 'N', 'M', 'X', and a power button clearly visible. The overall color scheme is dark with blue and green highlights.

Digital Transformation Benefits


Standardization

RFI and Response Database

Comparative analytics

Deeper due diligence

Communication and Transparency

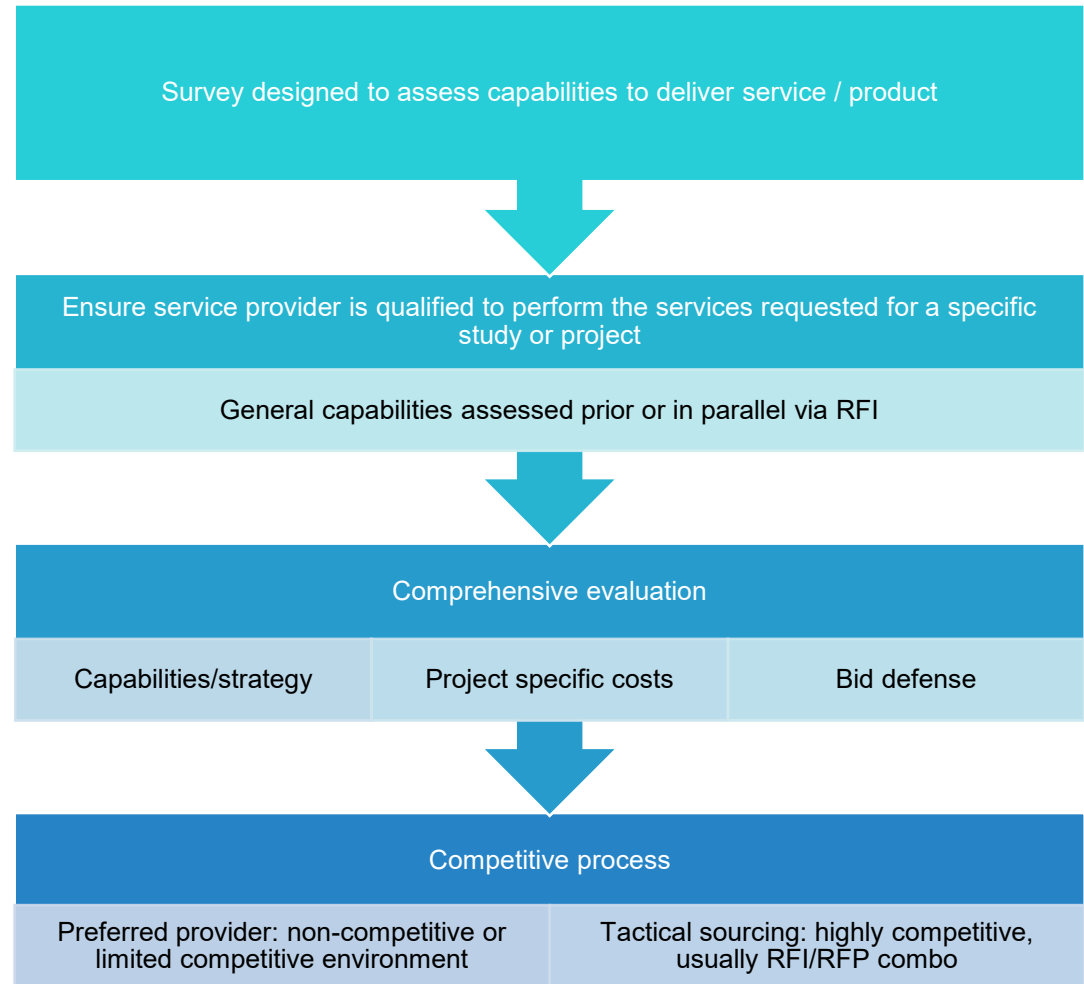


Requests for Proposal/Quotation (RFP/RFQ)

Leverage technology to
deepen due diligence
during RFP/RFQ process



Vendor Selection Process via RFP/RFQ process



RFP/RFQ Core Components

Project specifications

- E.g. clinical study assumptions, protocol, desired execution strategy, timelines

Service specifications

- E.g. desired services and responsibility (RACI) matrix

RFP/RFQ Timelines and Instructions

- E.g. expectation on proposal submission, bidding behavior

Budget Request

- Bid grid: standardized or service provider format

Survey questions

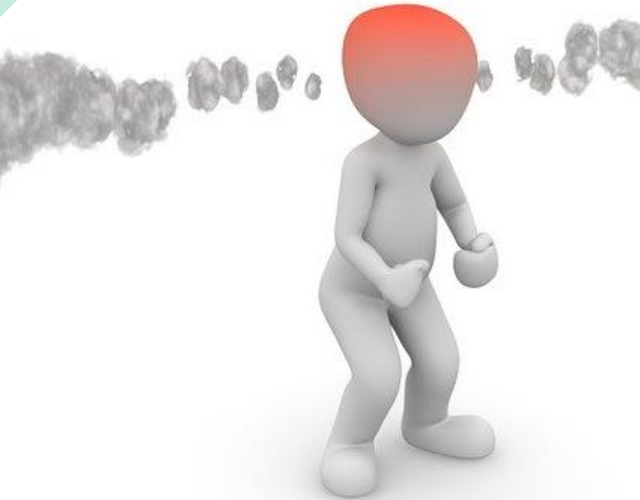
- Quantitative and qualitative assessment questions

Selection Criteria

- Decision framework



Pain Points in Traditional RFP Management



Manual

- Excel or Word, not conducive to dynamic comparisons and trending

Unstandardized

- Variety of templates, unstandardized questions/qualification criteria

User unfriendly

- Difficult to analyze, compare side by side

Static document management:

- RFI/Answers library in multiple folders with limited search capabilities

Difficult to compare answers across providers and over time

- e.g. what is RFI answer question of Vendor1? How did Vendor1 answer compare to Vendor 2 answer for same question?

Difficult to evaluate and score

- Scoring done verbally or via trackers maintained in disparate documents

Modern RFP: Technology Driven

System-based

- RFI send and responses received by system, not email

Standardized

- Templates and Question Library

User Friendly

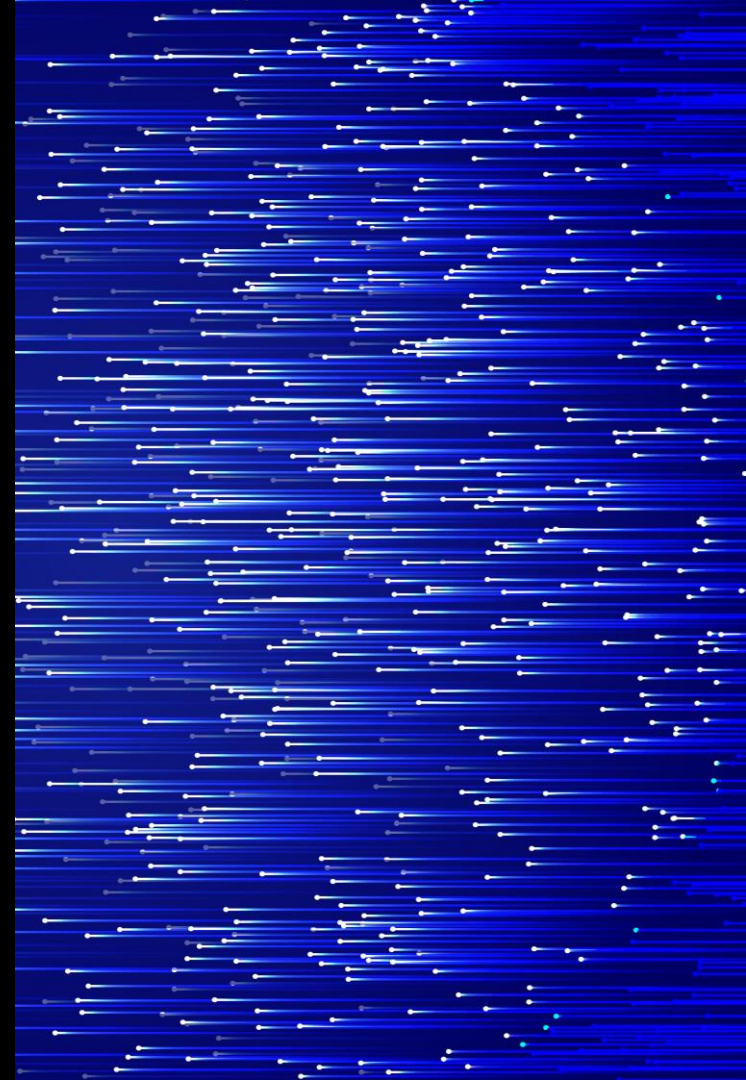
- Embedded text editor and comparative analytics

Knowledge Database


- Instant look up of historical answers for same vendor and across entire portfolio

Comprehensive analytics and reporting

- Dashboards and alerts ensure visibility and pro-active qualification process



RFP Template with Timelines, Assumptions, Scoring Criteria

PortfolioSourceContractsProvidersInternal Contacts

Sourcing Projects > CRO Selection 274

OverviewProject TimelinesStudy ProfileStudy AssumptionsQuestionsRequestsCriteria

Send to Vendor

Sourcing Project Name:
CRO Selection 274

Requesting Department:
Clinical Operations

Request for Service Type:
RFP

Study:
[ONC-274](#)

Scenario:
[Scenario One](#)

Status:
Plan

Locations:
China, Japan, Denmark, Germany, USA

Team Lead:
Andrei Antonescu

Approver Name:
Bert Madison

Team Members:
Andrei Antonescu, Claudia Dumitrescu, Bert Madison

Attachments:
[Study-Protocol.pdf](#) [Confidentiality-Agreement.docx](#)


Links:
[www.example.com](#)

Description:
Can be preset from template library - Lorem Ipsum is simply dummy text of the printing and typesetting industry. Lorem Ipsum has been the industry's standard dummy text ever since the 1500s, when an unknown printer took a galley of type and scrambled it to make a type specimen book. It has survived not only five centuries, but also the leap into electronic typesetting, remaining essentially unchanged.

Instructions:
Can be preset from template library - Lorem Ipsum is simply dummy text of the printing and typesetting industry. Lorem Ipsum has been the industry's standard dummy text ever since the 1500s, when an unknown printer took a galley of type and scrambled it to make a type specimen book. It has survived not only five centuries, but also the leap into electronic typesetting, remaining essentially unchanged.



Modern RFP: Study Profile



PortfolioSourceProvidersInternal Contacts

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Sourcing Projects > ONC-771-SP

OverviewProject TimelinesStudy ProfileStudy AssumptionsQuestionsRequestsCriteriaProvider Access

Send to VendorRevise Sourcing ProjectPrint View

Study Attributes

Name: ONC-771	Nickname:	Development Phase: Phase I		
Phase I Category: In patient	Phase I Assessment: Dose Ranging/Escalation	Dose Ranging/Escalation: Phase 1b - Multiple Ascending Dose		
Study Description:				
Synopsis/Protocol Documents:				
Internal Code:	Indication/Disease Target: AML/MDS	Therapeutic Area: Oncology	Patient Type: Adult	Investigation Type: Sponsor Initiated
Route Of Administration: Oral	Administration Type: Multiple Administration (Dose)	Dose Level: Multiple Ascending Dose (MAD)		

Study model

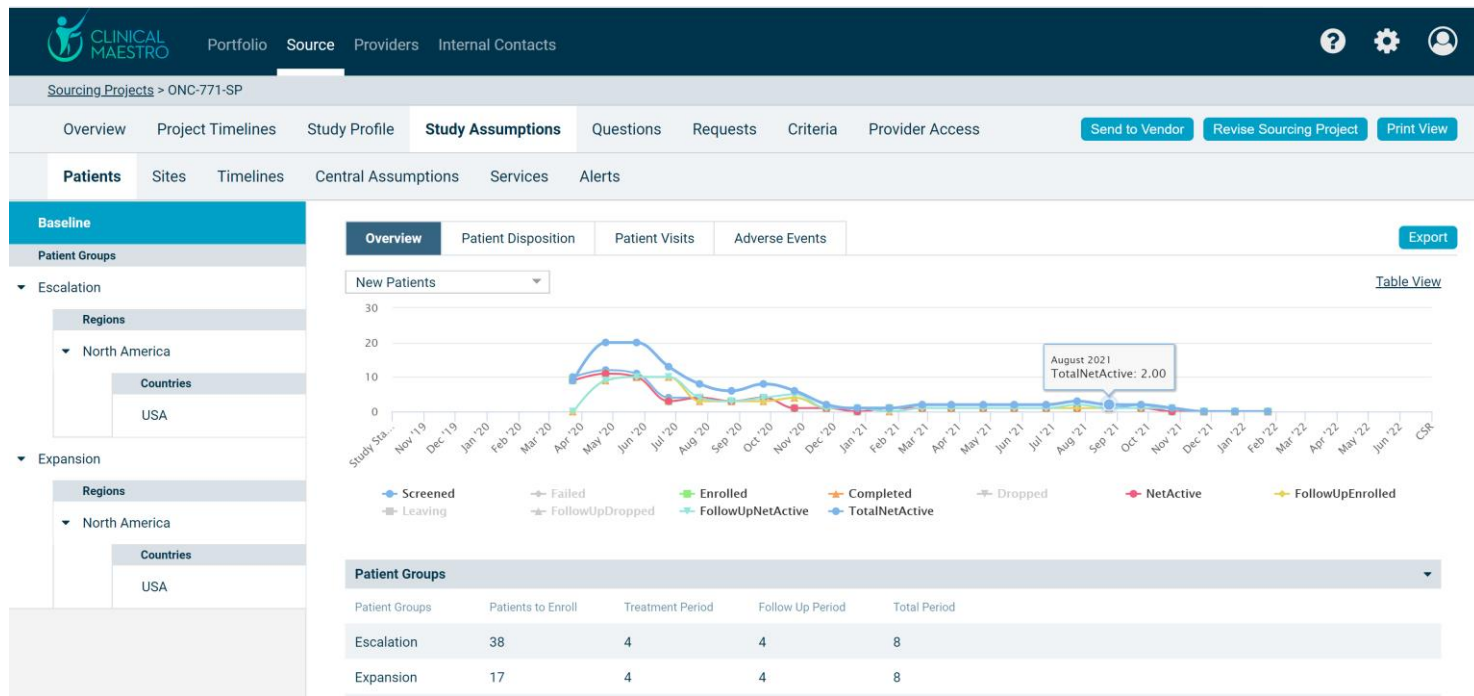
Study Model: Interventional				
Allocation: Not Randomized	Masking Type: Unblinded (Open Label)	Stratification: Not Stratified	Study Design:	Control: Uncontrolled

Outcomes

Patient Source
Patient Source: New Patient



Modern RFP: Study Assumptions



Modern RFP: Multiple Bidding and Rebidding Options

Select Providers and Bidding Options



Bidding options

Assumptions

- ☒ Bid to Specification (Provider cannot change Sponsor assumptions)
- ☐ Bid to Expertise (Provider can change Sponsor assumptions)

Costing

- ☐ Bid to Units (Provider submits units and costs)
- ☒ Bid to Effort (Provider submits effort and cost)
- ☐ Bid to Resources (Provider assigns resources to tasks)

Bid Grid

- ☐ Flexible Bid Grid (Provider can add minor tasks)
- ☐ Share pre-RFP estimate (Provider can see Clinical Maestro budget)

Select Providers:

- ☐ CRO 1
- ☐ Ponderas Hospital
- ☐ Princeton General Hospital
- ☐ Strategikon Pharma
- ☐ University of Alabama Hospital
- ☒ Vendor1
- ☒ Vendor2
- ☐ Vendor3

Select Contacts:

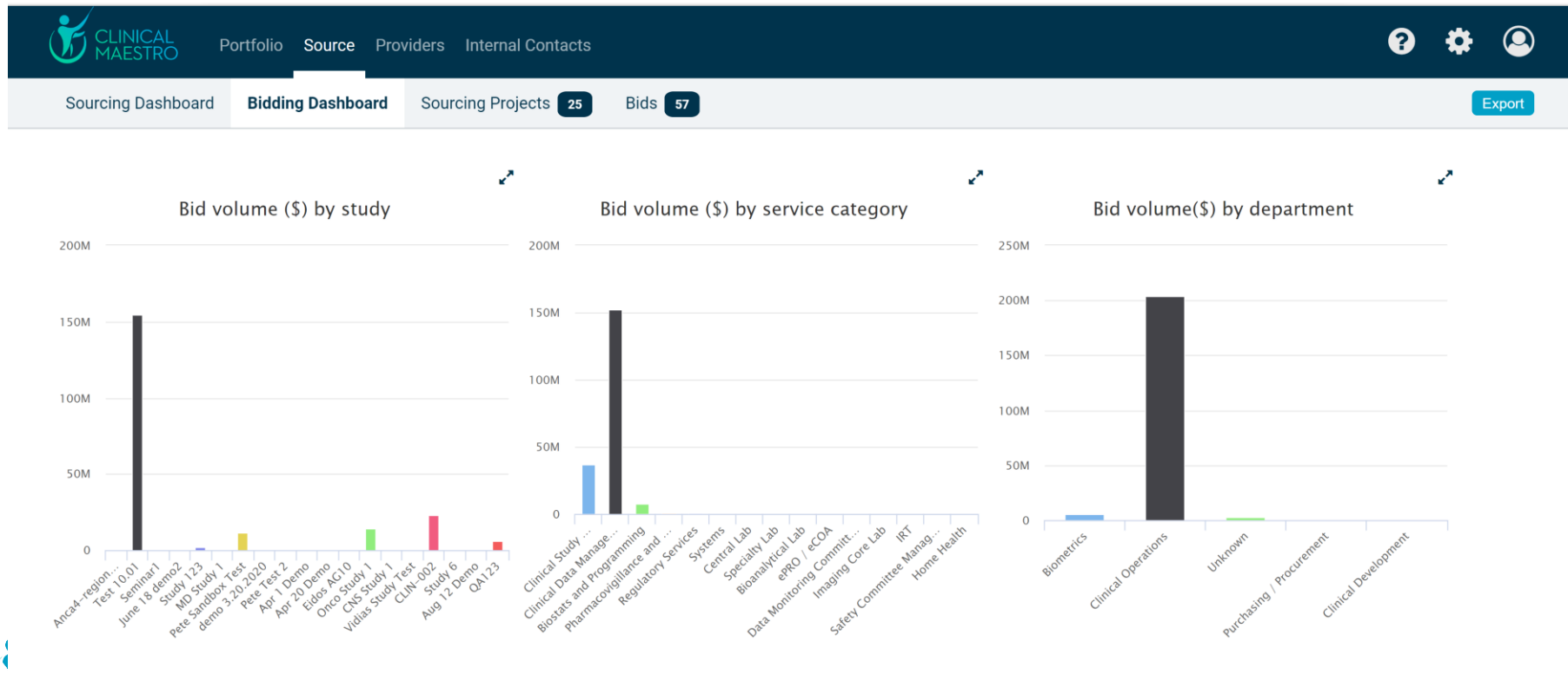
☒ Vendor2 - Leonard Bernstein ☒ Vendor1 - Carlos Kleiber




Cancel

Send

Modern RFP: Bidding Dashboard



Modern RFP: Bid Tracking in Analytical Database



PortfolioSourceContractsProvidersInternal Contacts

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Bids > CRO Selection 274

Search Bids


Type:Study:Requested Services

AllAllAll

<input type="checkbox"/>	Name	Status	Date of Response	Direct Cost	PTC Cost	Patient Cost	Discount	Total Cost	Score
Vendor 1									
<input type="checkbox"/>	Bid 1 Bid to Specification	Returned to Sponsor	17/04/2020	\$25,571,201	\$166,000	\$2,497,000	\$0	\$25,737,201	★★★★★ 4.9
<input type="checkbox"/>	Bid 2 (Rebid) Bid to Expertise	Waiting for Response	-	-	-	-	-	-	-
Vendor 2									
<input type="checkbox"/>	Bid 1 Bid to Specification	Returned to Sponsor	17/04/2020	\$32,000,577	\$166,000	\$2,497,000	\$0	\$34,663,577	★★★★☆ 4.0



Modern RFP: Compare Bid Versions to Benchmarks



PortfolioSourceContractsProvidersInternal Contacts

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Bids > CRO Selection 274

🔍 Search Bids

Type:Study:Requested Services

AllAllAll


<input type="checkbox"/>	Name	Status	Date of Response	Direct Cost	PTC Cost	Patient Cost	Discount	Total Cost	Score
Vendor 1									
<input checked="" type="checkbox"/>	Bid 1 Bid to Specification	Returned to Sponsor	17/04/2020	\$25,571,201	\$166,000	\$2,497,000	\$0	\$25,737,201	★★★★★ 4.9
<input type="checkbox"/>	Bid 2 (Rebid) Bid to Expertise	Waiting for Response	-	-	-	-	-	-	-
Vendor 2									
<input checked="" type="checkbox"/>	Bid 1 Bid to Specification	Returned to Sponsor	17/04/2020	\$32,000,577	\$166,000	\$2,497,000	\$0	\$34,663,577	★★★★☆ 4.0

2 bids selected

Compare

Compare to RFP

Modern RFP: Cost Drill Down


Portfolio
Source
Contracts
Providers
Internal Contacts
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[Bids](#) > [CRO Selection 274](#) > [Bid Comparison](#)

Timelines
Patients
Sites
Adverse Events
Budget
Service Assumptions
Export

Totals
Distribution

Service Category:
All

Service:
All

Compared value:
Direct Cost

Difference between:
CRO Selection 274 - RFP

Princeton General Hospital - Bi...

Highlight Values:
Select...

Highlight Variances greater than (absolute):
Select...

	CRO Selection 274 - RFP	Vendor 2 - Bid 1	Vendor 1 - Bid 1	Difference	Variance	
Clinical Data Management	\$464,944	\$520,998	\$464,944	\$-56,053	-11%	▲
Clinical Study Management	\$24,844,788	\$31,511,109	\$25,440,017	\$-6,666,321	-21%	▼
Protocol Development and Feasibility	\$64,105	\$64,105	\$64,105	\$0	0%	▼
Development and Feasibility	\$64,105	\$64,105	\$64,105	\$0	0%	▼
Conduct Protocol/Study Design Feasibility	\$15,383	\$15,383	\$15,383	\$0	0%	
Conduct Country - Level Protocol Feasibility	\$18,230	\$18,230	\$18,230	\$0	0%	
Develop Protocol	\$10,146	\$10,146	\$10,146	\$0	0%	
Protocol Development - Statistical Section	\$4,172	\$4,172	\$4,172	\$0	0%	





Digital Transformation Benefits

Standardization

RFP Bid Database

Comparative analytics

Deeper due diligence

Communication and Transparency



Award to Contract Process

Best Practices in
Communication
Management



A 3D puzzle with one red piece standing out among grey ones. The puzzle is set against a dark background with a blue horizontal line at the top left.

Best Practices Communication

- Maintain communication throughout entire RFI/RFP process
 - Before RFP/RFI: describe context/objectives
 - During RFP/RFI: answer questions, provide assistance
 - Post RFP/RFI: communicate award/reject decision and reason why

Award to Contract Transition



Approval process

Contract negotiation: Master of Service Agreement (MSA) and Scope of Work (SOW)

Budget confirmation and approval

Legal signatures



Document Management

Traditional: manually store documents in vendor selection/contracts folder

Technology enabled: automatic bid history retention in database



Contract Reporting Considerations

Earned Value Analysis: Post-award budget (unit or activity level) tracking

Accrual reporting: assess actual spend and verify invoices

Reforecasting: proactive change order management





Case Studies

How technology saves >75% of effort allocated to strategic sourcing process and drives RFP cost down through Fair Market Value

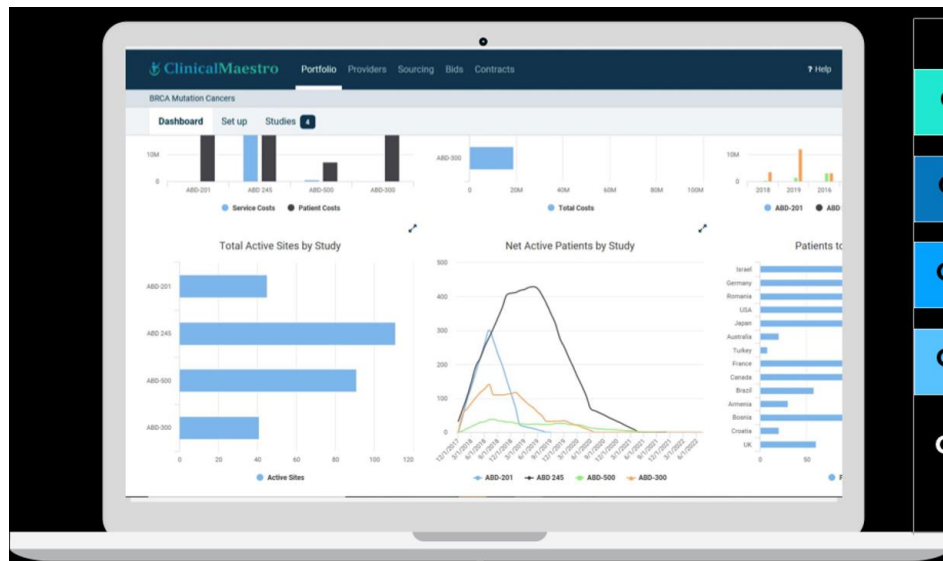




Login

Case Study: **Clinical Study Planning, Budget simulation and RFP Process of a Phase 3 Clinical Trial for Rare Disease Indication using Clinical Maestro™ Modular Applications**

- Client- mid-size biotech
- Study: global, 20+ countries, 500+ patients, 80+ sites
- Plan and Budget
 - Pre-RFP clinical trial plans and budget scenarios were built in Clinical Maestro™ PORTFOLIO using our proprietary INTELLIGENCE BANK.
 - Baseline budget was leveraged to negotiate bids during outsourcing process.
- RFP and Bidding
 - Client created an electronic RFP from in **SOURCE** Application.
 - Bidders (CROs) were set-up in the **VISION** application for bid and contract management.
- Bid to Contract
 - Using SOURCE, four CROs were invited to bid directly in Clinical Maestro™.
 - The bid due diligence, provider scoring and contract award were conducted in Clinical Maestro™



Clinical Maestro™ US\$26.8M

CRO 1 US\$24.6M

CRO 2 US\$26.5M

CRO 3 US\$26.0M

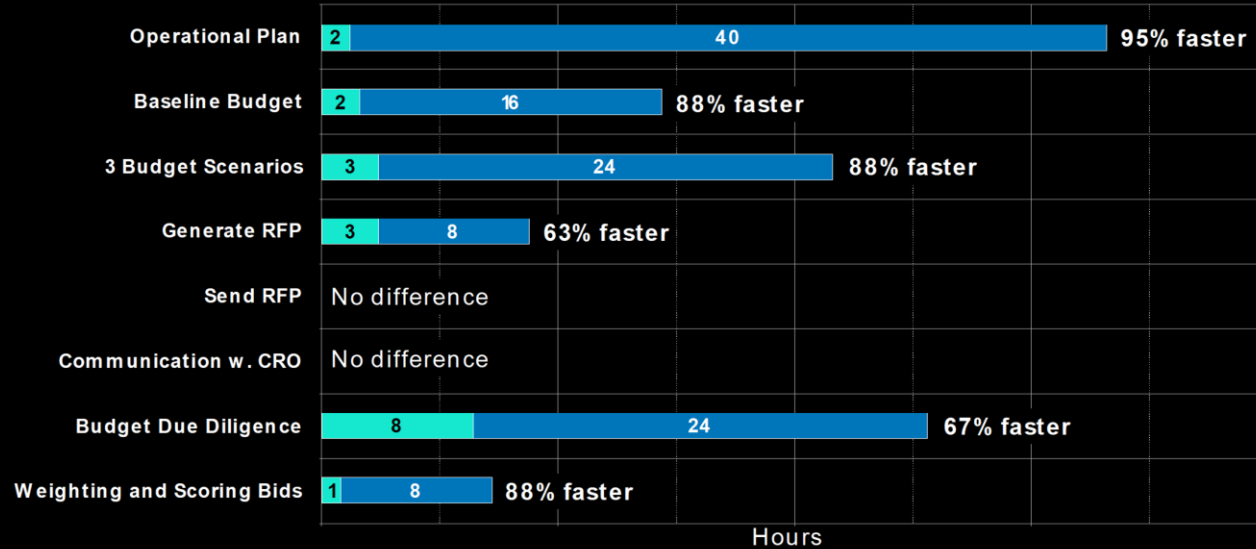
CRO 4

Results: Accuracy

- 3 out of 4 CROs responded in Clinical Maestro
- Baseline study simulation was within 100% in range and within 98% of median CRO bid

Clinical Maestro
Traditional

Results: Efficiency

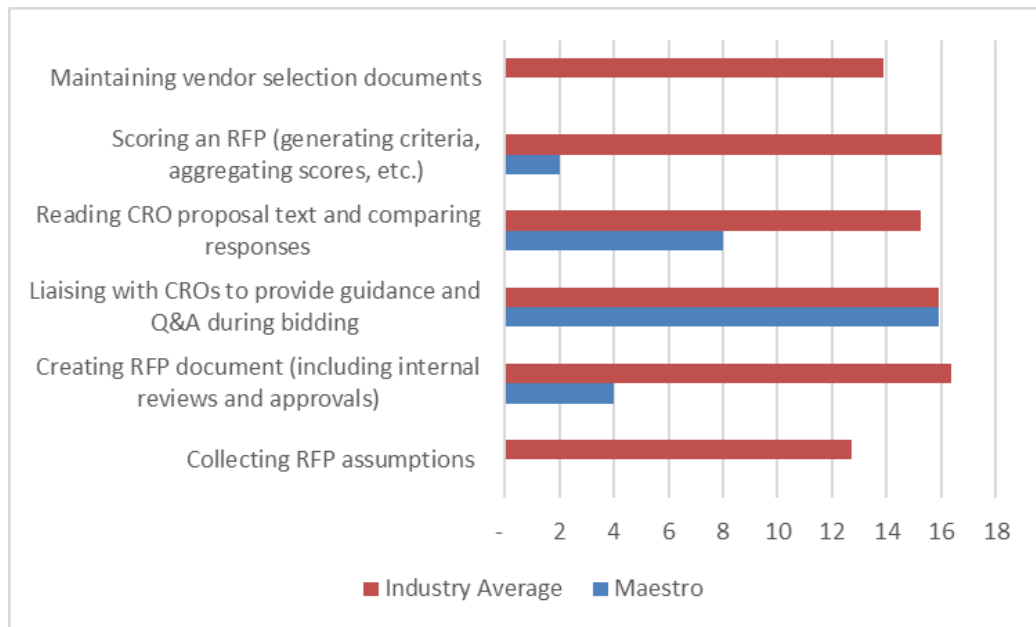


Results: Efficiency

- The Sourcing Project was completed in <100 hours, estimated 85% faster than classic methods (manual Excel due diligence, paper RFP)

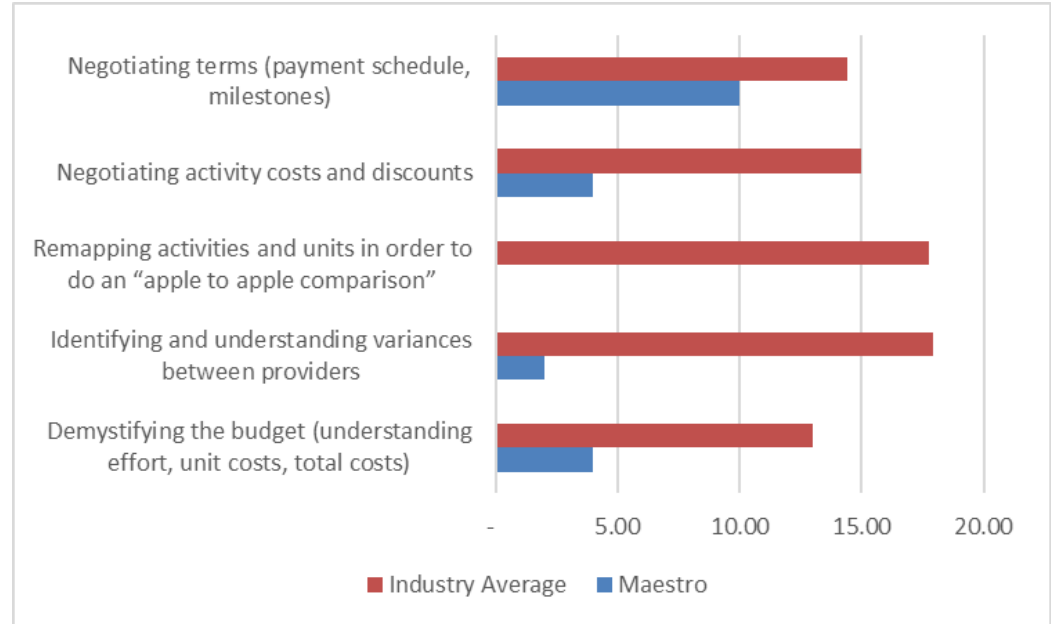
Clinical Maestro™ Sourcing Efficiencies *vs. Industry Average*

- 60-85% less effort than industry in RFP / Proposal Management
- Saves on average 100 hours per full-service RFP and 60 hours per non-CRO RFP



Clinical Maestro Budget Analyses Efficiencies *vs. Industry Average*

- 75% less effort than industry average
- Saves on average 60 hours per proposal in the initial RFP due diligence (excluding scenario modeling/ re-bid analyses)



Awards

- 2020
 - Top 10 eClinical Trial Management Providers
 - Strategikon CEO: Top 30 CEOs in 2020
- 2019
 - Commercial launch
 - Top 20 most promising Biotech solution providers
 - Gartner: 2019 Hype Cycle for Life Sciences Clinical Maestro listed on “**slope of enlightenment**” for high productivity tools
 - CARE Awards Finalist in 2 categories





Modernize Outsourcing

Embrace Digital
Transformation

Questions?

-
- Share your thoughts

Anca Copaescu: acopaescu@strategikonpharma.com

- Evidence and Case Studies

<https://strategikonpharma.com/evidence-and-resources/case-studies/>

- Request a demo:

info@strategikonpharma.com

- Visit our Clinical Maestro website:

<https://strategikonpharma.com/>

