RH Bouchard & Associates

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◆ BioPharma/Clinical Research Consulting

13th Annual Partnerships with CROs

How to Scope a Project

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How to Scope a Project

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How to Scope a Project

- ◆ Goals
    - ■ Interactive session
    - ■ Clearly defined team roles
    - ■ Tips on how to scope a project for an optimal response
    - ■ Tips on how to review proposals - what to look for
    - ■ Tips on how to identify scope creep

How to Scope a Project

- ◆ Why is an accurate detailed Project Scope important? It can…
  - Accelerate the bidding process, which in turns accelerates the start of the project
  - Saves money, time and effort on potential miscommunication, timeline discrepancies, and budget disputes.

Team Roles

◆ Who's Who?
- From Sponsor:
  - Central Outsourcing Group
  - Functional Group
- From CRO/Other Outsourcing Partners:
  - Proposal Group
  - Functional Group

Team Qualifications

- Who has a team approach to outsourcing?
- Who has served on a scoping team?
- Who has been responsible for the scope through the life of a project?

Scoping a Project - Key

- ◆ What is one of the most important things to have when defining the scope of a project?

- ◆ What is usually not available when you scope a project?

Scoping a Project - Key

THE PROTOCOL!

Scoping a Project - Team

- ◆ How do you get around this?
    - ■ The team approach to scoping
- ◆ Who should be on the Team?
    - ■ Someone from each function being outsourced
- ◆ What is their role?
    - ■ To provide Bidders with the **maximum** amount of information on the project

Scoping a Project – Team Role

- ◆ Develop project specs for their function
- ◆ Include assumptions, don't have each Provider make up their own
- ◆ Set the timeline, be realistic
- ◆ Be available for questions
- ◆ Attend scoping meetings

Scoping a Project - Information

♦ Critical Information

- Timeline Expectations

- Dedicated Resources

- Level of Experience Required

- Key Project to the Company

- Responsibilities

- Other Providers (IVRS, drug distribution, etc.)

- Detail, details, details

Scoping a Project - Details

♦ The more level of detail provided, the better!

- More accurate bidding

- Continuity between the bidders

- Comparison becomes easier (overcoming Provider differences in process)

Scoping a Project - Tools

- ◆ SOW
- ◆ RFP
- ◆ Scoping checklist (giveaway)
- ◆ Budgets
- ◆ Timelines
- ◆ Contract

Scoping a Project - Tips

♦ Don't assume you are speaking the same language (a rose it not always a rose)

♦ Even if the Provider has more experience ask them to propose the work based on the provided scope, then request alternatives

Proposal Review - Basics

- ◆ The Proposal
  - Did the Provider follow instructions
  - Is their level of expertise demonstrated
  - Did they offer creative alternatives
  - Did they provide a project plan or just a boilerplate proposal
  - How much experience do they have with similar work

Proposal Review - Feasibility

♦ The Proposal (continued)

- Did they propose a core project team
  - Did they meet your requirements for experience
  - How long has the Core Team been at the Company
  - Were you provided with CVs
- Was a feasibility review done
  - Sites
  - Patients
  - Recruitment Plan

Proposal Review - Timeline

♦ The Proposal (continued)

  ▪ Can they meet the project goals

    ● Timeline

    ● Budget

  ▪ Can they do better than requested

Proposal Review – Proposal Defense

♦ **Attend the Proposal Defense Meeting and ask questions**

- Do not allow a boilerplate presentation
- Prepare questions in advance and let them know what you want to focus on
- Insist the Core Team is present
- Require demonstrations of any technology components-not just PowerPoint
- Ask for a communications plan

Proposal Review - Tips

- ◆ Review proposals for content and creativity not just $'s
- ◆ Recommend the top 2-3 providers
- ◆ Vote on who should win the work
- ◆ Review the final scope of work
- ◆ Be consistent among providers so you are comparing similar bids– if one calls for clarification, make sure you notify the other bidders of your response.

Project Award - Contract

- ◆ Scoping Document
  - Attachment to the contract
  - Will likely be modified during the course of the project
  - Must be specific—draw a line in the sand
  - Each functional team member must feel comfortable with the Providers plan for their portion of the study

Project Award – Kick-off Meeting

- Attend and be prepared at the Kick-Off meeting - the final scoping meeting before contract

  - The scope will change as the process for working together is further defined at the Kick-off Meeting

  - These scope changes must be documented. Functional team members are responsible for making the final scoping document reflect the work to be done

Project Award – Scope Changes

- ◆ New Assumptions Mean Scope Changes
  - Does it effect the timeline
  - Does it increase or decrease the number of patients, sites, visits, tests, etc.

- ◆ Scope creep will catch up with your project and will effect the budget.

Scope Changes - Tips

♦ Avoiding Scope Creep (Out-of-Scope Work)

  ▪ Know what is in the Scope of Work for your project

  ▪ When the Provider changes something, determine if it will require modification to the contract

  ▪ Don't approve additional work without understanding the potential effect

Scoping a Project - Importance

♦ Even though this is not your full time job, it is an important one.

♦ Your role on the team assures expertise in your function is captured in the scoping, selection and contract monitoring process

♦ Better planning up-front results in a better project