Partnerships with CROs

Standardizing the RFP
Jennifer Goodfellow, Sepracor
William Colman, Daiichi
Cynthia Jerrems, Outsourcing Management
Rikki Bouchard, RH Bouchard & Associates
AGENDA

- Introductory Remarks
  - POMA Initiative
  - Perceived Benefits
  - One Sponsor’s Perspective
- Survey Results
- Panel Discussion
- Q & A
The Pharmaceutical Outsourcing Management Association (POMA) developed a standard Request for Proposal (RFP), along with a budget grid and cost matrix.

The POMA group gathered commonly used RFP documents and shared their own experiences in developing the final products.
The RFP covers every aspect of what would be expected of a CRO in clinical research, from study design and event scheduling to key milestone dates and site and data management… a way to codify the sponsor’s expectations of the CRO.

The sponsor only needs to use sections of the document that apply. The budget grid corresponds to the RFP parts and is designed so only required services are included.
The documents are generalized and appropriate for any size company to use and include:

- RFP Cover Letter
- RFP
- Guidelines and timelines
- Deliverables
- Compound program overview, general summaries
- Study Specifications
- Study Budget Bid Grid
- Intent to Respond Document
Next steps are to encourage use of the templates and gather feedback during the next year. Teleconferences are scheduled to assess industry interest.

These templates are now available on the POMA website www.pomasite.com
<table>
<thead>
<tr>
<th>Last</th>
<th>First</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barth</td>
<td>Susan</td>
<td>AAI Development Services</td>
</tr>
<tr>
<td>Guarasci</td>
<td>Greg</td>
<td>PRA International</td>
</tr>
<tr>
<td>Hallett</td>
<td>Stewart</td>
<td>Xoma</td>
</tr>
<tr>
<td>Jerrems</td>
<td>Cynthia</td>
<td>Outsourcing Management, Inc.</td>
</tr>
<tr>
<td>Joyce</td>
<td>Jay</td>
<td>Procter &amp; Gamble</td>
</tr>
<tr>
<td>McKelligott</td>
<td>Betty</td>
<td>Endo Pharmaceuticals</td>
</tr>
<tr>
<td>Oscherwitz</td>
<td>Brian</td>
<td>Biovail</td>
</tr>
<tr>
<td>Stubenhofer</td>
<td>Scott</td>
<td>PharmaMediation</td>
</tr>
<tr>
<td>Vanasse</td>
<td>Chuck</td>
<td>PharmaMediation</td>
</tr>
<tr>
<td>Veno</td>
<td>Holly</td>
<td>Berlex</td>
</tr>
<tr>
<td>Wall</td>
<td>Michele</td>
<td>Endo</td>
</tr>
<tr>
<td>Wauk</td>
<td>Linda</td>
<td>Pharmaceuticals Protein Design Labs</td>
</tr>
<tr>
<td>Goldberg</td>
<td>Caryn</td>
<td>POMA</td>
</tr>
</tbody>
</table>
Benefits

- Common Theme

- Standard Terminology, Standard Template Will Result in Better Proposal Evaluations
Standardization Makes Things Better

- Better Evaluations are Better for Everyone
- Better Evaluations Ultimately Yield Better Selections = Better Results
Increased Efficiencies

For All Parties – Common Equation

- TIME EQUALS MONEY

Increased Efficiency = WIN/WIN
Better Evaluations = Better Proposals

- Better Evaluations = Better Feedback
- Better Feedback = Better Future Proposals
Benefits for Sponsors and Providers

- For Providers
  - Reduced Internal costs
  - Potential for slight increase in profits

- For Sponsors
  - Reduced external costs
  - Potential for slight decrease in expenses

- Standardization of the RFP and RFP process has the POTENTIAL of reducing costs for all parties and increasing the operational efficiency for all involved
Demographics

- 47% favored a standard RFP, 53% no or indifferent
- No differentiation by job function
- 5-10 years of experience, 67% in favor
- <5 years or >10, 40%
- People “in the trenches” looking for standardized approach
Outsourcing Activities

- More time spent on outsourcing = less desire for standardization

- Individuals responsible for supporting outsourcing activities (Operations) are more inclined toward standardization
Benefits

- Biggest Benefit—Easy Button
  - Sponsor: Ability to compare responses (33%)
  - Provider: Easier to prepare proposals (31%)

- Least Benefit
  - Less than ¼ thought it would save time
  - Only 6% thought it would save cost
Drawbacks—We’re Too Special

- 39% felt their projects could not be “standardized”
- 30% felt they would need to customize the “standard” RFP in order to use it
Respondents Thoughts

- Sponsors
  - Company’s needs are specific
  - Projects are too different

- Providers
  - A plain bad idea
  - Ability to propose innovation is lost
  - Options are more important than standardization
  - CROs can’t differentiate themselves
Sponsor Viewpoint

In favor
- Easier to compare results 71%

Not in favor
- Projects not standard 31%
- Too much customization 35%
- Company culture 63%
Provider Viewpoint

- In favor
  - Easier to prepare proposals 83%

- Not in favor
  - Projects not standard 69%
  - Too much customization 50%
  - Too time consuming 50%
Who will use a standard RFP?

- Pharma
  - Yes 44%
  - No 56%

- Biotech
  - Yes 47%
  - No 53%
Provider Expectations

- Timelines to submit a proposal will be shortened; resources needed will remain the same
- Only 20% believe it will increase efficiency or reduce costs
Provider Comments

- Pros
  - Provide detailed information
  - Allow for apples to apples comparisons

- Cons
  - Increase proposal preparation-lengthen the process
  - Decrease opportunity to differentiate, lose uniqueness
  - Standardization stops thinking
  - Increase internal costs initially
  - Difficult to use
  - Annoying
What should be standardized?

- Pharma and Biotech
  - Terminology
  - Budget model

- CROs
  - Assumptions and project specifications (69%)
  - Bid grids (55%)
Strong Support Not Evident

- Support for Standardization
  - 55% of Pharma
  - 41% of Biotech
  - 42% of Providers
Flexibility?

- Sponsors 42% would be willing to modify their processes

- 66% of Providers are willing—CROs are flexible!
Willingness to Support

- Approximately 1/2 of the Providers and Sponsors think their Companies would support development of a standardized tool
- and -
- Half think they would NOT!
Respondents Thoughts on Standardization

- A "standard" RFP format—a "kitchen sink" approach
- Promotes commodity pricing—"buying a bag of nails"
- RFPs should provide flexibility in order to define value
- Providers need flexibility to demonstrate differences
- No opportunity to propose innovation and process
- Providers that execute RFPs efficiently have a competitive advantage—standardization will remove
- Will decrease turnaround time and increase costs of proposals
Respondents Thoughts on Standardization

- Good idea IF process can be created to reduce costs to respond
- Some sponsors want the provider to define assumptions
- Unlikely that one model will ever fit across all companies
- Standardization would greatly streamline the process
- Standardization of a budget grid may be productive, study assumptions more challenging
Summary-Results

- Not an overwhelming interest in standardization
- Providers are concerned about differentiation and cost to implement
- Without obvious benefits, Sponsors/Providers will be unlikely to support with resources
Summary—Our Viewpoint

- No mandate by industry or FDA
- Implementation would be difficult
  - Intellectual Property
  - Ownership—who drives the process?
  - Maintaining the standard
  - Multiple templates needed (Phase/Service)
  - Inability to modify to fit unique needs
  - Internal support processes vary (finance, legal)
  - No agreement on what to standardize
  - No agreement on standard definitions
Questions, Answers, Suggestions?

THANK YOU!

Rikki@RHBassociates.com