
Partnerships with CROs

Standardizing the RFP

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AGENDA

- Introductory Remarks
 - POMA Initiative
 - Perceived Benefits
 - One Sponsor's Perspective
 - Survey Results
 - Panel Discussion
 - Q & A
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POMA Standard RFP

- 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
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POMA Standard RFP

- 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.
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POMA Standard RFP

- 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
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POMA Standard RFP

- 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
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PROJECT RECOGNITION

Last	First	Company
Barth	Susan	AAI Development Services
Guarasci	Greg	PRA International
Hallett	Stewart	Xoma
Jerrems	Cynthia	Outsourcing Management, Inc.
Joyce	Jay	Procter & Gamble
McKelligott	Betty	Endo Pharmaceuticals
Oscherwitz	Brian	Biovail
Stubenhofer	Scott	PharmaMediation
Vanasse	Chuck	PharmaMediation
Veno	Holly	Berlex
Wall	Michele	Endo
Wauk	Linda	Pharmaceuticals Protein Design Labs
Goldberg	Caryn	POMA

Benefits

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

- Better Evaluations are Better for Everyone
 - Better Evaluations Ultimately Yield Better Selections = Better Results
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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
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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
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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
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Outsourcing Activities

- More time spent on outsourcing = less desire for standardization
 - Individuals responsible for supporting outsourcing activities (Operations) are more inclined toward standardization
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Benefits

- **Biggest Benefit—Easy Button**
 - Sponsor: Ability to compare responses (33%)
 - Provider: Easier to prepare proposals (31%)
 - **Least Benefit**
 - Less than $\frac{1}{4}$ thought it would save time
 - Only 6% thought it would save cost
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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
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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
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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%
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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
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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
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What should be standardized?

- **Pharma and Biotech**

- Terminology
- Budget model

- **CROs**

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

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

- Sponsors 42% would be willing to modify their processes
 - 66% of Providers are willing—CROs are flexible!
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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!
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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
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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
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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
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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
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Questions, Answers,
Suggestions?

THANK YOU!

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