Common RFP Template, Sponsored by POMA

Date

Name
Address

RE: PROGRAM TITLE

Dear _____:

We are pleased to invite you to submit a proposal to assist with the management of _____ Pharmaceutical's PROGRAM TITLE Clinical Development Program for the treatment of _____ according to the responsibilities and requirements delineated in the attached Request For Proposal (RFP).

At this point in time the program is comprised of X# studies.

- PROTOCOL TITLE #1
- PROTOCOL TITLE #2
- PROTOCOL TITLE #3

Your proposal will be a key source of information for SPONSOR in selecting the CRO for this program.

This RFP contains the following documents:

1. General Proposal Guidelines & Timelines
2. List of Proposal Deliverables
3. _____Program Overview and General Assumptions
4. Study Specifications Worksheets
5. Budget Worksheets
6. Intent to Respond Document

All information in this RFP and in the supporting documentation is confidential and all information _____ receives from you will be treated confidentiality.

By *DATE,* please submit any questions you may have about the RFP to the SPONSOR team via email at _____. The team will promptly answer your questions and also provide any relevant clarifications or updates.

WE EXPECT TO RECEIVE YOUR COMPLETED PROPOSAL NO LATER THAN NOON PACIFIC TIME ON DATE.

Please submit an electronic copy of your proposal via email. Please also submit three (3) hard copies (at least one unbound copy) of your proposal to me via express mail.

Thank you very much for your participation in this process.

Sincerely yours,

B I O P H A R M A S P O N S O R L O G O

Request for Proposal

PROGRAM Name

Protocol -01
Protocol-02
Protoco l 03

DATE Distributed

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GENERAL PROPOSAL GUIDELINES AND TIMELINE

GENERAL

The Request for Proposal (RFP) is to remain confidential, and the contents shall not be disclosed to anyone outside of the Contract Research Organization (CRO) without SPONSOR Pharmaceutical Inc.'s (SPONSOR) written permission. Please ensure that you have completed and returned SPONSOR's Confidential Non-Disclosure Agreement.

All proposals submitted become the property of SPONSOR and will not be returned to the CRO. The contents of all proposals, correspondence, financial data, or any other medium, that discloses any aspect of this proposal, shall be held in confidence by SPONSOR and its agents/consultants.

The selected CRO agrees to accept the contents of their proposal and any addenda provided as obligations in a contracted agreement. Failure to meet these obligations may result in cancellation of the contract.

All CRO responses to this RFP may be validated using demonstrations and reference checks. The selection of a successful CRO will not be based solely on the CROs response.

RESPONSIBILITIES OF THE SERVICE PROVIDER

By accepting this RFP, the CRO assumes the responsibility for maintaining the confidentiality of this document.

The CRO is responsible for including in the proposal all necessary items required to meet deliverables as defined in the CRO proposal. Missing budget items or other proposal-related information must be provided as requested by SPONSOR, before a proposal will be evaluated.

RFP PROCESS

A. Correspondence: Unless otherwise specified, all correspondence and documents should be sent to Name at email address If e-mail cannot be used or is not appropriate, the preferred methods for sending documents, in descending order of preference, are:

   i. Express Mail:

      ATTN: _____
      SPONSOR Pharmaceutical Inc.
      ADDRESS
      City, State, Zip
      Phone: _____

   ii. Fax:

      Fax number
      Attn: _____

B. Grids & Other Details: Please complete all grids and forms sent to you in this packet in the level of detail specified. In many cases, the level of detail you provide will indicate your capabilities to us.

C. Cost Matrix: Complete and return the attached cost matrix with your proposal. **Please complete a cost matrix for each individual study and a summary cost matrix for the combined execution of the entire program taking into account efficiencies that may be achieved.**

D. Team Leaders/Communication: All communications and documents related to this negotiation must be directed to Name @ phone.

E. Deadlines: This CRO selection is a competitive process. Therefore, it is critical that deadlines specified be met.

MILESTONES

In order to enable SPONSOR to successfully initiate this process, please note the following short-term deadlines:

A. NDA: By noon PST on March 3, 2004, please fax to (XXX) XXX-XXXX, Attn. Name, an executed NDA. Follow-up the fax with two originals by express mail to Name. We will sign both copies and return one to your office. If an appropriate NDA is already in place this process will not be duplicated.

B. Intent to Participate: By EOBD on March 9, 2004: please email to Name at email address notification of your intent to submit a proposal for this selection process.

C. Proposal: By Noon Pacific Time on March 16, 2004, please email to Name at email address your completed proposal. Please follow up your e-mail with three (3) hard copies via Express Mail.

D. We anticipate that through the week of March 22, 2004, we will be contacting you with a list of additional questions and points of clarification. More specifics will be provided at a later date.

E. We anticipate proposal presentations by the finalist will occur the week of April 5, 2004.

F. We anticipate project award during the week of April 12, 2004.

SELECTION CRITERIA

The CRO will be selected based on responses to this RFP, and the following criteria:

- Quality of response to RFP, including comments and suggestions.
- Experiences/skill level of company representatives assigned to this project.
- Quality and applicability of proposal presentation.
- Understanding of the indication and experience in related areas.
- Value for the cost of service proposed .

RFP DELIVERABLES

When preparing and submitting your proposal, please submit a carefully considered, detailed description of your approach to performing these studies. Given SPONSOR's requirements, describe how your approach and staff will enable your team to meet study timelines, insure quality results, and minimize expenses.

Please be sure to include the following information in your proposal.
(SAMPLE Questions)

1. Company Information
    - Please provide corporate headquarters, location, and contact information.
    - Please provide the location where the work will be performed and the contact information.
    - Please provide size of company. Please include revenue and number of full time employees and number of temporary or consultant staff.
2. A description of your processes and how they would be applied to the management of this program.
3. A list of studies managed over the last 3 years in relevant indications.
4. A description of lessons learned in similar previous clinical studies and how such lessons can be applied to enhance your deliver of this program.
5. Project management plan including proposed timelines, the team and organizational structure.
    - Resumes of the key team members, including: Project Manager/Director, Lead CRA, Regulatory Specialist, Lead Data Managers, and Project Physician that will be assigned to this project. Please also provide resumes of several CRAs that will be assigned to the project.
    - In addition, please attach a list of relevant titles/functions that would be involved, a brief description of the work each is expected to perform, minimum education level, minimum number of years of work experience, a brief description of the training required for that role, and the number of hours of training required.
    - Example of tools and status reports that you intend to supply SPONSOR.
6. Proposed method and frequency of communication between you, SPONSOR and investigator sites for the successful management of these studies.
7. A copy of your insurance certificate(s), if you have not provided them to SPONSOR within the past six months.
8. Proposed business terms and fee schedules to meet timelines and milestones.

COMPOUND™ PROGRAM OVERVIEW AND GENERAL ASSUMPTIONS

SPONSOR AND THE _____ PROGRAM

- SHORT NARRATIVE ABOUT THE SPONSOR COMPANY.
- SHORT NARRATIVE ABOUT THE STUDY OR PROGRAM.

The CRO will provide clinical development management and execution including, but not limited to: site initiation and startup, perform routine site monitoring visits, management and correspondence with the site, drug accountability, and obtaining updated study/regulatory documents, data management, and aspects of medical management.

Company Name
STUDY-SUMMARIES

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Protocol Title

Study Summary	
Company Name and ADDRES	Specific Contact Information
Product name:	
Protocol Number:	
Protocol title:	
Clinical phase:	Phase II
Study objectives:	**Primary**: •
	Secondary: •
	Safety Objective: •
Methodology:	
Critical Inclusion/Exclusion Criteria:	**Inclusion:** •
	Exclusion: •

Study Summary	
Efficacy Endpoint	
Safety Endpoint(s)	
Statistical Methods:	
Dosage form:	
Indication:	
Age range of subjects:	

Participating countries	No. Of sites	*IRB/Ethics Committee (# Central/# local)*	Expected no. Of patients enrolled/site
USA			
Canada			
Poland			
Ireland			
Germany			
UK			
France			
Italy			
Turkey			
Total			

Subject Information	Comment
Number of screened subjects:	
Number of enrolled subjects	
Duration of each subject's participation	
Duration of subject enrollment period:	

No. Of CRF pages / Case books:	
Anticipated no. Of concomitant meds per subject:	
Estimated no. AEs:	
Estimated no. SAEs:	
Laboratories	
Type of Laboratory Used (Central and/or Local)	
Number of Central Laboratories	
Number of Local Laboratories	
Format of Laboratory Data (Electronic, CRF or Lab Reports)	

Schedule of Events (Subject Visit Schedule)

	Screening	Day 1 [a]	Day 14 (+/– 1 day) Phone Visit	Day 30 [b] (+/– 1 day)	Day 45 [c] (+/– 3 days): Termination Visit
Informed consent	X				
Medical history	X				
Vital signs and weight	X	X		X	
Physical examination	X				
Clinical laboratory tests	X			X [d]	X [e]
Urine pregnancy test [f]	X	X			
Concomitant medications	X	X		X	X
Adverse events	X [g]	X	X	X	X
Serum Assay	X [i]	X [j]		X	
Dispense study drug [l]		X			
Study termination assessments					X

Key Milestone Dates	
CRO Begin Work:	
Protocol approved:	
Investigator Meeting:	
First patient screened:	
Last patient screened:	
Last patient complete	
Final database lock:	
Draft tables, listings, graphs, and statistical methodology:	
Final tables, listings, graphs, and statistical methodology:	
Draft Clinical Trial Report:	
Final Clinical Trial Report:	
All Study Documentation Returned To Sponsor:	

[Insert Program Roles and Responsibilities Matrix]

STUDY BUDGET SCHEDULE

In order for your proposal to be considered, you must use the Study Budget Schedule provided in the attached excel file.

INTENT TO RESPOND FORM

This form must be faxed by 12:00 Noon PST on 9 March 2004

Attn: NAME

Fax: (XXX) XXX-XXXX

Please state your intentions with regard to this RFP by checking one of the boxes below:

☐ We intend to respond to this Request For Proposal (RFP) by the specified due date. We understand that complete response is due no later than 16 March 2004

☐ We do not intend to respond to this Request For Proposal (RFP).

_____
Company Name

_____
Contact Person

_____
Signature of Contact Person

_____
Date