

SERVICE PROPOSAL WORKSHEET

General Information

_____ Your Name	_____ Title or Dept
_____ Company Name	_____ Telephone
_____ Address 1	_____ Fax
_____ Address 2	_____ E-mail
_____ City, State	_____ Web Address
_____ Country, Zip Code	

Project Description *(Include study product indication for use)*

Study Product Type

- Device
- Pharmaceutical
- Biologic

U.S. Regulatory Status of Product

- Investigational
- Cleared by FDA for U.S. Marketing

Reason for Request

- Proposal for funding
- Competitive CRO assessment
- Other _____

By what date would you prefer to have our proposal? _____

Please complete the remainder of this worksheet and submit via FAX or e-mail to:

Promedica International Business Development
Fax: 714-460-7364 or E-mail: bd@promedica-intl.com

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Study Information *(Please provide requested information below, or forward study protocol outline in Case Report Forms)*

-
1. What is the total number of study subjects (test & control)? _____
 2. What is the total number of US study sites? _____
 3. What is the total number of study sites outside US? _____ Location(s): _____
 4. What is the total number of core laboratories/reading centers? _____
 5. What is the number of laboratories at each site? _____
 6. When is the anticipated date for study initiation? _____
 7. How long will it take to enroll all subjects? _____
 8. How many interim analyses are planned? _____

(Please list ALL study exams below, unless ALL CDFs are provided with this submission)

Study Visit	When Visit Occurs	# CRF Pages for Visit
1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____
6.	_____	_____
7.	_____	_____
8.	_____	_____
9.	_____	_____
10.	_____	_____

(Please provide the following information regarding study monitoring plans, if applicable)

-
1. Number of pre-study visits/site _____
 2. Number of study initiation visits/site _____
 3. Number of interim monitoring visits/site _____
 4. Percentage of subjects for whom all data will be source verified _____
 5. Number of core laboratory/reading center monitoring visits _____
 6. Number of close-out visits/site _____

Services Desired *(Please indicate below the services you would like to have included in our proposal)*

Clinical Study Site Management & Monitoring

- | | |
|---|---|
| <input type="radio"/> Site recruitment | <input type="radio"/> Study initiation visits |
| <input type="radio"/> Site qualification | <input type="radio"/> Interim study monitoring visits |
| <input type="radio"/> Site budget development | <input type="radio"/> Maintenance of essential regulatory documents |
| <input type="radio"/> Site contract negotiations | <input type="radio"/> SAE/UADE initial contact & follow-up |
| <input type="radio"/> IRB/Ethics Committee submission coordination | <input type="radio"/> Site/subject payment administration |
| <input type="radio"/> Site training program development | <input type="radio"/> Study product inventory management |
| <input type="radio"/> Investigator meeting | <input type="radio"/> Study close-out visits |
| <input type="radio"/> Study participation recruitment program development | |

Other: _____

Clinical Study Data Management/Biostatistics

- | | |
|---|--|
| <input type="radio"/> CRF development | <input type="radio"/> AE coding |
| <input type="radio"/> Database development | <input type="radio"/> Data QC |
| <input type="radio"/> Data entry & verification | <input type="radio"/> Subject randomization plan development |
| <input type="radio"/> Query generation & resolution | <input type="radio"/> Statistical analysis |

Other: _____

Medical Writing

- | | |
|--|--|
| <input type="radio"/> Protocol development | <input type="radio"/> Clinical study report(s) development |
| <input type="radio"/> Clinical Investigator Brochure development | |

Other: _____

GCP Compliance

- | | |
|---------------------------------------|---|
| <input type="radio"/> Study audit | <input type="radio"/> GCP training |
| <input type="radio"/> SOP development | <input type="radio"/> Assistance with FDA site inspection |

Other: _____

Regulatory Affairs

- | | |
|--|---|
| <input type="radio"/> Coordinate IDE/IND application | <input type="radio"/> Establishment registration |
| <input type="radio"/> Coordinate 510(k) application | <input type="radio"/> Product listing |
| <input type="radio"/> Coordinate PMA application | <input type="radio"/> Assistance with FDA site inspection |
| <input type="radio"/> Coordinate NDA application | |

Other: _____

Other Services Desired *(please specify below)*
