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 inication 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: more_info@promedica-intl.com

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

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

Other: _____

Clinical Study Data Management/Biostatistics

- ◯ CRF development
- ◯ Database development
- ◯ Data entry & verification
- ◯ Query generation & resolution
- ◯ AE coding
- ◯ Data QC
- ◯ Subject randomization plan development
- ◯ Statistical analysis

Other: _____

Medical Writing

- ◯ Protocol development
- ◯ Clinical Investigator Brochure development
- ◯ Clinical study report(s) development

Other: _____

GCP Compliance

- ◯ Study audit
- ◯ SOP development
- ◯ GCP training
- ◯ Assistance with FDA site inspection

Other: _____

Regulatory Affairs

- ◯ Coordinate IDE/IND application
- ◯ Coordinate 510(k) application
- ◯ Coordinate PMA application
- ◯ Coordinate NDA application
- ◯ Establishment registration
- ◯ Product listing
- ◯ Assistance with FDA site inspection

Other: _____

Other Services Desired *(please specify below)*

_____

_____

_____