

Cancer Prevention Clinical Trials Auditing and Informatics Support

ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS SAMPLE TASK ORDER

In addition to the instructions and format requirements for the business proposal that are contained in Section L of the solicitation, the information provided in this Attachment is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as attachments, the technical evaluation criteria, and, the RFP as a whole, in the development of your proposal. The information provided here should be used as further guidance for the development of your Business Proposal. The Sample Task Order period of performance is for 12 months.

The following uniform cost assumptions shall be used by all offerors in preparation of their cost proposal.

1. Clinical Trials Support

A. Consortia 2003

The initial DCP Consortia program (Consortia 2003) for early clinical development of cancer preventive agents was funded in 2003 with a core of six (6) major medical research centers serving as Consortia Lead Organizations (CLO) and 124 national and international participating organizations associated with one or more CLO.

Consortia 2003 has activated a total of 52 trials of which 50 trials have submitted data using OC-RDC. Of these 50 trials, there are 10 trials active and open to accrual in OC-RDC, 14 trials closed or completed with their OC-RDC database lock pending, and 26 trials closed with a locked database.

The total planned accrual for the active and open studies is approximately 700 participants. Approximately 50% of these participants are accrued and eligible. The total accrual for all closed and locked Consortia 2003 studies is approximately 2300 participants. No additional studies are planned for activation in the Consortia 2003 program.

The Contractor will provide services to support the continuation and completion of clinical trials initiated under the Consortia 2003 mechanism.

- Services required for the 10 active and 14 closed/completed trials (with database lock pending) include but are not limited to:
 - centralized data management using the Contractor –hosted instance of OC-RDC, including discrepancy resolution and study-specific database lock,
 - database maintenance, including modifications required for changes in protocol requirements,

- audits and/or closeout visits of the CLO study sites, including verification of OC-RDC data to ensure site compliance with DCP's protocol, regulatory, pharmacy and data collection requirements
- Services required for all Consortia 2003 clinical trials include but are not limited to:
 - the transfer of OC-RDC data for each clinical trials as files and datasets to DCP's central database (DESK) the Clinical Data Transfer (CDT) website for retrieval by the CLOs, and the DCP Collaboration Repository for archiving or storage,
 - providing data reports to the CLO and DCP for use in data management, clinical trials management and regulatory activities
 - HelpDesk support for Consortia 2003 clinical sites and site staff to address questions and issues regarding OC-RDC data management, auditing and/or general administrative issues for all studies.
 - The estimated average number of queries per month is 125 (e-mail and phone)

Education and training services will be provided for study site staff for Consortia 2003 activities and processes. Services include but are not limited to providing educational materials and programs including OC-RDC training, DCP Standard Operating Procedures, and educational sessions as specified by the COR. .

These services will continue for the period of performance for this Task Order, the completion of the Consortia 2003 program, or as directed by the COR.

B. Consortia 2012

The Consortia program was renewed in 2012 (Consortia 2012) with a core of five (5) major medical research centers chosen to lead the program as the CLOs, and 79 national and international participating organizations associated with one or more CLO.

Each Consortia 2012 organization is expected to activate one or more clinical trials each year and accrue 75 or more participants yearly. Approximately three (3) task order requests for clinical trial proposals will be released annually to the Consortia 2012 Lead Organizations. Currently seven (7) clinical trial protocols have been approved for development, and five (5) proposals are in review by DCP. During this task order period, DCP anticipates that three (3) to six (6) clinical trials will be open to accrual.

The Contractor will provide the services required to support the clinical trials under the Consortia 2012 mechanism. These services include but are not limited to:

- audits of the study sites, including specimen inventory/tracking and verification of clinical trials data submitted to DCP, to ensure site compliance with DCP's protocol, regulatory, pharmacy and data collection requirements;
- education and training programs and materials for Consortia 2012 activities and processes such as DCP Standard Operating Procedures, and educational sessions as specified by the COR.

For studies conducted under the 2012 Consortia, participant data for each study are collected, entered and managed by each CLO, using a clinical data management system

(CDMS) of the CLO's choosing. Each CLO will electronically submit a subset of data from each clinical trial to DCP monthly as a standardized minimum data set (MDS) defined by DCP. The Contractor will not provide centralized data management services for the Consortia 2012 program.

These services will continue for the period of performance for this Task Order or as directed by the COR.

2. Travel

- A.** Assume two (2) staff will be required to travel two (2) times per year to each of the Consortia 2003 and/or Consortia 2012 Lead Organizations (CLO) at various locations in the USA to perform auditing and data verification services for cancer prevention clinical trials conducted at each CLO. Assume costs for a three (3) night stay, ground transportation, per diem (calculated per the current GSA rates), and airfare.

The CLOs are located in the following cities:

Rochester, MN

Houston, TX

Chicago, IL

Tucson, AZ

Madison, WI

Orange, CA (NOTE: travel will be required to this CLO during Year 1 only.)

3. Other Costs

- A.** Costs for electronic communications include the total costs for :
- Websites to support OC-RDC activity, user access to resources available on the CDT, and secure file transfer,
 - Helpdesk support provided by electronic methods (e.g. e-mail),
 - OC-RDC training using electronic methods (e.g. webinars)
- a.** The Offeror shall supply and host an instance of Oracle-Clinical-Remote Data Capture (OC-RDC) compatible with the current OC-RDC system (V4.6 or later) to meet the requirements of this proposal for data management, data transfer and reporting, and data verification of Consortia 2003 studies. Hosting includes, but is not limited to, the following:
- Providing an instance of OC-RDC (V4.6. or later), the appropriate infrastructure and license
 - Maintaining patches and updates
 - Backing up the system
 - Ensuring appropriate access
 - Building and maintaining clinical trials in OC-RDC v4.6 (or later)

- b. Costs associated with assuring the Offeror's compliance with FISMA and other IT security requirements of this proposal should be considered as part of the Offeror's overhead costs.