

**Sample Task Order 0002 for Task Area II
Request for Proposal (TO-RFP)
RFP N02CM31002-75**

Task Order Title

Cancer Trials Support Unit (CTSU) Core Support Services and the CTSU Enterprise of Systems

Statement of Work

Background:

Historically CTSU support has primarily been limited to the Cooperative Group treatment program. The portfolio of organizations and research areas supported by the CTSU are described in the contract statement of work.

Objectives:

To ensure that Cancer Trials Support Unit (CTSU) is centralized and fully operational.

Technical Requirements:

Please see Task Area II – “CTSU Core Support Services and the CTSU Enterprise of Systems” of the SOW for the entire technical requirement.

The CTSU Core Support Services consists of the provision of broad-based, centralized, and fully integrated operational, administrative, regulatory, and logistical support services to all CTSU supported NCI multi-center coordinating centers and participating sites, with a specific sub-set of specialized core services for the new NCI National Clinical Trials Network (NCTN) Program. CTSU Core Support Services sections cover operational efficiency; National Clinical Trials Network (NCTN) Program and Multi-Center Organizations (MCOs) and selected trials of those organizations; project management; institutional and individual (person) roster support; regulatory support; protocol documentation/development support; IT support, maintenance, and development; disaster recovery; maintenance and enhancement of CTSU enterprise applications; system integration; system security; help desk; and other IT requirements. Current CTSU systems involved requiring support include the CTSU website; Regulatory Support System (RSS); Oncology Patient Enrollment Network (OPEN); and Clinical Data Management System (CDMS – Medidata Rave®). The specific sub-set of specialized CTSU Core Support Services, primarily for the NCTN, include NCTN compliance tracking and standards development and utilization; NCTN budget tracking;

CTSU awareness, education, and training; site auditing; and site data reporting performance tracking.

Reporting Requirements and Deliverables

The Contractor shall submit the following reports:

- Task Order Project Plan
- Monthly Task Order Progress Report
- Monthly Task Order Expense Report
- Annual Task Order Progress Report
- Draft Final Task Order Report
- Final Task Order Report
- Initial Transition Plan
- Final Transition Plan

Type of Task Order

Cost Reimbursement

Period of Performance of Task Order

September 1, 2013 to August 31, 2020

Technical Proposal Instructions

Technical Proposal should be 100 pages in length. See Business Proposal Instructions below for Technical Proposal COVER SHEET instructions.

A detailed work plan must be submitted indicating how each aspect of the Statement of Work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the task order being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided, which will demonstrate your understanding and management of this tasks.

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program

Resumes of all personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications. If an individual's resume was submitted with your original technical proposal, you do not need to include it again here. Only include resumes of individuals where one was not previously provided. Resumes do not count towards the page limit specified above.

Business Proposal Instructions

For Business Proposal COVER SHEET submit the following

- Solicitation or contract number
- Task Order Number
- Name and telephone number of point of contact
- Name, address, and telephone number of contract Administration Office, (if available)
- Date of submission
- Name, title and signature of authorized representative

Budget:

- Provide a breakdown of Proposed cost and/or price (Excel sheet); profit or fee (as applicable); and total.
- Please provide a budget yearly starting September 1, 2013 through August 31, 2020.
- Assume the following:
 - Together the NCTN and MCO, across their entire portfolio (treatment, prevention, cancer control, etc.) activate approximately 110 to 150 new trials per year, including approximately 30 phase III trials. At any given time, these organizations will have approximately 900 to 1,000 open trials. Approximately 10,000 investigators, from 2,000 institutions, participate in these multi-center programs. Annual trial accrual ranges from 25,000 to 40,000 patients per year.
 - Please note that Task Area II is divided into 4 major sections. Some services are for all NCTN/MCO organizations and some are just for the NCTN. Budget estimates shall reflect that.
 - *Tailoring CTSU Systems, Policies, and Procedures to Accommodate Expanded CTSU Portfolio*
 - The majority of these activities shall be completed within the first 6 to 18 months of the contract.
 - *Operational Efficiency*
 - Expressed or demonstrated logical cost-savings is expected.
 - *CTSU NCTN/MCO Working Groups*
 - Travel logistics for face-to-face meetings - The NCI anticipates approximately two face-to-face meetings a year during the first two years. Then years 3 -7 assume, one face to face meeting per year.

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Assume 6 travelers and assume the destination to be Rockville, MD for a two day meeting.

- *Special NCTN/MCO collaborations*
 - Plan for up to four Special NCTN/MCO collaborations per year
- *Disaster Recovery*
 - The secondary facility must be geographically separated from the primary facility, for all back-up data.
- *Clinical Data Management System (CDMS –Rave®) Support*
 - Rave® license, hosting, and maintenance will be provided by the NCI.
- *Help Desk*
 - For reference the current hours of operation are 9:00 AM to 8:30 PM ET.
- *Support for Continuance and Completion of Active Trials/Study Activities*
 - Assume 50% of Continuation activities will be complete at the end of contract year 1.
 - Assume 90% of Continuation activities complete at the end of contract year 2.
- *Flex Basic Services*
 - Assume Flex Basic Services will be provided for 30 trials.
- *Flex Complete Services*
 - Assume Flex Complete Services will be provided for 6 trials.
- *Site Auditing for Endorsement Program*
 - Anticipate that 2 qualified auditors to supplement NCTN coordinator-led audits will be required per month at the start of the contract for the first 18 months.
- *Increased Capacity for Section A-D*
 - **Please note that this should be priced out separately, this should be on a separate line item.**
 - Assume the additional workload will be approximately 25% of Section A -D