

OFFICE OF ACQUISITIONS  
NATIONAL CANCER INSTITUTE

REQUEST FOR PROPOSAL NUMBER: N02CN35003-43

Amendment No.: 4

Date of Issuance: 10/01/2013

The above numbered Request For Proposal (RFP) is amended as set forth below. The date specified for receipt of Offerors is changed to: 10/15/2013.

Offerors MUST acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by separate letter, telegram, or Electronic Mail which includes a reference to the RFP and Amendment number(s). For your convenience, the Proposal Intent Response Form is provided in SECTION J - List of Attachments of this RFP, for this purpose.

FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERORS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER.

**No additional questions will be accepted under this RFP.**

This Amendment revises the RFP as stated below:

1. Under Section L.1.b. - "Technical Proposal Instructions" - offerors are referred to Attachments No. 8, 4, and 3. However, Attachment No. 13 - "Additional Business Proposal Instructions - Sample Task Order" - contains uniform assumptions, particularly for Task Area 1 where information such as the status of clinical trials under Consortia 2003 and Consortia 2012 are described. We assume that offerors should also consider and address this information in the sample task order technical response (as well as the cost proposal). Please confirm.

**Answer:** Per Attachment 13: Additional Business Proposal Instructions, offerors are advised to carefully consider all materials provided as part of the RFP in the development of their proposal.

2. In Attachments 3 (overall IDIQ SOW) and 4 (Sample Task Order SOW), Task Area 2 is designated as "Auditing and Data Verification." However, some of the terms in the SOW for Task Area 2, Sections A and B, sound like typical monitoring tasks (initiation visits, interim visits, close out visits). Also, some of the deliverables seem to indicate that monitoring is required - for example, Deliverable # 25 (RFP pg. 13), which is "Initiation Visit Report." Additionally, the 2003 Consortia SOPs reference monitoring by a DCP Monitoring contractor, but the 2012 Consortia SOPs do not. Please clarify, are these monitoring-type visits only for the 2003 Consortia (or non-Consortia sites) and not the 2012 Consortia?

**Answer:** Per Attachment 3: Statement of Work and Attachment 4: Sample Task Order Statement of Work, the scope of the studies to be audited includes, but may not be limited to, studies funded under the 2003 and 2012 consortia mechanisms.

3. Please confirm that the term "DCP-contracted clinical trial site" in Task Area 2, A.2 refers only to the CLOs and not the POs as

well. In other words is a PO considered a DCP-contracted clinical trial site?

**Answer:** The term "DCP-contracted clinical trial site" in Task Area 2, A.2 refers only to the Consortia Lead Organizations (CLOs). Please see definitions for Consortia Lead Organization and Participating Organization in Attachment 21: Information to Offerors, List of Definitions and Acronyms.

4. Task Area 2, A.2.3 refers to "audit visits" conducted by the CLO, but according to Consortia 2012 SOP #9, and Consortia 2003, SOP #5, Monitoring is conducted by the CLO, not Audits. Please clarify.

**Answer:** The reference to "audit visits" in Task Area 2, A.2.3 in Attachment 3: Statement of Work (SOW) and Attachment 4: Sample Task Order Statement of Work is an error. This requirement should read as follows: "Ensure adherence of each Consortia Lead Organization (CLO) to the appropriate DCP Consortia Standard Operating Procedures (SOPs), and ensure that all monitoring visits by the CLO are conducted uniformly and consistently across sites."

The SOW will be updated to include this change at the time of award.

5. In Attachment 3 - under Scope: Auditing and Data Verification (pg. 1 of 10), the language says "The scope includes, but is not limited to, studies funded under the 2003 and 2012 consortia mechanisms". Also, in Attachment 4 - under Task Area 2, C.4 (page 9 of 11, at top), language says "Audit each CLO or clinical site at least once a year or as determined by the COR... (italics added for emphasis). Please clarify: does the "not limited to" language in Attachment 3 encompass the clinical sites that may be audited as noted in Attachment 4? Also: when would the audits apply to a site - for example, when a site does not have a CLO?

**Answer:** The scope of the studies to be audited, specified in Attachment 3: Statement of Work and Attachment 4: Sample Task Order Statement of Work, is inclusive of Phase 0-II and selected Phase III cancer prevention clinical trials for which the Division of Cancer Prevention is the study sponsor, Investigational New Drug (IND) sponsor and/or the agent supplier. This encompasses the clinical sites that may be audited as specified in Task Area 2, C.4 in both Attachments 3 and 4.

Individual clinical sites participating in a clinical trial, either through the DCP Consortia or other funding mechanism (e.g. NCI grant), may be audited as requested by the DCP.

6. The SOW for the Sample Task (Attachment 4) is identical to the SOW for the overall IDIQ portion (Attachment 3). Please clarify: can the written response for the sample task (which is page limited) refer to sections addressing the overall IDIQ requirements (e.g. for task order management)?

**Answer:** A separate and complete response is required for the Sample Task Order. This response must include a technical proposal that addresses the requirements of Attachment 4 and a budget proposal that addresses the requirements of Attachment No. 13 for the period of the Sample Task Order, and must be within the page limit specified in the RFP. The CVs of the proposed personnel for the Sample Task Order may be submitted as an attachment to the Sample Task Order.

Technical and/or Business Proposal attachments specified in the RFP may be referenced in the Sample Task Order.

7. Has the incumbent made customizations to their Oracle Clinical RDC system that would prevent a successful standard RDC to RDC study migration, and therefore would require a similar customization of the new contractor's system before study migration?

**Answer:** The incumbent has made customizations to Oracle Clinical RDC to support the current DCP project. The successful offeror will be provided with source code for the project including data definitions, view definitions and value lists that can be used to reconstruct the DCP database.

8. How has the incumbent implemented CTC AE coding in their Oracle Clinical RDC system? Has the incumbent customized the system in any way to allow the site users to select of CTC AE terms?

**Answer:** This information will be provided to the successful offeror.

9. At least one of the ongoing trials is randomized and multicenter. Has the incumbent implemented a central randomization process for any ongoing trial? If yes, please provide details to allow us to transfer this functionality without disruptions or user re-training.

**Answer:** The randomization process for any trial is the responsibility of the Consortia Lead Organization or the clinical site conducting the trial. The incumbent has no responsibility for the implementation of a central randomization process.

10. Are the current Oracle Clinical RDC servers owned by the Government? If so, will they be transferred to the new contractor?

**Answer:** The current Oracle Clinical RDC servers are not owned or maintained by the government. It is the responsibility of the successful offeror to host an instance of OC RDC for the DCP project.

11. The RFP references the DCP Enterprise System Knowledgebase (DESK) (e.g., @ Attachment 21, pg. 1 of 7). Will NCI consider providing the DESK User Guide to prospective offerors (as an amendment), so as to ensure that non-incumbents have sufficient knowledge of the system parameters upon which to base their proposals?

**Answer:** The successful offeror will be provided with the information and materials regarding DESK that are needed to ensure contract requirements are met.

12. Under Task Area 3 (of both the IDIQ and Sample Task SOWs) - Item #2 calls for the contractor to "provide... educational materials" which "include, but are not limited to, the HelpDesk, Remote Data Capture (OC-RDC) training as required, Recruitment and Retention guidelines, and DCP Consortia SOPs." Regarding the "guidelines": - are these guidelines for others to develop the materials, or are the materials themselves required as part of this SOW?

**Answer:** The successful offeror will develop and/or maintain guidelines for the implementation of selected processes in DCP's clinical trials program as well as templates to guide the development of materials by the Consortia organizations and other clinical sites participating in this program.

13. Also under Task Area 3 - Item 4.1 states "maintain and/or update the content of the existing DCP consortia clinical trials webpage in collaboration with DCP staff and DCP's regulatory and IT support contractors." Please clarify: is the contractor for this RFP expected to perform maintenance/updates, or provide recommendations for these tasks to be performed by other entities?

**Answer:** The successful offeror will review the DCP consortia clinical trials webpage and make suggestions for updates to its content and/or format. The successful offeror also will develop materials for posting to the webpage as requested by DCP. The maintenance and updates to the webpage, including the posting of materials developed by the successful offeror, will be performed by others.

14. Also under Task Area 3 - Item 5 states "provide support at the annual DCP Site Coordinators' Meeting which may include, but not be limited to, a poster session, roundtable discussions, and podium presentation." Please clarify: is the contractor expected to facilitate and provide logistical support at this meeting, or be a subject-matter participant? For example, would site selection/room rental, speaker travel reimbursements, and other logistical tasks be needed? (While we realize these items are not specified in the uniform cost assumptions for the Sample Task (Att. 13), further clarity on the extent and scope is needed for the response for the overall IDIQ proposal.)

**Answer:** The successful offeror will serve as a subject-matter participant at the DCP Site Coordinators' Meeting. Logistical support will be provided by others.

15. Attachment 1 (Packaging and Delivery) (as Amended per Amendment No. 1): On pg. 3, under Sample Task Order: it specifies the costs "for each Task Area." We presume this means the Excel workbook cost breakdown into Task Areas 1, 2 and 3, as well as Transition Costs (as specified in Attachments 3 and 4). Please clarify/confirm: should Transition Costs be included as part of the costs for the three Task Areas 1, 2, and 3, OR should they be proposed as a separate segment of the sample task costs (e.g., cost breakdown into 4 sections: Transition, Task Areas 1, 2, and 3)?

**Answer:** Offerors should propose the transition costs as a separate segment of the sample task order business proposal budget. However, a summary budget page should be provided to include both the transition costs and task areas 1, 2, and 3.

16. The Statement of Work, Task Area 2.C, paragraphs 4.2 and 4.6, seem contradictory. Paragraph 4.2 asks for verification of 25% of the participants' data, while paragraph 4.6 asks for 100%. Could you please clarify which is the DCP's required % of data verification?

**Answer:** DCP's requirement for audit and data verification is specified in Task Area 2C, 4.2 in Attachment 3: Statement of Work and Attachment 4: Sample Task Order Statement of Work. However, DCP may request an eligibility assessment and endpoint and/or response assessment for 100% of all participants as required. The SOW will be updated to include this change at the time of award.

17. Can NCI provide current 508 compliance waivers that are available under the current contract?

**Answer:** Section 508 is applicable to this RFP and no waivers will be provided.