RFP-NIH-NIAID-DAIT-04-44
Amendment #2 (Questions & Answers)

This Amendment provides questions submitted by potential applicants/offerors and the responses provided by the NIAID. The responses are offered for information only and do not modify or become part of this solicitation. This Amendment will be updated at least weekly to add any further questions and their related responses. All potential offerors are advised to refer back to this Amendment #2 for additional Q&A.

"REGULATORY MANAGEMENT CENTER - DAIT"

Amendment No.:	2 (1st Posting)
Amendment Issue Date:	January 21, 2004 (Questions 1-11)
Proposal Due Date/Time:	February 17, 2004, at 3:00 PM., EST
Issued By:	Barbara A. Shadrick Senior Contracting Officer RRCB/CMP/DEA/NIAID/NIH/DHHS 6700-B Rockledge Drive, Room 2230, Bethesda, Maryland 20892-7612
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Applicants/Offerors must acknowledge receipt of this Amendment # 2, for each posting, on each copy of the proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your proposal.

The hour and date specified for receipt of proposals HAS NOT been extended.

The following answers are provided concerning some inquiries we have received for the above numbered acquisition.

Question 1. Will the contractor be responsible for receiving all SAE reports directly from sites? If so, what is the typical mechanism for such reports (fax, telephone, etc.)?

No, other contractors will be responsible for this activity. The Regulatory Management Center will only be responsible for receiving completed SAE forms from DAIT and sending to the FDA or other regulatory agencies.

Question 2. Will the contractor be responsible for assessing the causal relationship of SAEs to study medications? Or will a DAIT medical officer provide assessment?

No. This will be done by DAIT.

Question 3. Will the contractor be responsible for following up directly with sites to obtain any additional information that is needed to make an assessment or to prepare safety reports?

No, this will be done by other contractors.

Question 4. Approximately how many SAE reports should the contractor anticipate yearly?

100 – 200 reports, yearly.

Question 5. Is it anticipated that the majority of the SAEs will be from ITN studies as opposed to the other networks or groups? If so, what percentage for ITN versus others?

As stated in Task #2, the contractor will only be responsible for ITN studies.

Question 6. Does ITN, the networks/groups or consortium have a single standardized SAE reporting process currently in place, or are there currently different procedures in place? If different, is it expected that a single SOP for the reporting will be developed?

There is a single standard reporting system for DAIT trials

Question 7. To provide support for preparation, distribution, and tracking of Investigational New Drug Applications (IND), we will need to obtain electronic copies (if available) and paper copies of all current INDs and their amendments. Will the current contractor deliver these to a successor? Will the successor need to arrange for transfer of these documents? Can the government provide an estimate of the volume of material that will be provided (i.e., # of file cabinets and size/type of cabinet)?

The current contractor will deliver the IND documents and files to the successor. There are 6-10, 5-drawer lateral file cabinets at the current contractor's office

Question 8. Could the government indicate what computer software application(s) is being used by the current contractor for electronic tracking of IND Safety Reports and the Clinical Site Registration system?

The current contractor uses an Access database for electronic tracking of IND reports and Clinical Site Registration.

Question 9. Will the successful contractor be responsible for (1) actually writing and preparing the Safety Reports or (2) simply submitting the Safety Reports to the FDA and distributing them to pharmaceutical companies, etc.?

The new contractor will only be responsible for submitting safety reports to the FDA and the pharmaceutical companies.

Question 10. One of the deliverables is "Monthly updates that list the records added each month." Does this refer to all new records that are added to any tracking database tables each month?

Yes.

Question 11. Should our proposal include transitioning the current IT systems from the incumbent? If so, can you provide information about the current systems (such as platforms and programming languages, database schemas, and processing and system component diagrams) so that we can to prepare a cost estimate?

The current contractor uses an Access Database and will be responsible for delivering the electronic information in this format tot he new contractor.