

RFP-NIH-NIAID-DMID-08-06
Amendment No. 1 (Questions & Answers) – 4th Posting

This Amendment provides questions submitted by potential 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 may be updated to add any further questions and their related responses. **All potential offerors are advised to refer back to this Amendment for additional Q&A.**

“Phase I Clinical Trial Unit for Therapeutics Against Infectious Diseases”

Amendment No.:	1 (4th Posting)
Amendment Issue Date:	March 23, 2007 (Questions 1 – 3) March 29, 2007 (Questions 4 – 7) April 25, 2007 (Questions 8 – 10) May 25, 2007 (Questions 11 – 15)
Proposal Due Date/Time:	July 2, 2006, at 3:00 P.M., EST (Unchanged)
Issued By:	Karen Gamble Contracting Officer Representative OA/DEA/NIAID/NIH/DHHS 6700-B Rockledge Drive, Room 3110 Bethesda, Maryland 20892-7612
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Offerors must acknowledge receipt of the final posting of Amendment #1, 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 PAGES PROVIDE ANSWERS CONCERNING INQUIRIES WE HAVE RECEIVED FOR THE ABOVE NUMBERED ACQUISITION:

Question 1 With respect to Attachment 7 “DMID-Funded Clinical Research Support Services Contracts,” please clarify the allowability of the Clinical Trials Management (CTM) Support contractor to submit a proposal to this RFP?

All qualified offerors will be considered. The NIAID has not identified any specific potential offerors for exclusion from the competitive process.

Question 2 With respect to Attachment 7 “DMID-Funded Clinical Research Support Services Contracts,” please clarify the role of the CTM Support contractor in this project?

The descriptions of the CTM contractor attached to the RFP are general and describe the activities performed under the CTM contract for all DMID sponsored clinical research. However, Attachment 3 “Statement of Work” of this RFP allows for independent monitoring teams (SOW Section 7, paragraph c) to be implemented by the contractor, as well as requiring the ability to perform independent auditing (SOW Section 10, paragraph b). Those functions will not be carried out by the CTM contractor and are to be performed by the successful offeror of this RFP. The CTM contractor will not play any role in the evaluation of the different offerors for this RFP, nor will it have access to proprietary information.

All protocols and associated documents to be carried out under this contract will be archived and stored at the CTM general protocol repository for DMID. All information stored at the CTM contractor is protected under the confidentiality clauses included in the CTM contract.

Question 3 What are the maximum number of trials per year which are likely to be conducted?

As provided in RFP Attachment 6 “Additional Business Proposal Instructions,” offerors should assume the initiation of 4 protocols per each year of the contract. All offerors are expected to be able to perform at least 4 such studies per year. Due to the uncertainties inherent in Research and Development contracting, the Government is unable to establish the precise number of trials per year, but recognizes that capacity and resultant contract budgets will be based upon the above mentioned assumption.

Question 4 Is Joint Commission on Accreditation of Healthcare Organizations (JCAHO) certification a requirement?

As stated in RFP Attachment 3 “Statement of Work” (SOW), Technical Requirements, Section 1, paragraph a., “These inpatient clinical research facilities shall meet the requirements of the Joint Commission on Accreditation of Healthcare Organizations.” An actual accreditation is not required by the SOW, but offerors must demonstrate that the proposed facilities are able to meet the requirements outlined by JCAHO. The offeror’s technical proposal, inclusive of proposed facilities, will be evaluated in accordance with the Technical Evaluation Criteria listed in Section M of the RFP.

Question 5 Can the standard clinical support services for inpatient care, 24 hours/day, 7 days/week be contracted out such that they are not on site?

The RFP requires that offerors be able to provide the standard clinical support services for inpatient care as described in SOW, Technical Requirements, Section 1, paragraph a., subparagraph 2. The decision as to how best provide the required services is at the offeror’s discretion and will be evaluated in accordance with the Technical Evaluation Criteria listed in Section M of the RFP.

Question 6 Must the Clinical Laboratory Improvement Amendment (CLIA) certified laboratory be onsite or can this be contracted out with a 12-16 hour turnover time for routine labs?

The RFP requires that offerors be able to provide clinical laboratory facilities for the trials to be conducted at both the Contractor's and affiliated sites as described in SOW, Technical Requirements, Section 1, paragraph c. The decision as to how best provide the required services is at the offeror's discretion and will be evaluated in accordance with the Technical Evaluation Criteria listed in Section M of the RFP.

Question 7 Can a research pharmacy be a room to control and dispense drugs with a pharmacist as part of the research facility (which is allowed in many states) rather than a licensed pharmacy?

As stated in the RFP SOW, Technical Requirements, Section 1, paragraph e., the contractor will be required to provide, "research pharmacy facilities and resources for the management of investigational products, according to protocol-specific requirements, to service inpatient and outpatient clinical trials conducted at the Contractor's site and at all affiliated clinical sites." It is left to the offeror's discretion as to how best define and propose implementation of the requirements of a research pharmacy, as described in the SOW, in a manner that satisfies all required laws and regulations.

Question 8 Who is the IND holder?

The IND will be held by DMID, NIAID.

Question 9 Will the contractor be responsible for producing investigational brochures?

No, the investigational brochures will be provided by the manufacturer.

Question 10 Will NIAID be providing any direction on the protocol development?

The protocol development is a collaborative team effort as described in the RFP SOW, Technical Requirements, Section 5, paragraph b., subparagraph 2) [Protocol Team](#).

Question 11 Is there an estimate of the number of different sponsors participating in this contract?

NIAID, DMID is expected to be the sponsor of the majority of the trials. There is an option that the manufacturer will be the IND sponsor in selected cases. Although unknown at this time, assume that each of the four different trials to be performed per year will be done in collaboration with a different manufacturer.

Question 12 Can one anticipate that all the therapeutics for this contract will be applied in "first in man" studies? If not, what can the contractor expect in respect to the mix and phase of studies anticipated?

Assume all trials will be first in man. In certain circumstances pK/pD data will be needed in a therapeutic that already had preliminary safety evaluation in humans.

Question 13 What is the anticipated percentage of subjects that will be involved in pK/pD assessment of therapeutics?

Assume all trials will have pK/pD component.

Question 14 Is it expected that data management be conducted by means of electronic data capture at the level of the site? Can other systems or processes be considered should they meet the 72 hour turn around time for data captured?

Electronic data capture at the site level is expected. However it is up to the offeror to decide on implementation method and/or suggest other equivalent methods.

Question 15 Is it expected that the contractor hold and maintain the pharmacovigilance (PVG) Serious Adverse Event (SAE) database?

Safety information should be captured as part of the clinical database. The PVG database is maintained by the Clinical Trials Management (CTM) contractor (see Attachment 3, SOW, Technical Requirements, Section 11, paragraph c., and Attachment 7). There will be double reporting of SAEs to the clinical database and the PVG database.