RFP-NIH-NIAID-DAIT-04-08
Amendment #1 (Questions & Answers)

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 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 #1 for additional Q&A.

"Atopic Dermatitis and Vaccinia Immunization Network: Statistical and Data Coordinating Center"

Amendment to Solicitation No.:	NIH-NIAID-DAIT-04-08
Amendment No.:	One (1) 1st Posting: Questions 1-12 (posted 7/14/2003)
Amendment Date:	July 14, 2003
RFP Issue Date	April 18, 2003
Proposal Due Date/Time:	July 28, 2003; at 4:00 P.M., EST
Issued By:	Barbara A. Shadrick Contracting Officer CMB/DEA/NIAID/NIH/DHHS 6700-B Rockledge Drive, Room 2230, Bethesda, Maryland 20892-7612
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Offerors must acknowledge receipt of this Amendment #1, 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 questions and answers are provided concerning a number of inquiries we have received for the above numbered acquisition:

Question 1 In reviewing RFP NIH-NIAID-DAIT-04-08 and RFP NIH-NIAID-DAIT-04-06, neither the Statistics and Data Coordinating Center (SDCC) nor the Clinical Studies Consortium contractor (CSC) appear to have responsibility for distribution and tracking of clinical trial material for studies conducted under an IND, particularly those for which the NIH holds the IND. Does one of these entities have responsibility for this activity for ADVN, or does NIH intend for it to be supported by a mechanism outside these two contracts ?

The distribution of clinical trial material (e.g., viruses of other materials for testing human immune responses) is expected to be provided by Industry directly to the Clinical Studies Consortium. The SDCC will not be responsible for this. As indicated in Statement of Work paragraph 7.b.3, the SDCC will be responsible for tracking material.

Question 2 The RFP for the CSC does not address support of INDs. As such, we are interpreting that the responsibility for the technical content of the RFP, particularly for sections such as the Previous Human Experience Section, the Pharm/Tox section, and the Chemistry and Manufacturing Controls section rests with the SDCC. Is that interpretation correct ?

The interpretation is correct. As described in Statement of Work paragraph 7.c, the SDCC has a set of responsibilities for preparing, distributing and tracking INDs

Question 3 The RFP for the CSC discusses a specimen repository, but this function is not addressed in the SDCC RFP. Consequently, we presume that all functions related to tracking and distribution lie solely with the CSC and that the SDCC will have no responsibility for supporting these functions. Is that interpretation correct ?

The interpretation is correct. The specimen repository is the responsibility of the Clinical Studies Consortium and not the SDCC.

Question 4 The RFP requires resumes of key personnel. Given the page limitations, are biosketches or other shorter resumes rather than full Curriculum Vitae acceptable?

2-page biosketches are preferred but it is up to the contractor to make sure these biosketches or other shorter resumes fit in your proposal and still stay within the page limit stated in the RFP.

Question 5 The RFP indicates that the SDCC is responsible for maintenance of the patient registry but that the CSC is responsible for recruitment. We have several questions about the division of responsibilities and about the structure of the registry. First, what is the primary role of the registry? Is it primarily for the collection of specimens for mechanistic studies, or is it primarily a recruitment pool for the clinical studies, or some combination of the two? Second, will pediatric patients be included in the registry? Finally, are the clinical sites primarily responsible for obtaining consent for the registry participants, or is that the responsibility of the SDCC?

The primary role of the patient registry is a recruitment pool for the clinical studies. Pediatric patients are likely to be included in the registry. The clinical sites are primarily responsible for obtaining consent, not the SDCC.

Question 6 The CSC RFP indicates that the SDCC is responsible for purchasing computers for each of the clinical sites, but that issue is not addressed in the SDCC RFP. Is the SDCC to provide data collection computers for each of the clinical sites, and if so, should we assume a total of seven sites per the maximum in the CSC RFP? Similarly, the Animal Studies RFP indicates that the SDCC will be responsible for providing computers to the animal study sites? Will these computers have the same potential regulatory issues as those for the CSC sites (maintaining compliance with 21CFR11), and again, should we assume a total of six sites?

The RFP 04-08 inadvertently omitted that the SDCC needs to purchase computers. For cost estimating, assume that 7 sites will be the maximum (and 5 an average estimate) for the Clinical Studies Consortium, and 6 sites will be the maximum (and 4 sites an average estimate) for the Animal Studies Consortium. We do not anticipate any potential regulatory issues with Animal Studies. It is extremely unlikely that any of the animal studies data will be considered to be preclinical studies for an IND.

Question 7 Our experience suggests that many sites now require translation of Consent materials into Spanish. Are such translations the responsibility of the SDCC or are they the responsibility of each clinical site or the CSC?

The SDCC will have the responsibility of translating the Consent materials into Spanish.

Question 8 The Notes section has an inconsistency related to travel for the Executive Committee and the Sub Committees. It suggests that the meetings will be held at the same time, but the Subcommittee meetings are alternated between Bethesda and Chicago while the Executive Committee Meetings are all held in Bethesda. Are the meetings only held concurrently every other year, or should the Executive Committee meetings also alternate? Also, for budgeting purposes, should we assume that the meetings in Bethesda will be held at NIH facilities or should the costs include budgets for hotel meeting rooms?

The Notes to RFP 04-08 inadvertently omitted that the Subcommittees are expected to meet twice a year (not once a year). One of those meetings is, as described, with the Executive Committee in Bethesda. The other meeting, not with the executive committee, is expected to alternate between Bethesda and Chicago.

Question 9 The role of the SDCC in expedited reporting of SAEs to FDA for those protocols for which NIH holds the IND is somewhat vague. Is the SDCC responsible for providing a medical monitor and for handling all of the expedited reporting, or will that function be handled by NIH staff or through another contractual mechanism?

The SDCC will be responsible for providing a medical monitor and for handling all of the expedited reporting. NIAID is likely to provide a Medical Officer to work with the medical monitor. However, the medical monitor provided by the SDCC will have primary responsibility.

Question 10 The resources required for regulatory support on studies for which the NIH holds the IND is obviously a function of the number of sites in that study. For costing purposes, should we assume that all network sites will participate in all studies?

For cost estimating, assume that all Clinical Studies Consortium clinical sites will participate in all studies.

Question 11 For costing monitoring, we are assuming that all clinical sites will be domestic with no need to address international travel or regulatory issues. Is that assumption correct?

For cost estimating, assume that all clinical sites will be domestic.

Question 12 Are any of the animal studies expected to have regulatory status in that they will provide background support for an IND for a clinical study? If so, is the SDCC responsible for assuring that the animal study sites meet all regulatory requirements and for conducting monitoring relative to GLP?

It is possible that the Animal Study sites will provide background support for an IND for a clinical study. However the animal study sites should not require SDCC input for regulatory issues and should not require monitoring.