Amendment #2
to RFP-NIH-NIAID-DMID-01-14
"DATA COORDINATING CENTER FOR CLINICAL AND EPIDEMIOLOGIC STUDIES IN INFECTIOUS DISEASES"

Amendment to Solicitation No.:	NIH-NIAID-DMID-01-14
Amendment No.:	2
Amendment Date:	September 7, 2000
RFP Issue Date:	July 1, 2000
Issued By:	Barbara A. Shadrick Senior Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Lois W. Eaton, Contract Specialist Direct Line - 301-496-0611 Main Office Line - 301-496-0612
Name and Address of Offeror:	To All Offerors

The above-referenced solicitation is hereby amended as follows to respond to questions presented by recipients of this RFP:

1. The RFP suggests that the DCC will be responsible for doing most of the data entry for the supported trials, but there is also technical assistance requested for data management, etc. at the clinical sites. Have these DMID-supported studies previously used distributed data entry? Do you have an estimate as to how many studies will use distributed data entry and how many will require central data entry? ***One of the VTEU sites has used distributed data entry for a multicenter study. We envision central data entry being the norm for multicenter studies.***

2. Centralized training is mentioned in three different Notes to Offerors. In Note 1 there is a brief mention that an annual working meeting might be a training meeting. In Note 5, it states that *study-specific* central training will happen annually in the DC area. In Note 10, it says to budget for one central training meeting per year. Can you clarify if these references are all to the same, single, annual central meeting, or whether several meetings are envisioned (e.g. one per active study)? ***Each of these Notes is discrete. The training mentioned in Note 1 refers to participation in DMID-provided training to all contractors.***

3. Can you identify the language(s) for which we are likely to need to provide translation services? Costs can vary widely depending on the language. ***We cannot provide language at this time. In the past we have needed translations from Italian and Swedish. Submit an estimate based on your assessment of the requirement. This can be negotiated.***

4. We presume that, as the DCC, we would be required, in addition to providing input on randomization *methods*, to operationalize the randomization process. That is, we would need to provide the treatment assignments as patients were enrolled. Is this assumption correct? ***The DCC will help design the randomization method and be responsible for implementing it. We have usually used coded envelope methods. We have not used call-in systems that randomize as you go.***

5. Will any of the 10 trials for which we would need to provide partial support (General Note #2) be actively observing patients at the time of contract start, or will these studies be closed to active participation by that time? ***We envision the current contractor completing analysis of trials they have started. Some studies may be actively enrolling at the contract transition.***

6. We would like to clarify that all three Phase III vaccine trials mentioned in this Note (#2c) actually have *20,000* subjects each. ***Correct.***

7. The RFP does not specify that the DCC will organize any DSMB meetings or pay for any DSMB travel. Is the assumption that the DCC will not be responsible for DSMB organization correct? ***DCC may organize meetings but will not pay for travel for DSMB members.***

- Except as provided herein, all terms and conditions of this RFP remain unchanged and in full force and effect.
- The hour and date specified for receipt of offers is NOT extended.
- Offerors must acknowledge receipt of this Amendment #2, on each copy of the submitted proposal.

Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.

Top | RFP-NIH-NIAID-DMID-01-14

NIAID Contracts Home | NIH RFP Directory | NIH Home