Questions/Answers
to RFP-NIH-NIAID-DMID-01-10

"Bacteriology & Mycology Biostatistical & Operations Unit (BAMBU)"

Solicitation No.:	NIH-NIAID-DMID-01-10
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Issued By:	Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Dawn Caracci, Contract Specialist
Name and Address of Offeror:	To All Offerors

The purpose of this Question/Answer posting is to provide answers to questions posed on the subject solicitation. Since these questions are for clarification purposes only and do not result in changes to the content of the solicitation, an amendment to the solicitation is not necessary. Offerors are reminded to refer to RFP NIH-NIAID-DMID-01-11, "The Bacteriology and Mycology Study Group (BAMSG)", as BAMBU will support clinical trials conducted by the BAMSG, and as some of these questions overlap both solicitations.

Offerors are encouraged to check back to this website periodically for any further question/answer updates.

Question #1

RFP NIH-NIAID-DMID-01-11 (Section 2.0 Orphan Studies) indicates that BAMSG will negotiate and secure funds for BAMBU. What are the expected responsibilities of BAMSG to negotiate on behalf of the BAMBU contractor? Will any additional funds from industry go to BAMBU through BAMSG as a subcontract?

Answer #1

If there are expenses for an Orphan Study that exceed the capacity of the Reserve Funds, BAMSG will be encouraged to seek outside support for that study which could come from industry, a foundation, or other Government agencies.

Question #2

For funds available from industry for clinical sites (e.g., when NIAID holds the IND), would the funds go through BAMBU after BAMSG completes the negotiations? Please clarify.

Answer #2

No

Question #3

In BAMSG Statement of Work 4.c., and BAMBU Statement of Work D.2., each group is asked to provide support associated with IND applications. This is confusing. Which group has the primary responsibility?

Answer #3

BAMBU

Question #4

There are multiple overlapping areas in which BAMSG and BAMBU are preparing documents (LORs, study documents) in collaboration. Will there be travel funds for BAMSG and BAMBU to have face to face working meetings?

Answer #4

No, unless face-to-face meetings would be critical. It is expected that this work could be accomplished by mail, telephone conversations and/or teleconferences. Use of travel funds to attend such meetings would require the prior approval of the Project Officer.

Question #5

Please clarify the intended role of BAMBU in organizing and interacting with the BAMSG Steering Committee. Statement of Work (BAMSG) 3.c. states that BAMSG will be organizing and supporting the functions of the Steering Committee but in 4.j., Statement of Work, has BAMSG and BAMBU collaborating in this effort. This is confusing.

Answer #5

BAMSG will provide the operational support for the BAMSG Steering Committee. BAMBU will collaborate in the development of policies for the committee.

Question #6

Statement of Work 4.k states that BAMSG will assist BAMBU in obtaining necessary regulatory documents from the BAMSG sites. There appears to be significant overlap in the BAMBU and BAMSG statements of work relating to interactions with sites. Please clarify which group will be interacting with sites to collect and verify regulatory documents.

Answer #6

BAMBU will have the lead for obtaining the necessary documentation from the BAMSG sites. BAMSG will be expected to engender the cooperation of the BAMSG sites in responding appropriately to these requests and requirements.

Question #7

After reviewing the BAMBU RFP, we see no comments or instructions related to the need for a specimen repository or drug distribution center. Who is responsible for the costs related to these activities? How will these functions be handled?

Answer #7

Regarding the specimen repository, this was not included in the RFP. If a BAMSG or Lyme disease study should need a specimen repository and BAMBU was determined to be the best site for it, the funds to

support that activity (purchasing of freezers, etc.) would have to come from the financial sponsor of the study (which could be and industry sponsor or the reserve funds for the orphan studies, for example.)

Regarding the distribution of study drugs, this will typically be done by the industry sponsor or through a DMID contract with McKesson Bioservices. The BAMBU offeror will not distribute drugs but will be expected to track study drug distribution and disposition per section D.8. of the SOW.

Question #8

How many of the protocols have completed development?

Answer #8

Protocols specified in Section G (see table) are ongoing. Contrary to what is in the RFP, MSG Studies #37 and #46 will not be transferred. No new protocols are anticipated before award of the contract.

Question #9

It is understood that the investigators provide input, but who actually writes the protocols?

Answer #9

BAMBU staff will "write" the protocols. See Section C (Operations and Support), #3-7.

Question #10

Have any of the clinical trials begun enrollment? If so, please identify the studies.

Answer #10

MSG #44 (high risk treatment trial and low risk observational study) and CSCLD seropositive and seronegative studies are ongoing. We anticipate that MSG #43 will begin enrollment this week. As of June 1, 2000, the number of subjects enrolled is as follows:

MSG #44 - high risk: 18 (out of 300); low risk: 68 (out of 200)

CSCLD seropositive - 73 (out of 194); CSCLD seronegative - 45 (out of 66)

Question #11

Is the database platform(s) (eg, Oracle, Access, etc) known?

Answer #11

The data are in Access Database.

Question #12

Is it possible to obtain copies of data collection documents used in any trials that are currently underway? If they are not available, is there an estimate of the number of pages of data expected to be collected for each study?

Answer #12

The files for the data collection documents are too large to make individual copies available (64,000 total pages of data) as follows:

MSG #43: 75 pages per patient X 24 patients (est.) = 1,800 pages
MSG #44 : HIGH RISK: 105 pages per patient X 300 patients = 31,500 pages
LOW RISK: 30 pages per patient X 200 patients = 6,000 pages
CSCLD Seropositive: 55 pages per patient X 194 patients = 10,670 pages
CSCLD Seronegative: 55 pages per patient X 66 patients = 3,630 pages
CSCLD Screening Data: 4 pages per screenee X 2,600 screenees = 10,400 pages

Question #13

According to "Note 14 to The Offeror" on Page 13 of the RFP, "there are approximately 40 different clinical sites currently participating in the MSG and CSCLD studies. The number of new sites that may need initial site visits will depend upon the studies to be designed" and "the Offeror should assume there will be ten (10) initial site visits per year". Does the phrase "new sites" refer to sites other than the approximately 40 that are currently active or does it refer to all sites that participate in a new study, whether or not the sites are currently active?

Answer #13

New sites refers to sites other than the approximately 40 that are currently active.

Question #14

Should it be assumed that every site which participates in a new trial will require an initial site visit when that trial starts, even if the site has recently had an initial site visit for another trial?

Answer #14

No. Every new site added to the study group will have an initial site visit but not every site involved in a new clinical trial will have a site visit.

Question #15

The assumption of 10 initial site visits per year implies a total of 50 initial site visits over the course of the contract. According to "Note 2 to Offeror", "the Offeror should assume that approximately 12 studies will be initiated during the contract period." If all sites that participate in a new study receive an initial site visit for that study, then, on average, four sites will participate in each new study. This seems low, given that approximately 8 of the new studies will be Phase III trials and the Phase III trials in the table on page 16 of the RFP include an average of 14 sites each. Please clarify.

Answer #15

Not all sites that participate in a new study will have an initial site visit. See response above.

Question #16

The acronym CTBM is used in the RFP without definition. Could you please define the acronym and explain its relationship to BAMSG, CSCLD, MSG, etc.

Answer #16

CTBM=Clinical Trials in Bacteriology and Mycology. This acronym applies to clinical trials supported by research contracts from the Bacterology and Mycology Branch, DMID, NIAID.

Question #17

Do you have an estimated timeframe for the initiation of new studies after the start of the BAMBU contract? This impacts the timeframe for the development of the computerized data management system.

Answer #17

It is difficult to predict but we would guess no less than 6 months and maybe at least a year.

Question #18

Will studies that have already begun collecting data prior to the initiation of the BAMBU contract continue to use their software, or transfer to the new system?

Answer #18

It will depend on how dissimilar the systems are.

Question #19

Is there a possibility of a new study being initiated shortly after new contract is begun, before the completion of a functional data management system?

Answer #19

It is doubtful.

Question #20

There is no mention of NDAs in the RFP. Is writing and compiling NDAs likely to be a BAMBU responsibility?

Answer #20

No.

Question #21

The BAMBU RFP doesn't explicitly say that the BAMBU will be responsible for data entry. It states the BAMBU will collect the data from study sites, and then verify, process, monitor, correct, update, file, and store the data. The BAMSG RFP suggests that clinical sites are responsible for "completion and submission of case report forms." Do you anticipate that most or all of the studies will require centralized data entry performed by the BAMBU? Or is distributed data entry system envisioned? Or should we plan for a mixture?

Answer #21

In the past, data entry has typically been centralized; innovation would be welcome in future studies.

Except as provided herein, all terms and conditions of the RFP document NIH-NIAID-DMID-01-10 remain unchanged and in full force and effect.

*The hour and date specified for receipt of offers is **NOT** extended.*