AMENDMENT OF NIAID SOLICITATION
"Management of Information Resources on Therapeutic Agents for HIV and Opportunistic Infections"

Solicitation Number:	RFP-NIH-NIAID-DAIDS-07-27
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Issued By:	Eileen Webster-Cissel Contracting Officer NIAID, NIH, DHHS Office of Acquisitions, DEA 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Eileen Webster-Cissel, Contracting Officer E-mail: webstere@niaid.nih.gov

This amendment is being issued in order to take corrective action resulting from a protest submitted in response to this solicitation. The amendment provides answers to additional questions regarding the RFP and extends the due date for proposals (see above).

Offerors who submitted proposals previously should review the amendment and determine if revisions to their proposals are needed. If revisions are to be submitted, they must be received by the due date and time specified above. If no revisions to a previously submitted proposal will be made, Offerors must indicate this in writing to the Contracting Officer by the due date and time specified above.

Offerors must acknowledge receipt of this Amendment No. 3 by identifying this amendment number and date of the amendment on each copy of the offer submitted. Failure to receive your acknowledgement may result in the rejection of your offer. Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full force and effect.

Questions and Answers (numbering continued from Amendment No. 2)

66. RFP Evaluation Criterion 1 states that the Principal Investigator should have a doctoral degree in medicinal chemistry/biology. Can the NIAID make this requirement less restrictive?

Yes. As a result, the following sections of the RFP are revised to reflect changes:

- PART I, THE SCHEDULE, SECTION C, DESCRIPTION/SPECIFICATIONS/WORK STATEMENT, ARTICLE C.1., ATTACHMENT 4, STATEMENT OF WORK
- PART III, SECTION J – ATTACHMENT 6, APPENDIX A - ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS AND FORMAT FOR TECHNICAL PROPOSAL TABLE OF CONTENTS
- PART IV, SECTION M – EVALUATION FACTORS FOR AWARD

PART I, THE SCHEDULE, SECTION C, DESCRIPTIN/SPECIFICATIONS/WORK STATEMENT, ARTICLE C.1., Attachment 4, Statement of Work, is hereby revised to delete paragraph 8, SCIENTIFIC AND TECHNICAL PERSONNEL, and to renumber the remaining paragraphs accordingly. A revised Attachment 4, Statement of Work is included with this Amendment.

PART III, LIST OF DOCUMENTS, ATTACHMENTS AND OTHER EXHIBITS, SECTION J, ATTACHMENT 6, APPENDIX A – ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS AND FORMAT FOR TECHNICAL PROPOSAL TABLE OF CONTENTS, SECTION 2, SCIENTIFIC AND PROFESSIONAL PERSONNEL, is hereby revised to read as follows. A copy of the revised Attachment 6, Appendix A, Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents, is attached to this Amendment.

SECION 2 - SCIENTIFIC AND PROFESSIONAL PERSONNEL

1. **Principal Investigator**: Describe the experience, training, expertise, qualifications, and percentage of effort of the Principal Investigator proposed to lead and direct the activities to be carried out under this contract. The Principal Investigator should have education and experience commensurate with his/her expected role including experience and training in one or more of the following: medicinal chemistry/biology, microbiology or virology. In addition, the Principal Investigator should have documented expertise in the computer science aspects of database software/hardware similar to that used under this contract. Describe this individual's capacity to monitor progress, assess performance, identify performance problems and implement corrective actions. Describe experience in leading and directing projects of comparable content and complexity and familiarity with past and current microbiological research in the areas of HIV and opportunistic infections (OI), antivirals, and other antimicrobials.

2. **Key Scientific and Professional Personnel**: Describe the experience, training, expertise and qualifications, as well as percentage of effort, for all proposed key scientific and professional personnel, including subcontractors and consultants. This includes scientific and technical expertise and knowledge and familiarity in: past and current microbiological research in the area of HIV and OI, antivirals, and other antimicrobials, in vitro assays and animal models for testing antimicrobial efficacy; conducting on-line literature searches in appropriate chemical and biological databases; qualifications to serve as a resource to NIAID Division of AIDS for advice on the computer science requirements of the contract; and expertise in relational databases and preparation/formatting of text and graphic data for Web site inclusion.

3. **Data Entry and IT Personnel**: Describe the experience, training, expertise, qualifications, and percentage of effort, for all proposed data entry and IT personnel, including subcontractors and consultants. This includes scientific and technical expertise and knowledge in: chemical structures and data entry, quality control and database management. Describe previous experience in preparation of text and graphic data in html and gif format for Web site inclusion and with the use and maintenance of ORACLE and MDL software or similar software for database management.

SECTION J – LIST OF ATTACHMENTS - Is revised to include Attachment 13 and updated Attachments 4 and 6 that include revisions as a result of Amendments 1, 2 and 3:

Attachment No.	Title	Location
Attachment 4	Statement of Work dated 7/6/2007	End of Amendment 3
Attachment 6	Appendix A – Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents dated 7/6/2007	End of Amendment 3
Attachment 13	Representative File of a Table with Data Field Types and Definitions	End of Amendment 3

PART IV, REPRESENTATIONS AND INSTRUCTIONS, SECTION M, EVALUATION FACTORS FOR AWARD, paragraph 3, Technical Evaluation Criteria, Criterion 1, subparagraphs a, b, and c are amended to make the criteria for the Principal Investigator and other staff less restrictive.

SECTION M is hereby revised to read as follows:

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against three factors. The factors, in order of importance are: technical, cost/price, and past performance. Although technical factors are of paramount consideration in the award of the contract, cost/price, and past performance are also important to the overall contract award decision. All evaluation factors, other than cost/price, when combined, are significantly more important than cost or price. In any event, the Government reserves the right to make an award to that Offeror whose proposal provides the best overall value to the Government. The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy. If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range, you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

3. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the Technical Evaluation Committee when reviewing Technical Proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria listed below are in the order of relative importance with weights assigned for evaluation purposes. Sub-criteria are listed in order of descending importance. Offerors and reviewers are advised to refer to Appendix A – Additional Technical Proposal Instructions of this solicitation package for guidance and information related to the preparation and format of Technical Proposals.

CRITERIA	WEIGHT
CRITERION 1: SCIENTIFIC AND PROFESSIONAL PERSONNEL	**40 points**

a. Principal Investigator

Adequacy and suitability of the documented training expertise, education, training and availability of the Principal Investigator for planning, managing and directing the proposed activities in the Statement of Work including experience in administering a project of comparable content and complexity; experience and training in one or more of the following: medicinal chemistry/biology, microbiology or virology; and familiarity with past and current research in the areas of HIV and opportunistic infections (OI), antivirals, antimicrobials, and microbiology. Documented knowledge and expertise in

the computer science aspects of the database software/hardware similar to that used under this contract.

b. Key Scientific and Professional Staff

Adequacy and suitability of key scientific and professional staff (including consultants and subcontractors) with respect to their demonstrated qualifications, availability, experience, education and training in the following areas: familiarity with past and current microbiological research in the area of HIV and OI, antivirals, and other antimicrobials, in vitro assays and animal models for testing antimicrobial efficacy; experience in conducting on-line literature searches in appropriate databases. Capability to function as a resource to the NIAID Division of AIDS for advice on the computer science aspects of the contract. Expertise in relational databases and preparation/ formatting of text and graphic data for Web site inclusion. Knowledge and experience with the database software and hardware to be utilized under this contract or similar software.

c. Data Entry and IT Personnel

Adequacy, availability and suitability of training, qualifications and experience of data entry and IT personnel, including consultants and subcontractors, with respect to chemical structures and data entry; quality control; preparation of text and graphic data in html and gif format for Web site inclusion; database management, and use and maintenance of hardware and software to be utilized under this contract such as Molecular Design Limited (MDL) and Oracle or similar software.

CRITERION 2: TECHNICAL APPROACH **40 points**

a. Adequacy and feasibility of the technical approaches and proposed plans to survey the literature and select citations that contain chemical and biological information on experimental therapies for HIV and OIs; to identify and abstract relevant chemical and biological information; to determine the validity and authenticity of the data; and to update the chemical and biological databases, the literature citation database, and the publicly available Web database with the corresponding information.

b. Adequacy and appropriateness of the proposed data management procedures for updating and maintenance of the databases, quality control, disaster recovery, software development and maintenance, and security and confidentiality of the data; adequacy of the approaches for overcoming potential problems in the administration of a reliable, efficient, fully operational and responsive data management system.

c. Adequacy and feasibility of the technical approach for performing substructure and full structure preclinical information searches; adequacy and soundness of the approach and rationale for selecting the most promising chemical structures for the four sample search requests provided.

CRITERION 3: PROJECT MANAGEMENT **10 points**

a. Adequacy and appropriateness of the proposed overall project organization and staffing; and plans and procedures for the close monitoring, tracking, coordination and management of all contract activities, including interacting and communicating with the Project Officer and Contracting Officer to ensure the

efficient planning, initiation, implementation, monitoring and management of all projects carried out under the contract.

b. Appropriateness and feasibility of the plans for the prioritization of projects and procedures for the implementation and timely completion of projects; previous experience with the timely completion of comparable tasks. Organization's ability to provide appropriate trained personnel and flexible resources for the project to meet contract requirements.

c. Demonstrated organizational experience in computerized chemical database management, maintenance, and quality control.

d. Appropriateness and adequacy of the procedures to safeguard confidentiality and intellectual property of data and materials provided by third parties or the Government, as well as data generated by the Contractor.

CRITERION 4: FACILITIES AND RESOURCES **10 points**

Adequacy and availability of all necessary facilities, equipment, and resources required to carry out the contract requirements, and if applicable, the facilities, equipment, network and computational resources of subcontractors and consultants.

a. Computational facilities and support to conduct work described in the Statement of Work including high speed Internet capability, software, hardware, and other necessary equipment.

TOTAL: **100 Points**

4. **PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's

reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

67. Five of the six chemical and biological databases that the Contractor is required to maintain and update are not public. Are the databases different in any way?

The non-public data bases are set up in the exact same manner as the public data bases. There is no difference between the two other than the data that is entered.

68. The NIAID provides no details relating to the structure table and each of the main data tables that are necessary to properly address the RFP requirements and prepare a realistic cost proposal. Can the NIAID provide additional information?

The database record structure was provided as Attachment 12 with Amendment No. 2. The structure is the same for the public and non-public databases.

NIAID does not require that the Contractor who receives this award to use the same processes and procedures to perform the work as those of the incumbent contractor. Each offeror should provide its own plan and technical approach that clearly exhibits its experience and expertise related to providing the required services.

Public data are to be derived from the literature and other publicly available sources. Proprietary data are to be provided by the NIAID contract testing organizations under agreements that preclude the data from being made available to the public. Public and proprietary data are maintained together in the data tables. All data are available to NIAID staff, while only the public subsets of data are available on the public Web database. An example of the field definitions further describing the data to be populated is included below for a representative data table. Offerors are not restricted to these fields but should propose their own plan and technical approach for abstracting and updating HIV and OI-related chemical/biological data. Required fields to be populated will vary depending on particular data assays and results. Protocols for formatting data or abbreviation conventions generally should adhere to normally acceptable conventions (use of commas with large numbers, leading zeros with a decimal, ug/ml for microgram per milliliter, etc.) and would depend on the offerors' technical approach. Drop down boxes for data entry may be used for data management purposes as each offeror may elect to propose or not. **Attachment 13** to the RFP includes a representative file of a table with data field types and definitions.

69. The descriptions are silent with respect to specialized database interface screens that are utilized and required for database entry/editing/quality control, and database management and maintenance. Can the NIAID provide additional information to assist Offerors in submitting their proposals?

Offerors are to provide their own plan and technical approach for performing the work in order to exhibit both the experience and expertise to carry out the proposed work. NIAID is mindful that the approach that works for one contractor may not work for another.

A major contract requirement is to provide chemical/biological data identification, collection, and management related to HIV and AIDS-related OI experimental therapeutics research. Offerors are to describe their particular technical approach and methods by which they will identify, abstract, enter, and manage HIV/OI data; how they will perform structure and preclinical information searches; and how that information

and structures will be combined in the NIAID Therapeutics database. See Section 3 – Technical Approach, Attachment 6.

A sample MDL ISIS interface that might be used for data entry, editing, and/or deleting data fields is provided below. This is only a sample. Offerors are not restricted to the listed fields. Offerors may wish to include or exclude specific data fields with Project Officer's approval. Offerors should identify in their proposal and technical approach those fields they intend to use for the abstraction, entry, and update of HIV and OI-related chemical/biological data. The following is a screen shot of the sample MDL ISIS user interface referenced above. (See Response to Question 32 for detailed data definitions of the fields below).

HIV#	AIDS#	LITREF#	SOURCE_ID	SALT_FORM	SUPPLIER
HIV#	AIDS#	LITREF#	SOURCE_ID	SALT_FORM	SUPPLIER

STRAIN_TYPE	HIV_STRAIN_TYPE	CELL_TYPE	EC50_MOD	EC50	IC50_MOD	IC50	TI_MOD	TI
STRAIN_TYPE	HIV_STRAIN_TYPE	CELL_TYPE	EC50_MOD	EC50	IC50_MOD	IC50	TI_MOD	TI

EC_PCT_CONC_MOD	EC_PCT_CONC	EC_PCT_MOD	EC_PCT	IC_PCT_CONC_MOD	IC_PCT_CONC	IC_PCT_MOD	IC_PCT	CONC_UNITS
EC_PCT_CONC_MOD	EC_PCT_CONC	EC_PCT_MOD	EC_PCT	IC_PCT_CONC_MOD	IC_PCT_CONC	IC_PCT_MOD	IC_PCT	CONC_UNITS

COMB_RAT	COMB_EFF	CONTROL	ASSAY_METH	TOX_ASSAY_METH	TARGET	MUTATIONS	DRUG_SEL
COMB_RAT	COMB_EFF	CONTROL	ASSAY_METH	TOX_ASSAY_METH	TARGET	MUTATIONS	DRUG_SEL

REL_RES_FOLD_INC_MOD	REL_RES_FOLD_INC	ACT_RATING	COMMENTS	CHEM_DATE	CHEMIST	REVIEW_DATE	REVIEWER	SECURITY	ROW_ID	CELL_TYPE 2
REL_RES_FOLD_INC_MOD	REL_RES_FOLD_INC	ACT_RATING	COMMENTS	CHEM_DATE	CHEMIST	REVIEW_DATE	REVIEWER	SECURITY	ROW_ID	CELL_TYPE2

The above screen shot of the HIV in vitro and microbicides table is exactly the same data template that is used for both the public and non-public data. It shows all data table fields for use with entry, editing and deleting for both kinds of data. Table structure and data content for both public and non-public data is identical, only the source is different. Drop down boxes for data fields are not used.

70. **NIAID's response to Question 12, RFP Amendment 2, is inadequate because Attachment 10, entitled Sample Biweekly Literature Surveillance Memo, was not representative as it contained three links to a single database – NLM's Entrez PubMed database and no online library links. Can the NIAID provide more information to assist Offerors in preparing their proposals?**

The following is NIAID's response to this assertion:

Literature Surveillance Memos are posted on the NIAID Therapeutics Database Website at http://chemdb2.niaid.nih.gov/struct_search/default.asp and can be accessed by selecting the "Select Citations Memo" tab. Where available, URL hyperlinks to article abstracts are captured and included for three separate

online databases. Links to PubMed (ncbi.nlm.nih.gov) are available to all users. Links to Web of Science (publishorperish.nih.gov) or Science Direct (sciencedirect.com) are only available to NIH staff inside the NIH firewall or to other registered users of these Web sites.

An additional hyperlink is included in the memo that directly links to the data on the NIAID Therapeutics Web database if it is available. (Data hyperlinks to the NIAID Therapeutics Website do not work outside of the Website environment. They only are active on the memos directly posted on the Literature Surveillance page.)

Example 1: ONLINE DATABASE SEARCH - HIV-LS-365-MEMO
This memo contains hyperlinks to two of the three online databases (PubMed and Web of Science).

Example 2: ONLINE DATABASE SEARCH - HIV-LS-366-MEMO
This memo contains hyperlinks to all three online databases (PubMed, Web of Science, and Science Direct).

Both of these examples can be accessed and inspected in detail using the above URL.

71. **The NIAID failed to provide requested information that would provide potential bidders with information that was necessary to address requirements of the Statement of Work and RFP evaluation criteria. Specifically, the NIAID could have provided more information in response to Question 33, Amendment 2 of the RFP, and did not in regard to the technical details regarding the process by which open literature portions of the data fields from the HIV, OIs, TB, and microbicides databases are transferred to the publicly available Web database (see RFP, SOW Attachment 4 at 3). Please provide additional information.**

The NIAID provides the following response:

The successful offeror will be required to meet with NIAID's Technology staff to develop procedures and protocols that are mutually agreeable for data transfers. A security field presently is used in the HIV, microbicides, and OI/TB tables to identify public data. For Web database transfers, the security field is used to identify the subset of data that is to be loaded into the publicly available Web database. Oracle dumps are made of the data subset and copied to media specified by NIAID Technology staff. Contractor staff then transfer the media to the NIAID hosting site and upload the subset of data to the Oracle database Web server under the supervision of NIAID Technology staff.

72. **There is little or no information in the RFP regarding the Transition steps as well as the equipment, databases, back up tapes, hard discs, hardware and software, source code for all developed software, documentation, and licenses that are anticipated to be transferred from the incumbent contractor. Please provide additional information to assist Offerors in preparing proposals.**

We have asked the incumbent contractor for their transition plan. They have provided the following information:

Transition Steps:
Day 1: Meet with DAIDS Project Officer and successful contractor to discuss specific transition steps.
Days 5 - 15: Transfer materials to the successful contractor's facility

The transfer of materials will follow the schedule decided on in the initial transition meeting between current contractor staff, the successor contractor's personnel, and the Project Officer.

The items to be delivered to the successor contractor will include:

- Reference materials;
- Shelf supplies;
- Government-furnished equipment;
- Software programs for which contract funds were expended;
- Backups in the form of magnetic tapes, SDfiles, and Oracle dumps of data;
- Documentation (installation, keys, licenses) for any software transferred; and
- Electronic versions of materials developed under the contract and Web-related files.

Specific items/files to be delivered include:

- Source code for Web application (including GIFs and PDFs) required to host the NIAID HIV/OI/TB Therapeutics Web database.
- HIV biological (enzyme, in vitro, microbicides) data tables.
- OI (opportunistic infections) biological data table.
- Web database tables.
- Literature citation database of articles abstracted for Web site.
- Master structure database of combined public and proprietary compound structures.
- Database of literature memos citations.
- Article reproductions.
- Contract investigator reports of proprietary data.
- Current backup tapes for all data.
- Hard copy of OI and HIV memos.

73. RFP Amendment 2, response to Question 16. No information was provided as to the legibility, readability, uniformity, number of text pages, or condition of the hard copy. Please provide more

Data reports are provided as hard copy report format or as electronic files in Word or Excel format. Reports in Word format historically have varied in quality as to readability, uniformity, number of pages, and condition. Reports in Word format are in narrative text with tables containing biological inhibition assay data results. The majority of current Word reports are uniform in format and are on average 45 - 50 pages in length. Reports in Excel format contain biological inhibition assay data results in spreadsheet format without narrative text. Historically, 6 - 7,000 lines of confidential data are received for entering into the data tables per year. (A line of data is understood to contain all the information associated with a single biological assay data result.)

The data reports are provided by independent private testing laboratories under confidentiality agreements between the laboratory and NIAID. NIAID has no control over the format or presentation of the data; moreover, the laboratory population is not static and from time to time report formats and processes have changed and are expected to change in the future.

74. The NIAID Non-Clinical Evaluation Agreement (Attachment 8) and the Intellectual Property Option (Attachment 8-10) of Appendix C are not reasonably related to the subject matter of the RFP. Both documents referred to "Materials" which was defined in Attachment 8 at 3 under Subheading 1, Definitions. The subject matter of the RFP deals with information related data and not "chemical matter and compositions submitted by the

The NIAID included the Material Evaluation Agreement (Attachment 8) because the Contractor will have access to proprietary data from third party organizations about compounds and will be performing literature searches on these compounds.

75. The NIAID stated in response to Question 20, Amendment 2, that the Contractor will be given access to computerized data information systems with the exception of CAS-ONLINE and International

Pharmaceutical Abstracts and full text U.S. and European patent databases. It is difficult to provide realistic cost estimates based on so little information. Please provide additional information.

The list of computerized data information systems was a suggestion only. Offerors are expected to possess baseline familiarity with biological/chemical literature surveillance and are expected to know how to use these and other online sources appropriate to the areas of surveillance. NIAID provides access to the systems that are made available through master NIH contracts. The vendors supported by those contracts change from time to time. CAS-ONLINE and International Pharmaceutical Abstracts (IPA) services are not available through the NIH. Offeror has the option of subscribing to these or other for-fee-services they might propose to use for surveillance activities. NIAID encourages the use of free, or low-cost, online sources to perform contract services wherever possible and appropriate to the contract requirements. Full text US and European patents are freely available, or available at low-cost, online with appropriate searches.

NIAID is informed that the yearly cost for CAS-ONLINE use varies with specific subscriber requirements. Each offeror is expected to consider how, if at all, a particular service or combination of services would be used to fulfill NIAID's requirements and to negotiate its own terms of subscription.

76. **The NIAID has stated that there are no unique software or hardware requirements to carry out the Statement of Work (see RFP Amendment 2, response to Question 23). This appears to be in contrast to other statements made in the RFP. Please clarify.**

There are no unique software requirements for the contract. Off-the-shelf software such as ProCite, Oracle, and MDL products that are commonly used for bibliographic and biological and chemical data management can be used to meet all contract requirements. The software currently used to manage the data include:

Software Name	Current version(s)	Operating System	Paid For
ProCite	5.0.3	Windows	under contract
Oracle SQL Plus	8.1.7.4.5	Windows	under contract
Oracle Server EE	8i/9i	Windows	under contract
MDL ISIS Base	2.5SP1	Windows	under contract
MDL ISIS Host	5.0	Windows	under contract
MDL ISIS Direct	5.0	Windows	under contract
MDL QSAR	2.2	Windows	under contract

This software will be transferred to the successful offeror upon contract award.

The Contractor will purchase the licenses for use of the software and be reimbursed for the cost under the contract. The yearly cost of the license for MDL software is $24,593 and for the license for Oracle software is $2,163.

There are no unique hardware requirements for the contract. Below is the hardware currently furnished by the Government under the contract.

Manufacturer	Model	Use
Dell server	Power Edge 4400	data hosting
Dell server	Power Edge server 2500 SC	Web development
Dell desktop	2400	data management
Dell desktop	2400	data management
eMachine desktop	T2885	data management
Systemax desktop	Venture B515	data management
Systemax desktop	Venture B515	data management
Systemax server	SYXS-ST	test server for version upgrades

This equipment will be transferred to the successful offeror upon contract award.

77. NIAID did not provide a response to the following question. With respect to the phrase "to determine the validity and authenticity of data," please describe the work to be performed and provide one or more concrete examples.

NIAID provided a response to this question (see Amendment No. 2, Response to Question 30, d. Additional information, including an example is provided below.

The data abstraction process should account for any shortcomings of original research findings that are identified in the literature to support useful conclusions regarding subsequent drug development research activities. Data results described in the narrative, for example, may differ from those presented in summary tables. Scientific judgment and evaluation may be required to determine which value is correct and/or whether the author should be consulted for clarification. Generally such contacts require the attention of an individual with similar training and experience as the author. Resolution of specific stereochemical questions associated with the rendition of a compound presented in 2D format often is required during QC activities. Validation that a compound drawn from a chemical name is correct is always required prior to registration of the compound into the structure database. These situations require the application of judgment by appropriately trained and experienced biological data specialists and medicinal chemists.

78. NIAID has failed to describe the format of database fields, field delimiters, and record layout for bibliographic databases maintained by ProCite software. Please provide this information.

Formats and delimiters will vary from different online sources. Depending on the sources that offerors propose to use to support their technical approach for this activity, appropriate field tags from the sources can be linked to the maintenance database. Currently the ProCite "Journal Long Form" is the workform used for citation maintenance. Offerors are required to describe their own approach to this task. NIAID does not require that offerors utilize precisely the same approach or select the same entry workform to perform this work as the current incumbent contractor uses. A typical record layout extracted from the current ProCite bibliographic database is:

1. 59950 HIV-LS-366; EMBASE-HIV-1/21/2007
   Inhibition of HIV-1 infection by synthetic peptides derived CCR5 fragments
   Imai, Masaki, Baranyi, Lajos, Okada, Noriko, and Okada, Hidechika
   Biochemical and Biophysical Research Communications **2007**. 353(4): 851-856
   HYPERLINK: http://www.sciencedirect.com/science/article/B6WBK-4MMFRH8-2/2/b882e26891c7ee211710ebf48b2223d7

The configuration file for database fields and field delimiters for the Journal Long Form is provided below.

Biblio-Link II Configuration Report

Configuration File:
File Name: NIAID.cfg

Record Identification Information:
Record Begins With: " # of #"
Record Terminated By: Blank Line

Field Identification Information:
Field Tag Format: "$ "
Field Tag Length: Fixed: (02)
CR Follows Tag? No
Fields Terminated By: "."

Empty Field Filler: ""
Line Continuation: Indented
Default Case Conversion: No Conversion

Database ID: NIAID
Description: Default Database Definition
Target Workform: Journal Long Form

32 fields have been defined:

Tag	Description	Target Field
AB	abstract	(43) Abstract
AD	address	(37) Address/Availability
AU	authors	(1) Author, Analytic
BP	begin page	(25) Page(s)
CY	country	(18) ---
DE	notes	(42) Notes
DP	pub date	(20) Date of Publication
DT	data type	(27) ---
EP	end page	(25) Page(s)
ID	keywords	(45) Keywords
IP	issue	(24) Issue ID
IS	issn	(41) ---
JI	journal title	* Do Not Transfer
LA	language	(18) ---
MH	med heading	(45) Keywords
NI	?	* Do Not Transfer
PD	pub date	(20) Date of Publication
PG	no of pages	(25) Page(s)
PM	PMIDNO	(38) Location/URL
PT	pub type	(5) Medium Designator
PY	pub year	(20) Date of Publication
RN	notes	(42) Notes
RO	?	* Do Not Transfer
SB	?	* Do Not Transfer
SI	notes	* Do Not Transfer
SN	issn	(41) ---
SO	journal title	* Do Not Transfer
TA	journal title	(10) Journal Title
TI	title	(4) Article Title
UI	start ref	* Do Not Transfer
VI	volume	(22) Volume ID
VL	volume	(22) Volume ID

79. The Statement of Work, Task 6b, is lacking in specific detail to permit an offeror to respond. Please describe what software development has occurred and make available for review documentation for maintenance updates to fix bugs, improvements for security issues, or enhancements such as structure queries for the Oracle data.

There are no specific requirements for software development recited in the RFP. Software programs used for this work have not been developed by the incumbent contractor or any previous contractor; all software is "off the shelf." Software programs have been updated and upgraded to newer versions to meet specific requirements of the various software vendors as they relate to one another within the context of overall contract requirements. During the current contract, for example, local PC MDL software has been updated

yearly. MDL server versions have been updated on two occasions, first from ISIS Host 3 to ISIS Host 4 and then from ISIS Host 4 to ISIS Host 5. Oracle also has been upgraded twice, first from Oracle 7 to Oracle 8, and then, from Oracle 8 to Oracle 9i. ProCite has been upgraded, during the current contract, from version 5.0 to version 5.0.3.

Contract maintenance and security requirements are addressed through the deployment of various management technologies, security tools, subscriptions to security forums, and use of appropriate software vendors. Patch management is provided by Windows Server Update Services, and all updates and patches are tested on development hardware systems before they are deployed to the NIAID server and/or contractor production environments. All MDL and Oracle software products are covered under maintenance agreements that are specifically tailored by the vendor to meet the particular service requirements of the contractor, and those vendors are consulted for support as needed during performance. Offerors will be expected to develop appropriate maintenance and security plans, consistent with their own corporate IT policies and the ISSP that each offeror is required to provide under the RFP.

END OF AMENDMENT #3 to RFP-NIH-NIAID-DAIDS-07-27

STATEMENT OF WORK

MANAGEMENT OF INFORMATION RESOURCES ON THERAPEUTIC AGENTS FOR HIV AND OPPORTUNISTIC INFECTIONS
RFP NIH-NIAID-DAIDS-07-27

OVERALL OBJECTIVES AND SCOPE

This contract provides for the management of chemical and biological databases which serve as tools for the rational selection and discovery of potential therapies for AIDS and opportunistic infections (OIs). The Contractor shall update the databases with pertinent published literature and NIAID confidential data and information on the chemical, virological, immunological and microbiological aspects of therapeutic agents for HIV, OIs, and TB, and on microbicides.

The chemical and biological databases which the Contractor shall maintain and update are incorporated into a master database and are described as follows:

1. Anti-HIV Therapeutic Agents Database – contains in vitro inhibitory and enzyme mechanistic data from the public literature linked to over 99,529 compounds;
2. Co-infections Database – contains data from the public literature on OI therapeutics, data on tuberculosis-associated agents, and data containing propriety information on more than 108,459 investigational compounds;
3. M. tuberculosis Database – contains data on over 94,386 compounds tested for activity against *M. tuberculosis*;
4. Topical Microbicides Database– contains experimental data on over 1,645 topical agents tested against the spread of HIV;
5. Literature Citations Database – contains over 14,634 references from published literature, patents, and meeting abstracts that can be searched by author, title, journal, patent number or year of publication, and that are linked to Medline abstracts in the PubMed database; and
6. Publicly Available Web Database – located at http://chemdb.niaid.nih.gov, contains non-confidential portions of the master database. Currently, there are over 138,703 compounds linked to over 2,908,104 lines of data on this public website. In addition to the chemical and biologic data, the public website contains links to bi-weekly Literature Surveillance Memos that identify relevant published research on pre-clinical experimental therapies for HIV, OIs, and other viral pathogens.

The scope of information resource management activities to be performed by the Contractor include literature surveillance on experimental therapeutic agents for HIV and OIs, abstraction of relevant data and updating of the chemical and biologic databases, maintenance and updating of the literature citations and publicly available Web databases, maintenance of the computer systems and provisions for quality control. The Contractor shall exercise considerable professional judgment in surveying a broad base of literature sources and in selecting citations that contain information pertinent to HIV and OI preclinical therapeutic and drug discovery efforts.

The sources of data for updating the databases are as follows:

- Public literature (including publications, patents and meeting abstracts)
- HIV and co- infections data reports from DAIDS-supported screening contractors performing in vitro and in vivo biological assays. The data reports will be provided to the Contractor by the Project Officer.

TECHNICAL REQUIREMENTS

Independently and not as an agent of the Government, the Contractor shall furnish all services, qualified personnel, materials, equipment and facilities not otherwise provided by the Government under the terms of this contract as needed to perform the work described below.

The major tasks to be carried out are as follows:

1. Initial Transition
2. Literature Surveillance
3. Abstraction of Data and Updating of Databases
4. Maintenance of a Literature Citation Database
5. Maintenance of the Publicly Available Web Database
6. Software/Hardware Maintenance, Development and Provision of Security
7. Assembly of Preclinical Information Search Requests
8. Facilities, Equipment, and Other Resources
9. Project Management
10. Final Transition

1. INITIAL TRANSITION

In the event the incumbent contractor is not successful in the recompetition, the Project Officer will provide the Contractor with a copy of the incumbent contractor's Final Transition Plan concurrent with the contract award.

a) Within fifteen (15) calendar days of contract award, the Contractor shall submit for Project Officer review and approval, an Initial Transition Plan and timetable for the receipt, storage, and transfer of all items in the incumbent contractor's Final Transition Plan. This Plan shall include, but may not be limited to equipment, databases, back-up tapes, hard discs, hardware and software, source code for all developed software, documentation, and licenses.

b) Upon receipt of written approval by the Project Officer, implement the Initial Transition Plan to complete the tasks associated with the initial transition within thirty (30) calendar days.

2. LITERATURE SURVEILLANCE

The Contractor shall perform literature searches for graphical and text data on experimental therapeutic agents for HIV and OIs.

a) Monitor current publications (including U.S. and foreign patents) in chemistry, virology, immunology, microbiology, biochemistry and biology, and identify relevant published research findings on experimental therapies for HIV and OIs. When requested by the Project Officer, provide hard copies of designated publications. Utilize electronic access to computerized data information systems such as Web of Science, CAS-ONLINE, CAS-SciFinder, DIALOG, MEDLINE, International Pharmaceutical Abstracts and full text U.S. and European patent databases. The Contractor shall have an Internet address and send and receive files electronically via standard file transfer protocol (FTP), secure file transfer protocol (SFTP), or other NIAID preferred protocol.

b) Within fourteen (14) calendar days after contract award, provide the Project Officer with the first bi-weekly Literature Surveillance Memos containing literature citations for bHIV and OIs of potentially relevant published research works identified in paragraph 2a. Subsequent biweekly Literature Surveillance Memos, containing an average of 90 literature citations, shall be provided to the Project Officer every two weeks over the contract's period of performance. Bi-weekly Literature Surveillance Memos shall be provided as hard copies and electronic files with links to online libraries and databases. The Biweekly Literature Surveillance Memos shall include the following elements:

A title page which includes: 1) Contract number and title; 2) Type of literature report, HIV or OIs; 3) Period of performance being reported; 4) Contractor's name and address; and, 5) A brief introduction describing the subject list, and

A list of citations which includes the following for each citation: 1) database used to generate the citation; 2) citation title; 3) citation author(s), and 4) journal or patent number and date of publication.

Within five (5) business days of receipt of the bi-weekly Literature Surveillance Memos, the Project Officer will review the literature citations, and provide the Contractor with a subset for abstracting. An average of 70 citations for abstracting is anticipated on a monthly basis.

3. ABSTRACTION OF DATA AND UPDATING OF DATABASES

The Contractor shall identify and abstract relevant chemical and biological information on experimental therapies for HIV and OIs from the public literature and from HIV and co-infections data reports from DAIDS-supported screening contractors for updating of the HIV, OI, TB and microbicides databases.

a) Identify, for inclusion into the HIV, OIs, TB and microbicides databases, relevant chemical and biological data described in paragraph 3.b) below, from a subset of the citations in the bibliography described in paragraph 2.b), and from public or confidential HIV and co- infections data reports from DAIDS-supported screening contractors performing in vitro and in vivo biological assays. The subset of citations and the public or confidential contract data reports for abstracting will be provided by the Project Officer. Exert a critical expert opinion on the validity and authenticity of the identified relevant data.

b) Abstract the following relevant chemical and biological information:

1. chemical structure, name and synonyms;
2. chemical class;
3. *in vitro* antiviral activity against HIV-1 and HIV-2, simian immunodeficiency virus (SIV), and feline immunodeficiency virus (FIV);
4. *in vitro* antimicrobial activity against M. tuberculosis, M. avium, Pneumocystis carinii, Toxoplasma gondi, Cryptosporidium parvum, Microsporidium, Cytomegalovirus, fungi (Cryptococcus, Candida, and Aspergillus), Hepatitis C, and other AIDS-related pathogens;
5. inhibitory activity against relevant isolated enzymes (e.g. reverse transcriptase, protease, integrase and dihydrofolate reductase, etc.);
6. *in vivo* biological activity in relevant animal models of AIDS-related infections;
7. possible mode(s) of action;

8. major research finding(s) if any. Such findings may include, but not be limited to, a new class of chemicals with potent biological activity, a new mode of action, or activity against resistant strains;
9. literature reference(s); and
10. NIAID contract or grant source number if applicable and available.

c) Add abstracted information specified above from the subset of literature citations and the HIV and OIs contract data reports to the corresponding HIV, OIs, TB and microbicides databases. The HIV and OIs contract data reports contain data compatible with the HIV, OIs, TB and microbicides database fields.

d) Transfer the open literature portions of the data fields from the HIV, OIs, TB, and microbicides databases to the publicly available Web database.

4. MAINTENANCE OF A LITERATURE CITATION DATABASE

The Contractor shall maintain and update a literature citation database containing bibliographic data relevant to HIV, OIs and TB therapies using ProCite software.

a) Update the literature citation database with all the biweekly literature citations contained in the Literature Surveillance Memos as described in paragraph 2.b). The literature citations database shall include author(s), title, journal, patent number, year of publication, and name of the electronic database searched.

b) Maintain and update a PDF file containing the subset of citations selected to be abstracted as described in paragraph 3.a), as an Oracle table and link each citation to the corresponding chemical structure and biological data in the HIV, OIs, TB, and microbicides databases.

c) Transfer all the biweekly literature citations in HTML format and with links to PubMed abstracts to the publicly available Web database.

d) Provide hardcopies of reprints requested by the Project Officer. All reprints shall be the property of DAIDS and shall be located in the offices of DAIDS staff in Bethesda, Maryland. Reprints requested by the Project Officer shall be delivered within two business days after the request.

5. MAINTENANCE OF THE PUBLICLY AVAILABLE WEB DATABASE

a) Assist NIAID Office of Technology Information Systems (OTIS) staff in maintaining the availability of the public Web database without interruption by identifying and correcting problems. Upload of all updates and computer programs from the Contractor to the publicly available database server will be performed by OTIS staff.

b) Update the Web database every three (3) months through the transfer of non-confidential data fields from the HIV, OIs, TB and microbicides databases. Update the web database biweekly with literature citations described in paragraph 2.b). All updates shall be provided to the assigned OTIS staff responsible for the upload through e-mail or computer disc. The contents of the Web database are available on the website http://chemdb.niaid.nih.gov.

c) Wherever possible, link compounds directly to other NIH literature or chemical databases, including PubMed, PubChem and the National Library of Medicine's ChemID Plus database.

6. SOFTWARE/HARDWARE MAINTENANCE, DEVELOPMENT AND PROVISION OF SECURITY

a) Provide software and hardware maintenance, computer update support, biweekly backups, and adequate security provisions to protect the confidentiality, integrity, and availability of the data as approved by the Project Officer. The Contractor shall perform database entry/editing/quality control, and management and maintenance of Molecular Design Limited (MDL) software ISIS/Base, ISIS/Draw, ISIS/Host, ProCite and Oracle software. The Contractor shall provide modifications to maintain and enhance effectiveness, reliability, and integration of disparate databases, and correct any identified problems in the systems.

b) Utilize industry best practices in the development of all software which includes, but is not limited to maintenance updates to fix bugs, improvements for security issues, or enhancements (such as improved structured queries for the Oracle data) as requested by the Project Officer. Any software developed shall conform to NIAID OTIS standards and be compatible with existing NIAID infrastructure and applicable Federal Information Processing Standards (FIPS), HHS, NIH, and NIAID ADP and Information Security policies. These standards will be provided to the Contractor by OTIS staff.

c) Provide NIAID with onsite media and **one license each** for all required software (e.g. MDL ISIS, Oracle, etc.), documentation and source code of all developed software. All computer software, documentation and deliverables shall be the property of the U.S. Government.

d) Utilize staged deployment techniques as deemed necessary by NIAID OTIS staff; thoroughly test software in the development arena before staging on quality assurance (QA); participate in QA testing when appropriate; develop automated software installation where possible; and support deployment on production systems that would minimize adverse operational impact.

e) Assist NIAID OTIS staff with the production of security Certification and Accreditation (C&A) documents by providing information as demonstrated for testing of system security controls. Develop, with NIAID OTIS input, a Plan of Action and Milestones (POA&M), that describes the measures that have been implemented or planned: (i) to correct any deficiencies noted during the assessment of the security controls; and (ii) to reduce or eliminate known vulnerabilities in the information system. The Contractor will provide NIAID OTIS (specifically the NIAID Information System Security Officer [ISSO]) a copy of the System Security Plan (SSP).

f) Develop a Disaster Recovery Plan within six (6) months of contract award, document a detailed list of disaster recovery procedures, and provide onsite assistance for the publicly available web database in the event disaster recovery is needed. A copy of the Disaster Recovery Plan shall be submitted to the Project Officer, Contracting Officer, and NIAID OTIS staff for review and approval, be located at the NIAID and will be the property of the NIAID.

7. ASSEMBLY OF PRECLINICAL INFORMATION SEARCH REQUESTS

a) At the request of the Project Officer, the Contractor shall use literature sources, including commercially available databases and the databases maintained by the Contractor, to survey, retrieve, and assemble preclinical information on designated drugs or agents. The Contractor shall process each request utilizing appropriate expertise, and check the output for accuracy, completeness, and relevancy.

b) Within two (2) business days of receipt of the request from the Project Officer, the Contractor shall present the data to the Project Officer in a written format or as specified by the Project Officer.

8. FACILITIES, EQUIPMENT, AND OTHER RESOURCES

The Contractor shall provide and maintain the following facilities, equipment and resources to carry out the requirements set forth in the Statement of Work:

a) A facility or facilities for literature surveillance, abstracting of chemical and biological data, ad updating of the databases.
b) Computer hardware and software and computer equipment.
c) Dedicated space for staff and equipment.
d) Controlled access areas for secure storage of data reports and confidential information.

9. PROJECT MANAGEMENT

a) **Overall Management**

Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and management and completion of all projects carried out under this contract. This infrastructure shall include a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting on project status, progress and costs.

b) **Meet with the Project Officer**

Meet with the Project Officer and appropriate DAIDS staff every two months for one day at NIAID offices in Bethesda, Maryland, to review progress, discuss anticipated or existing problems, and the work to be performed in the near future.

c) **Communicate Effectively with the Project Officer**

1) Establish electronic communication with the Project Officer sufficient to support exchange of e-mail and the submission of data files and reports when requested.
2) Provide periodic updates of project status, at a frequency to be scheduled after contract award, via telephone or e-mail.
3) Submit, Technical Reports, and Other Reports/Deliverables in a timely fashion in accordance with the Reporting Requirements and Deliverables Section of this contract.

10. FINAL TRANSITION

The Contractor shall ensure an orderly and efficient transition of contract-related materials to a successor contractor or to the Government by the expiration date of the contract, if required by the NIAID:

a) Prepare and submit, for review and approval by the Project Officer and the Contracting Officer, a written Final Transition Plan three (3) months prior to the expiration of this contract. The Final Transition Plan shall detail the transfer of all or part of this project to a subsequent contractor or the Government.

b) Implement the Final Transition Plan as approved by the Project Officer and the Contracting Officer for the transfer of data, back-up tapes, hard discs, software, source code of all developed software, documentation, and related licenses. Complete documentation shall accompany all software. Any software, licensing, intellectual rights, source code, and documentation developed by the Contractor for these systems shall become the property of the Government.

c) Provide the successor contractor with all acquired publications, reprints, abstracts and any other documents, results of all searches, database entries, and files necessary for the continuation of this contract.

MANAGEMENT OF INFORMATION RESOURCES ON THERAPEUTIC AGENTS FOR HIV AND OPPORTUNISTIC INFECTIONS
RFP NIH-NIAID-DAIDS-07-27

APPENDIX A - ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS FORMAT FOR TECHNICAL PROPOSAL – TABLE OF CONTENTS

It is strongly recommended that Offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal shall be presented in the order specified below.

The following additional Technical Proposal instructions reflect the requirements of the RFP and are meant to provide additional instructions as well as a uniform format for Technical Proposals. The information requested in these instructions shall be used as a guide for formatting and preparing the Technical Proposal. Offerors shall follow the instructions in Section L of the solicitation, and include the information requested in this appendix.

Offerors are advised to give careful consideration to the Statement of Work, all reference material, appendices and attachments, the Technical Evaluation Criteria, and, the RFP as a whole, in the development of their Technical Proposals.

Offerors who propose subcontracts to perform portions of the Statement of Work shall clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration between the prime and subcontractor(s), and the expected advantages of such an approach.

Offerors are reminded that the total page limitation for the **entire** technical proposal package is **200 pages** including all appendices and attachments. Any pages in excess of this limit will be expunged from the Technical Proposal and will not be considered in the technical review.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1

1. **PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.**
2. **PROJECT OBJECTIVES (NIH FORM 1688-1)**
3. **GOVERNMENT NOTICE FOR HANDLING PROPOSALS**
4. **PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)**
5. **TABLE OF CONTENTS**

SECTION 2 – SCIENTIFIC AND PROFESSIONAL PERSONNEL

The Technical Proposal should include all information relevant to document education, training, accomplishments, and relevant experience of all proposed personnel, as well as the percentage of time each will be committed to the project. This includes staff of the Offeror and all proposed subcontractors and consultants. Resumes, endorsements, and explanations of previous efforts should reflect length and variety of experience in similar tasks and should clearly demonstrate specific accomplishments. Documentation should include all previous and current projects of a similar nature, including the contract number or grant number, the sponsoring agency, the Project Officer, and a description of the project. Limit CVs to three (3) pages for the Principal Investigator

and two (2) pages for all other key personnel. Provide selected references for publications relevant to the scope of the RFP.

1. **Principal Investigator**: Describe the experience, training, expertise, qualifications, and percentage of effort of the Principal Investigator proposed to lead and direct the activities to be carried out under this contract. The Principal Investigator should have education and experience commensurate with his/her expected role including experience and training in one or more of the following: medicinal chemistry/biology, microbiology or virology. In addition, the Principal Investigator should have documented expertise in the computer science aspects of database software/hardware similar to that used under this contract. Describe this individual's capacity to monitor progress, assess performance, identify performance problems and implement corrective actions. Describe experience in leading and directing projects of comparable content and complexity and familiarity with past and current microbiological research in the areas of HIV and opportunistic infections (OI), antivirals, and other antimicrobials.

2. **Key Scientific and Professional Personnel**: Describe the experience, training, expertise and qualifications, as well as percentage of effort, for all proposed key scientific and professional personnel, including subcontractors and consultants. This includes scientific and technical expertise and knowledge and familiarity in: past and current microbiological research in the area of HIV and OI, antivirals, and other antimicrobials, in vitro assays and animal models for testing antimicrobial efficacy; conducting on-line literature searches in appropriate chemical and biological databases; qualifications to serve as a resource to NIAID Division of AIDS for advice on the computer science requirements of the contract; and expertise in relational databases and preparation/formatting of text and graphic data for Web site inclusion.

3. **Data Entry and IT Personnel**: Describe the experience, training, expertise, qualifications, and percentage of effort, for all proposed data entry and IT personnel, including subcontractors and consultants. This includes scientific and technical expertise and knowledge in: chemical structures and data entry, quality control and database management. Describe previous experience in preparation of text and graphic data in html and gif format for Web site inclusion and with the use and maintenance of ORACLE and Molecular Design (MDL) or similar software for database management.

SECTION 3 - TECHNICAL APPROACH

Technical Proposals shall describe specifically how the Offeror shall fulfill each of the items in the SOW.

Literature Surveillance (SOW Task 2)

Provide a plan/technical approach to survey a broad base of literature sources and for selection of citations that contain chemical and biological information on experimental therapies for HIV and OI. Describe previous experience with the preparation of scientific citation lists.

Abstraction of Data and Updating of Databases (SOW Task 3)

Describe the approach for identifying and abstracting relevant chemical and biological information related to HIV and OI experimental therapies, and for updating the corresponding chemical and biological databases**.** Delineate the process to be used to determine the validity and authenticity of the identified relevant data.

Maintenance of a Literature Citation Database (SOW Task 4)

Provide a plan/technical approach for maintaining and updating the literature citation database.

Maintenance of the Publicly Available Web Database (SOW Task 5)

Describe how the Offeror will maintain the availability of the public Web database to the public without interruption. Describe procedures to update the Web database through the transfer of information from the chemical and biological databases.

Software/Hardware Maintenance, Development and Provision of Security (SOW Task 6)

Describe the software/hardware maintenance and development procedures to be used for updating and for maintenance of the databases, quality control, disaster recovery, security and confidentiality of the data. Describe procedures to ensure industry best practices are followed in the development and maintenance of software. Discuss potential problems/obstacles and solutions/approaches to be used to ensure a reliable, efficient, fully operational and responsive data management system.

Assembly of Preclinical Information Search Requests (SOW Task 7)

Describe the technical approach for performing preclinical information search requests requiring substructure or full structure chemical searches. For each of the following search requests, provide the search strategy including the literature sources, the rationale for selecting the most promising chemical structure, the chemical structure, and mode of action if any, and a reference citation.

1. A fused quinoline ring system with anti-HIV activity
2. A fused quinoline ring system with anti-TB activity
3. A fused benzoquinone natural product with anti-HIV activity
4. A fused isoquinoline ring system with anti-HIV activity

SECTION 4 – PROJECT MANAGEMENT

1. Provide a plan for project organization, staffing, and management in relation to the implementation, conduct, monitoring and completion of the tasks identified in the Statement of Work. Describe in detail the responsibilities and level of effort of all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants and an administrative framework (including an organization chart) indicating clear lines of authority and responsibility for all proposed personnel.

2. Provide a detailed work plan with proposed time schedules satisfactory for achieving contract objectives and procedures for maintaining quality control over the implementation and operation of the contract.

3. Describe the organization's ability to provide appropriate trained personnel, and timely, flexible resources for the project to meet contract requirements. Discuss organizational experience in computerized chemical databases management, maintenance, and quality control. Discuss how projects are prioritized within the Offeror's organization, the level of priority this contract would receive, and procedures for initiation of contract requirements in a timely manner. Provide documentation of prior success in the timely completion of comparable tasks.

4. Discuss how the Principal Investigator will communicate contract progress and interact with the Project Officer and Contracting Officer to effectively monitor and manage the contract.

5. Describe the procedures that will be employed to safeguard confidentiality and intellectual property of data and materials provided to you by third parties or the Government, as well as data generated, during the performance period of the contract.

SECTION 5 - FACILITIES AND RESOURCES

The Technical Proposal shall document the availability and adequacy of facilities, equipment, space and other resources necessary to carry out the Statement of Work, including:

a. a description of the location and features of the proposed facilities including a detailed floor plan and a list of equipment and resources dedicated to the project; and

b. identification and description of all support resources (including IT systems) which will be required to effectively complete the contract requirements.

SECTION 6 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

Data Sharing Plan

Section L of the RFP specifies the minimum documentation requirements for Data Sharing. All related documentation shall be included in the proposal in this clearly marked section.

IT Systems Security

Section L of the RFP specifies the minimum documentation requirements for IT Systems security. All related documentation should be included in The Technical Proposal in this clearly marked section.

RFP NIH-NIAID-DAIDS-07-27, Amendment No. 3
ATTACHMENT 13 - Table with Data Field Types and Definitions

HIV IVT_Microbicides FIELDS	FIELD SIZE	FIELD DESCRIPTIONS
HIV#	CHAR(10)	Numbers assigned before compound structures are registered; necessary for new compounds, optional for existing compounds.
aids		Compound ID number.
LITREF#	NUMBER(10)	Literature Reference number associated with data.
SOURCE_ID	VARCHAR2(100)	How compound is identified from within the literature article that data is taken.
SALT_FORM	VARCHAR2(100)	Salt form of compound.Other chemical forms may also be entered, for example, MeOH EXTRACT etc.
SUPPLIER	VARCHAR2(100)	If indicated, where the compound was obtained by article investigators.Mainly for compounds not available commercially.
STRAIN_TYPE	VARCHAR2(200)	HIV subtypes, cell tropism(X4, R5 X4R5), wild type or drug-resistanct mutants, clinical isolates, pseudotyped, reporters.
HIV_STRAIN	VARCHAR2(400)	strain names, for example, 1(NL4-3), !(BAL), 2(ROD) etc; for mutants, provide details of mutations, for example, 1(RT-Y181C) etc.
CELL_TYPE	VARCHAR2(200)	Primary cells,Cell lines; associated with cytotoxicity or intracellular test assays; transfected cell lines, for example, MAGI cells(CD4+, HIV LTR-.beta.Gal+)
EC50_MOD	VARCHAR2(60)	This is for > or < and a text modifier for the concentration that inhibits 50% of the cellular process or activity.
EC50	FLOAT(22)	Numeric concentration that inhibits 50% of a cellular process or activity. (This is the same as the 50% effective concentration results.)
IC50_MOD	VARCHAR2(60)	This is for > or < and a text modifier for the cytotoxicity 50% inhibitory concentration results in uninfected cells.
IC50	FLOAT(22)	Numeric results of the cytotoxicity 50% inhibitory concentration in uninfected cells.
TI_MOD	VARCHAR2(60)	This is for > or < and a text modifier for the selectivity index.
TI	FLOAT(22)	Selectivity index for in vitro assays.
EC_PCT_CONC_MOD	VARCHAR2(60)	This is for > or < and a text modifier for concentration of compound tested for in vitro inhibition (cell free and intracellular assays).
EC_PCT_CONC	FLOAT(22)	Numeric concentration of compound tested for in vitro inhibition (cell free and intracellular assays).
EC_PCT_MOD	VARCHAR2(60)	This is for > or < and a text modifier for % of inhibition at the concentration specified in IVT_PCT_INHIB_CONC field.
EC_PCT	FLOAT(22)	Numeric results (other than 50% inhibition) of the % of inhibition.
IC_PCT_CONC_MOD	VARCHAR2(60)	This is for > or < and a text modifier for concentration of compound tested for cytotoxicity results in uninfected cells.
IC_PCT_CONC	FLOAT(22)	Numeric concentration of compound tested for cytotoxicity results in uninfected cells.
IC_PCT_MOD	VARCHAR2(60)	This is for > or < and a text modifier for the cytotoxicity % inhibition field.
IC_PCT	FLOAT(22)	The % of uninfected cells inhibited by the concentration specified in CYTOTOX_ICPCT_CONC. (Results other than 50% inhibition go here.)
CONC_UNITS	VARCHAR2(20)	Concentration units for in vitro inhibtion assays(uM or ug/mL).
COMB_RAT	VARCHAR2(150)	ratio of the compounds in the combination; for example, A:B=1:1 (molar ratio), 1:1 (uM) (FddC:ddC)
COMB_EFF	VARCHAR2(300)	drug effect of the combination as compared with that of individual drugs(synergistic, additive or antagonistic); CI(combination index) should be provided if available, for example, CI=0.72; SYNERGISTIC
CONTROL	VARCHAR2(150)	when only relative values are provided, for example, "change(fold) in EC50" for mutants, then EC50 of wild type can be used as a control
ASSAY_METH	VARCHAR2(300)	Identification of the cellular process or activity studied to determine the inhibitory activity of a compound. Examples include, P24, RT, CPE(cytopathic effect), luciferase, .beta.-Gal etc.
TOX_ASSAY_METH	VARCHAR2(200)	Methods used to determine cytotoxicity of drug in mock-infected cells, Examples include, MTT, XTT, neutral red etc.
TARGET	VARCHAR2(400)	HIV infection- or replication-related viral or cellular event(s) on which the drug shows activity. Examples include, RT, PR, INTG, GP120, CCR5 etc.
MUTATIONS	VARCHAR2(300)	Detailed mutaion sites in certain regions of viral proteins such as RT, PR etc.
DRUG_SEL	VARCHAR2(200)	Selectivity index for drug activity.
REL_RES_FOLD_INC_MOD	VARCHAR2(60)	This is for > or < and a text modifier for EC50(mutant)/EC50(wild type)
REL_RES_FOLD_INC	FLOAT(22)	EC50(mutant)/EC50(wild type)
ACT_RATING	VARCHAR2(40)	ACTIVE (EC50</=20uM), MOD ACTIVE (EC50>20 but </=50 uM), WK ACTIVE (EC50>50 but </=100 uM), INACTVE (EC50>100 uM)
COMMENTS	VARCHAR2(800)	Comments of interest identified in article.
CHEM_DATE	DATE	Date data was entered
CHEMIST	VARCHAR2(20)	Initial of data entry specialist
REVIEW_DATE	DATE	Date of data review
REVIEWER	VARCHAR2(20)	Initial of QC reviewer
SECURITY	CHAR(1)	Field that identifies data as public or proprietary
ROW_ID	NUMBER(10)	Row ID of data line
CELL_TYPE2	VARCHAR2(200)	Names of cells, parental cell lines