



REQUEST FOR PROPOSAL

Title: Central pharmacy services for a clinical trial titled Metformin in Alzheimer's dementia Prevention (MAP)

Due Date/Time: 5 PM December 5th 2024

Location: Columbia University Procurement Services
615 West 131st Street, 3rd Floor
New York, New York 10027

Columbia Representative(s):

Name: Michael Reich Director Lab & Medical Sourcing
Phone: 1 212 854 2337
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Name: Sam Cammack Research Manager Dept. of Medicine
Phone: 1 212 305 4057
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INFORMATION AND INSTRUCTIONS TO BIDDERS

Section 1 General Information to Bidders

Introduction:

Subject to the conditions set forth in this Request for Proposal, Columbia University is requesting **sealed** Bids for the following project:

Bid Name: Central pharmacy services for a clinical trial titled Metformin in Alzheimer's dementia Prevention (MAP)

Bid Deadline: PPM, 12/5/ 2024

Electronic Submission of Bids:

Columbia University Procurement Services
Mmr62@columbia.edu
For: Department of Medicine
Columbia University
615 West 131st Street, 3rd Floor
New York, NY 10027

Bidders may submit their Bids in accordance to instructions provided on page 7, Submission of Bids of this RFP document.

Columbia Representative(s):

Name: Michael Reich Director Lab & Medical Sourcing
Phone: 1 212 854 2337
E-mail: mmr62@columbia.edu

Name: Sam Cammack Research Manager Department of Medicine
Phone: 1 212 305 4057
E-mail: ac2239@cumc.columbia.edu

Definitions

Except as otherwise specifically provided, definitions are set forth as follows:

Columbia— Refers to Columbia University & Columbia University Irving Medical Center

Request for Proposal (RFP) - Refers to the document named Columbia’s Request for Proposal of Central pharmacy services for a clinical trial titled Metformin in Alzheimer’s dementia Prevention (MAP)

Addenda — Refers to the written or graphic instruments issued by the Columbia Representative prior to the Bid Deadline, which modifies or interprets the RFP by additions, deletions, clarifications, or corrections.

Bidder – Refers to the firm that is interested in and/or responds to the RFP.

Bid - Refers to all documents that the Bidder must submit to the Columbia Representative prior to the Bid Deadline.

Bid Deadline - Refers to the time and date indicated in the RFP as the latest date and time that a Bid will be accepted.

Contract – Refers to the final agreement reached between the successful Bidder and Columbia.

Contractor - The term Contractor shall mean the successful Bidder awarded the Contract.

Subcontractor — The term Subcontractor shall mean any individual, company, or corporation to whom the Contractor assigns any part of the Contract.

Code of Conduct and Fair Competition

It is the responsibility of the Bidder to notify the Columbia Representatives in writing of any possible conflict of interest as set forth below. Columbia will investigate the matter and determine if an actual conflict of interest exists.

A conflict of interest arises when a Columbia employee, officer or agent involved in the RFP process or Contract has a financial or any other interest in a Bidder. If a conflict of interest exists, the Bidder may not submit a Bid.

Columbia employees, officers and agents may neither solicit nor accept gratuities, favors, or anything of monetary value from Bidders, Contractors, or parties to sub-agreements. Any such actions must be reported to the Columbia Representatives immediately.

Columbia reserves the right to cancel the award if, in its sole discretion, it determines that any interest

disclosed from any source could give the appearance of a conflict or cause speculation as to the objectivity of the program to be developed by the Bidder. Columbia's determination regarding any questions of conflict of interest shall be final.

Compliance with Federal, State and Local Laws

Bidder warrants in submitting a Bid and in the performance of an award as a result of the Bid, that Bidder has complied with, or will comply with, all applicable federal, state, University, and local laws, ordinances and all lawful orders, rules and regulations hereunder. The Bidder, by submitting the Bid or performance that results from an award by Columbia, agrees not to discriminate against any employee or applicant based on an individual's race, color, religion, religious creed, ancestry, national origin, age (except minors), sex, sexual orientation, marital status, medical condition (cancer-related) and disability, and otherwise as required or permitted by law. Bidder further agrees that any sub-contract will contain a provision requiring non-discrimination in employment as specified above. Any breach of this provision may be regarded as material breach of contract and cause for cancellation.

Limitation of Liability

Columbia makes no representations, warranties, or guarantees that the information contained herein is accurate, complete, timely, or that such information accurately represents the conditions that would be encountered in pursuing the work or at the site(s) of work now or in the future. The furnishing of such information by Columbia shall not create or be deemed to create any obligation or liability upon it for any reason whatsoever and each Bidder, by submitting its Bid, expressly agrees that it has not relied upon the foregoing information, and that it shall not hold Columbia liable or responsible therefore in any manner whatsoever. Accordingly, nothing contained herein and no representation, statement or promise, of Columbia, its directors, officers, agents, representatives, or employees, oral or in writing, shall impair or limit the effect of the warranties of the Bidder required by this Request for Bid and that it shall not hold Columbia liable or responsible therefore in any manner whatsoever.

Neither the Trustees of Columbia, nor any officer, agent, or employee thereof shall be charged personally with any liability by a Bidder or another or held liable to a Bidder or another under any term or provision of this RFP or any statements made herein or because of the submission or attempted submission of a response hereto or otherwise.

Qualification of Bidder

Bidder must possess the potential ability to perform successfully under the terms and conditions set forth in the RFP. Consideration shall be given to such matters as Bidder integrity; record of past performance; and financial and technical resources.

Columbia shall make such investigations as deemed necessary to determine the ability of a Bidder to provide the specified equipment and perform professional services.

Columbia reserves the right to reject any Bid if the evidence submitted by, or investigation of, such Bidder fails to satisfy Columbia that said Bidder is properly qualified to carry out the obligations of the final Contract.

Section 2 Submission of Bids

Preparation of Bid

By submission of its Bid, the Bidder agrees that the Bid is predicated upon the acceptance of all the terms and conditions stated in the Request for Proposal, unless specifically excluded by the Bidder in its Bid. Part or all of the RFP and the successful Bid may be incorporated into the Contract.

Each Bidder shall furnish the information and documents required by the RFP. Failure to submit all required information may deem a Bid as non-responsive. Columbia is exempt from Federal Excise Taxes and is also exempt from New York State and local sales or use taxes. All costs associated with the Contract must be stated in U.S currency. By submitting a Bid, Bidder certifies that the prices proposed have been arrived at independently, without consultation, communication or agreement for the purpose of restricting competition as to any matter relating to such prices with any other Bidder or competitor. Bidders are cautioned to write all descriptions and prices clearly so there is no doubt as to the intent and scope of the Bid.

A person who is legally authorized to bind Bidder to a Contract shall sign the Bid. A Bid submitted by an agent shall have a current Power of Attorney attached, which evidences the agent's authority to bind Bidder. The person signing the Bid shall initial erasures or other changes.

Unnecessarily elaborate Bids beyond what is sufficient to present a complete and effective Bid are not desired and may be construed as an indication of the Bidder's lack of cost consciousness. Elaborate artwork, expensive paper and bindings are neither necessary nor desired. The cost incurred for the preparation of the Bid is the sole responsibility of the Bidder. Columbia does not assume any liability for any pre-contract activity and/or cost incurred by Bidders responding to this RFP.

Bid information is not considered confidential or proprietary. Trade secrets and other proprietary data contained in Bids may be held confidential if the Bidder requests, in writing, that Columbia does so, and if Columbia agrees, in writing, to do so. Material considered confidential by the Bidder must be clearly identified. Such confidential/proprietary information must be easily separable from the non-confidential sections of the Bid. Marking the entire Bid as proprietary will be neither accepted nor honored. Notwithstanding any of the foregoing, Columbia reserves the right to use any of the ideas presented in any reply, Bid, discussion, negotiations or presentation related to the RFP.

If a Bidder intends to use subcontractor(s), the Bidder must identify in its Bid the names of the subcontractors and the portions of the work the subcontractors will perform.

Communications Regarding the RFP

Requests for clarification and interpretations of the RFP must be made in writing via email during the period of 11/18/2024 through 11/26/2024. All questions regarding the RFP shall be directed to the Columbia Representatives in writing by e-mail. Two types of questions generally arise. One may be answered by directing the questioner to a specific section of the RFP. Other questions may be more complex and may require a written amendment to the RFP. The Columbia Representatives will make that decision.

The Columbia Representatives shall make clarifications, interpretations, corrections, and changes to the

RFP by written Addenda as specified below. **Questions will not be answered and clarification will not be given after 12/2/2024.**

Addenda to RFP

Addenda to the RFP will be issued in writing and will be communicated to all Bidders by e-mail and shall become part of the RFP. If the RFP is amended, all terms and conditions that are not modified by the Addenda remain unchanged and in effect as written. If an addendum is issued after Bids have been received and/or after a short list has been developed, the addendum may be provided only to those who submitted Bids or only to those on the short list, in the sole discretion of Columbia.

Each Bidder shall be responsible for making sure it has received all issued Addenda prior to submitting a Bid. **Addenda may be issued through 12/2/2024.**

Columbia reserves the right to change the RFP schedule and to issue addenda. Columbia also reserves the right to cancel, reissue, or to make corrections or amendments to the RFP due to errors or changes identified by Columbia or suggested by a Bidder, and to otherwise modify the terms of the RFP at any time in its sole discretion.

Submission of Bids

Bids are to be received in the designated office on or before the date and time specified as the Bid Deadline in the RFP. **Oral, telephone or facsimile Bids will not be considered.** If a Bid is to be sent by email as instructed in this section, a specific email address will be provided to the bid participants.

In the event it is required for physical bid proposals to be provided, bids shall be submitted in a sealed envelope or package as follows:

- 1 Addressed to the address specified on the cover page of this RFP,
2. Show the Bid Name, “Central pharmacy services for a clinical trial titled Metformin in Alzheimer’s dementia Prevention (MAP)
3. Give the Bidder’s name, primary contacts address, and
4. Show the date and time of the Bid Deadline as specified in this RFP

Please be sure to include one electronic copy of the Bid Proposal.

Columbia, or any Columbia representatives, officers, or employees, will not be held responsible for the pre-opening of, post-opening of, or the failure to open a Bid not properly addressed and identified.

Alternate or Substitute Bids

Bidders may submit more than one Bid. Alternate or substitute Bids must comply with the terms and conditions of the RFP and must contain all required documents as specified in the RFP.

Columbia is seeking Bids that meet its **minimum** requirements as outlined in the Scope of Work. If more than one method of meeting these requirements is proposed, each should be labeled primary, secondary, etc., submitted separately, and they will be evaluated in the specific priorities.

Late Submissions, Modifications, and Withdrawals of Bids

Late Bids: Bids received after the specified Bid Deadline will not be considered and shall be returned to the Bidder unopened.

Bid Modifications: Prior to the Bid Deadline, a submitted Bid may be modified by written notice, signed by a duly authorized person on behalf of the Bidder, to the Columbia Representative. The written notice shall be worded as not to reveal the amount of the original Bid.

Bid Modifications must contain all required documents as specified in the RFP. Failure to submit all required information can deem the Bid Modification as non-compliant and the contents of the Bid Modification will not be considered.

A previously submitted Bid will not be returned, unless written notice, signed by a duly authorized person, from the Bidding Company is received by the Columbia Representative.

Bid Withdrawal Notifications: Prior to the Bid Deadline, a submitted Bid may be withdrawn by written notice to the Columbia Representative up until the Bid Deadline. Written requests to withdraw must be signed by a duly authorized person on behalf of the Bidder and shall not reveal the amount of the Bid. Bids may not be modified, or withdrawn after the Bid Deadline.

A withdrawn Bid may be resubmitted prior to the Bid Deadline. All resubmitted Bids must fully comply with the RFP. Columbia will only consider the latest version of the Bid.

Section 3 Evaluation of Bids

Opening of Bids:

The assigned Columbia Representatives will not accept Bids received by the designated recipient after the specified date and time. Bid services and pricing will not be publicly announced. Bids will be reviewed and evaluated by Columbia. At any time, and from time to time after the opening of the Bids, Columbia may give oral or written notice to one or more Bidders to furnish additional information relating to its Bid and/or qualifications to perform the services contained in the RFP, or to meet with designated representatives of Columbia. The giving of such notice shall not be construed as an acceptance of a Bidder's Proposal.

All materials submitted in response to this RFP become the property of Columbia. Selection or rejection of a response does not affect this right. All copyright of materials produced under any contract or subcontract awarded as a result of this RFP shall be retained by Columbia. All forms of documents and data generated as a result of this contract are owned by and shall be delivered to Columbia at the direction of the Columbia Representative. During the period of performance, the information may not be disclosed by the Bidder to third parties, except as expressly provided in the Contract, without the written permission of the Executive Director of Purchasing.

Postponement of Bid Opening

If an emergency or unanticipated event interrupts normal University processes to cause the postponement of the scheduled Bid opening or the issuance of an addenda, the Columbia Representative will issue, in writing, to all Bidders, the new timeline and process.

Bid Evaluation and Selection Criteria

Evaluation Criteria

Columbia may use a variety of procedures and techniques in evaluating Bids and Bidders, including, but not limited to, creating a short list of Bidders, using upset levels, banding, comparative pairing, and price conversion techniques, requesting Best and Final Offers, conducting discussions, oral interviews and presentations, site visits, and negotiations, checking references, determining financial capability, and performing reevaluations of Bids as necessary. Through use of any procedure or technique, Columbia may limit the number of Bids to one or more that it will continue to consider. Columbia reserves the right to reject any Bid that does not meet prerequisites or minimum requirements or which scores below average on any of the criteria.

For Bids that are being engaged through the use of Sponsored funds, the evaluation criteria will be provided as an additional appendix of this RFP document.

Selection

Columbia reserves the right to make an award without further discussion of the Bids submitted; there may be no best and final offer procedure. Interviews and negotiations may be conducted with one or more of the Bidders, but there shall be no obligation to receive further information from any Bidder. Therefore each initial offer should contain the Bidder's best terms from a cost or price, service, and technical standpoint.

Columbia may consult references familiar with the Bidder regarding its prior operations and projects, financial resources, reputation, performance, or other matters. Submission of a Bid shall constitute permission for Columbia to make such inquiries and authorization to third parties to respond thereto.

Columbia may elect to initiate contract negotiations with one or more Bidders including negotiation of costs/price(s) and any other issues or terms and conditions, including modifying any requirement in the RFP. The option of whether or not to initiate contract negotiations rests solely with Columbia. No Bidder shall have any rights against Columbia arising from such negotiations. The Bidders will be responsible for their travel and per diem expenses, required for any presentations, discussions, and/or negotiations.

Columbia reserves the right to award the Contract to a supplier other than the Bidder presenting the lowest price. The Contract resulting from this solicitation will be awarded to the Bidder(s) whose Bid(s) Columbia believes will be the most advantageous to Columbia. The release of the RFP does not compel Columbia to purchase or to make an award. Columbia shall not be obligated in any manner to any Bidder whatsoever until a written Contract has been duly executed relating to an approved Bid.

Columbia reserves the right to award multiple contracts for the products, work and/or services that are the subject matter of this Bid and Bidder(s) are hereby given notice that they may not be Columbia's only Contractor or Bidder for such products, work and/or services.

As a result of the selection of a Bidder to supply products and/or services to Columbia, Columbia is neither endorsing nor suggesting that the Bidder's product or service is the best or only solution. The Bidder agrees to make no reference to Columbia in any literature, promotional material, brochures, sales presentation or the like without the express written consent of Columbia.

The Bidder will be expected to enter into a Contract with Columbia which is substantially the same as the contract included with this RFP. In no event is a Bidder to submit its own standard contract terms and conditions as a response to this RFP. If a Bidder objects to any of the provisions of Columbia's standard contract, it must identify in the Bid any clauses which are unacceptable and the reasons or problems and propose alternatives. The foregoing should not be interpreted to prohibit either party from proposing additional contract terms and conditions during negotiation of the final contract.

Rejection of Bids

Columbia has the right to reject any and all Bids for any reason.

Notification of Award

The Columbia Representative will issue "Notification of Award" letter(s) once a selection has been made.

Section 4 University Background Information

General Information

Columbia University Medical Center (CUMC) is a recognized leader in providing excellent patient care. The CUMC physicians, dentists, and nurses bring expertise from leading-edge research to benefit care delivered in offices, clinics, schools, nursing practices, and hospitals throughout the New York City metro area. CUMC is affiliated with major hospitals in New York City, including New York-Presbyterian Hospital and the New York State Psychiatric Institute, as well as hospitals in greater New York, New Jersey, Connecticut, and overseas.

Columbia University is an independent, privately supported, non-sectarian institution of higher education. One of the country's leading research universities, it seeks to make significant original contributions to the development of knowledge, to preserve and interpret humanity's intellectual and moral heritage, and to transmit that heritage to future generations of students. It pursues these missions through research and educational programs in a wide range of disciplines in the humanities, social sciences, the natural, biomedical and applied sciences, and various professions, and through cooperative agreements with other educational institutions, research centers and hospitals in the greater New York region, throughout the country and abroad.

The Division of General Medicine at Columbia University Irving Medical Center was founded in 1977, followed by its faculty group primary care practice, the Associates in Internal Medicine (AIM), in 1979. The Division of General Medicine's research program has grown over two decades to about \$20 million per year in federal funding. The division has multi-disciplinary strength in areas that include epidemiology, health behavior, behavioral medicine, psychology, and health services research. Specific areas of research focus include cardiovascular epidemiology and modeling of prevention and treatment strategies, hypertension, epidemiology of chronic pulmonary diseases, research on disparities in health and aging, and behavioral and psychosocial determinants and interventions for hypertension and cardiovascular disease.

The Section on Geriatrics, Gerontology, and Aging conducts epidemiological, translational, and intervention research in various areas of aging and Alzheimer's Disease and related dementias (ADRD). These areas include research in risk factors and prevention of ADRD and cognitive impairment including observational studies and clinical trials, research in the health of caregivers of persons with ADRD including observational studies and clinical trials, aging and brain outcomes of diabetes and related metabolic conditions including human and animals studies, detection of cognitive impairment in primary care and community settings, and health disparities in aging and ADRD. The research program is currently supported by research grants from NIA (R01AG058571, R01AG058969, R01AG050440, AG051556, AG055299, AG057898), NINR (R01NR014430), and NIDDK (U01DK04804, U01DK098246). The Section also includes a mentoring program supported by grants from NIA (K24AG045334, P30AG05903).

BIDDER'S DECLARATION

This Bid is in response to Columbia’s request for a Bid (“RFP”) for Central pharmacy services for a clinical trial titled Metformin in Alzheimer’s dementia Prevention (MAP)

This Bid consists of:

- Information & Instructions for Bidders
- Bid Part I - Bidder’s Declaration
- Bid Part II - Bidder Questionnaire
- Bid Part III - Scope of Work (“SOW”)
- Bid Part IV - Exceptions to Columbia Terms & Conditions and Appendix A

Bidder agrees to perform in accordance with all provisions of the RFP documents and any addenda thereto, except as may be specifically stated in this Bid, at the prices set forth herein.

Bidder agrees that this Bid is a firm offer to Columbia which cannot be withdrawn for 120 calendar days from and after the Bid due date.

Bidder certifies that it has thoroughly examined and fully understands all of the provisions of the RFP and the conditions of the contract documents attached thereto, as well as any addenda issued prior to the due date; that it has carefully reviewed and fully supports the accuracy of its Bid; has satisfied itself as to the nature and location of all work, the technical, general, and local conditions to be encountered in the performance of any work, the requirements of the Contract and all other matters which may in any way affect performance or the cost thereof; and that Columbia shall not be responsible for any errors or omissions on the part of the undersigned in preparing this Bid.

If awarded a Contract, Bidder agrees to execute the Contract and deliver it to Columbia within 15 calendar days, of such award, along with any required certificates of insurance.

_____ Authorized Signatory	_____ Title
_____ Company Name	_____ Date
_____ Company Address	
_____ Telephone Number	_____ Federal Taxpayer I.D. Number
_____ Email Address	_____ DUNS Number

BIDDER QUESTIONNAIRE

A. Bidder Business Structure

Provide your company's name and address, and the primary RFP contact's name, phone number, e-mail address and fax number.

C. Business Information

1. List any material claim asserted or threatened against Bidder that may have a significantly adverse effect on Bidder or adversely affect Bidder's ability to provide the goods or services required by this RFP.
2. List any business issue currently confronted by Bidder that may have a significantly adverse effect on Bidder or adversely affect Bidder's ability to provide the goods or services required by this RFP.
3. List 1 of your customers using the service covered by this Bid similar in size, industry sector, and geographical presence to Columbia. Please provide:
 - Customer name and address
 - Customer employee size
 - Contact names and telephones (business and technical)
 - Brief description of the service provided
 - How long has Customer been using Bidder to provide services?
5. Describe other current products/services Bidder has provided to Columbia (if applicable).
6. Describe any existing or pending contracts between Bidder and Columbia.
7. List the name and location of primary individual(s) who would be responsible for our account and provide a CV.

SCOPE OF WORK (“SOW”)

In support of an NIH/NIA funded multi-center clinical trial entitled: Metformin in Alzheimer’s Dementia Prevention (MAP), the provider will provide central pharmacy services for the 18 clinical sites participating in the study. Sites listed below: The details of the services are as follows:

- The study drugs, 140-count bottles of metformin 500 mg tablets and matching placebo tablets will require storage at 15-30°C and will be shipped via FedEx 2Day under ambient conditions.
- The provider will label the study drug and configure 1,980 of the 140-count bottles into kits of six (6) bottles each that will each contain two (2) 3-month sub-kits.
- Each of the 18 sites is expected to receive an average of approximately 18 shipments for a total of 330 shipments over the remaining 2 years of the study.
- The provider will interact weekly with the Prelude IRT like system to allocate as efficiently as possible the remaining IP inventory to support 18 months of dosing for up to 336 patients.
- Sites will be responsible for the destruction of any study drug remaining at their site in accordance with their institution’s policies. The provider’s budget must include processing a return from five of the 18 sites.
- In the event that the provider’s total number of shipments exceeds 330 shipments, the provider should propose any additional fees to be billed per shipment (include shipment preparation and Prelude IRT data entry).
- In the event that the provider is required to support the study longer than 24 months propose any additional project management, document management, and warehouse storage fees will be incurred and billed on a monthly basis.
- All study drug remaining in provider’s warehouse at the end of the study will be reconciled and sent for destruction. The cost for destruction should be included in the proposed budget.

Pricing Proposal Format

The pricing proposal should include, at a minimum, a breakdown, with unit costs, of the following details.

Incoming materials handling

Processing/Labeling

Shipment preparation

Data entry and maintenance

Returns handling

Courier fees

Project management and administration

Inventory disposal

List of Study Sites:

Columbia University
Boston University
SUNY-Upstate
University at Buffalo
Georgetown University
Old Dominion University (Eastern Virginia Medical School)
Wake Forest
University of Miami
University of Cincinnati
Medical School of Wisconsin
Rush University
University of Kansas
University of Texas Southwestern
University of Texas San Antonio
University of New Mexico
University of California, Irvine
Stanford University
University of Washington

NO-BID FORM

RFP TITLE: _____

RFP # : _____

Bidders choosing not to bid are requested to complete the portion of the form below:

It is our intention not to submit a proposal for the following reason(s):

- _____ we do not provide the requested services
- _____ we do not provide the requested goods
- _____ we are unable to meet the minimum qualifications
- _____ due to other engagements we would be unable to support this proposal
- _____ due to a conflict of interest we are unable to submit a proposal
- _____ other (*please provide additional rationale below*)

Signature: _____

Name: _____

Title: _____

APPENDIX A

Vendor to Provide Standard Service Agreement Template for Review

APPENDIX B

Evaluation criteria include, in no particular order:

Compatibility with current systems for management of investigational product

Price

Previous experience with multisite clinical trials.

Demonstrated capacity to label IP bottles.

Demonstrated capacity to track drug inventory using systems compatible with the MAP study.

Demonstrated compatibility of IT systems with the Electronic Data Capture system in the MAP study.

Demonstrated capacity to ship IP kits to 18 study sites.

Demonstrated capacity to interact with local research pharmacies at 18 study sites.