

Request for Quote/Proposal (RFQ/RFP)

Commodity/Service Required:	500 mg Azithromycin pills and placebo pills
Type of Procurement:	Purchase Order
Type of Contract:	Fixed Price
Term of Contract:	Approximately 2 years
Contract Funding:	11010704 PHS-NIH (NICHD)
This Procurement supports:	The Global Network for Women's and Children's Health Research
Submit Proposal to:	RTI International Email: mjallow@rti.org
Date of Issue of RFP:	December 14th, 2018
Date Questions from Supplier Due:	December 28th, 2018
Date Proposal Due:	January 21st, 2019 (Extended Date)
Approximate Date Purchase Order Issued to Successful Bidder(s):	Anticipated around March 2019

Method of Submittal:	
Email at mjallow@rti.org	
Respond via e-mail w/ formal quote attached. Offeror's Quote must be signed, printed on company letterhead, and must include all items and/or services in order to be considered for evaluation. The Offeror agrees to hold the prices in its offer firm until the full execution of the resulting contract(s), unless another time is specified in an addendum to this RFQ/P.	
	SSES-PHS-FY15-001 (Amended)

Attachments to RFP:

1. Attachment "A" – Commodity Specifications
2. Attachment "B" – Instructions to Bidders/Suppliers
3. All PO Terms and Conditions are listed on our website at: <http://www.rti.org/POterms>, http://www.rti.org/files/PO_FAR_Clauses.pdf or for commercial items: http://www.rti.org/files/PO_FAR_Clauses_Commercial_Items.pdf (hereinafter the "Terms"). Supplier's delivery of products, performance of services, or issuance of invoices in connection with this purchase order establishes Supplier's agreement to the Terms. The Terms may only be modified in writing signed by both parties.

All bidders/suppliers are responsible to carefully review each attachment and follow any instructions that may be relevant to this procurement.

Attachment A

Commodity Specifications/Statement of Work

Description of Activity/Service:

The Global Network for Women's and Children's Health Research is an international collaborative research network funded by the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development (NICHD). This network has been conducting research for over 15 years and is currently planning a clinical trial to test the use of 2 g azithromycin, provided as four (4) 500 mg pills or (2) 1g pills, for improved birth outcomes.

RTI International is requesting pricing information to evaluate and select a supplier to produce the azithromycin study drug and identical placebo. Please note that all activities listed must be conducted by the selected supplier and included in the proposal. All activities must meet GMP standards.

1. Initial project set up fees and cost of obtaining labeling and packaging license from local regulatory authorities, as applicable, and export certification documentation.
2. Define shelf life of manufactured 500 mg azithromycin and identical placebo.
3. Along with the QC Certificates, provide the detailed description of manufacturing facilities; details of your organization's approvals, and other regulatory certifications, including. GMP certification, US FDA / FDA or other regulatory approvals for the 7 countries listed.

Product or Service Expectations (both if applicable):

1. Packaging

Blister packs – 2 g total for each patient dose of Azithromycin or identical placebo pills packaged in either of the two below presentations (Include the cost of raw materials):

1. One blister pack of four (4) 500 mg pills or
 2. Two blister packs packaged together with two (2) 500 mg pills per blister pack.
2. Design and print label for each blister package incorporating the corresponding randomization identification number (Obtained from RTI International). Include the cost of materials.
3. Supplier provides Quality Assurance testing to RTI International prior to shipment. In addition, independent quality assurance testing will be contracted by RTI International prior to payment being authorized. Samples of product should be provided for each batch run and be of enough quantity to adequately test chemically.
4. Package drugs in blister packs with randomization identification number. The package labeling must not reveal the randomization assignment.
5. Products must be shipped to research sites in the following countries (Please confirm registration status or any other regulatory requirement to ship these items to these countries): Pakistan (Karachi), India location 1 (Nagpur), India location 2 (Belagavi), Kenya (Nairobi), Democratic Republic of Congo (Kinshasa), Zambia (Lusaka), Guatemala (Guatemala City), and Bangladesh (Dhaka). The cost of shipping materials will be the responsibility of RTI International.
6. Maintenance of documentation for up to 4 years.

Deliverables, Timelines, Special Terms and Conditions:

Shipment within 3 months of the award (anticipated in March/April 2019). While 3 months is ideal, if it does not seem feasible, please propose an alternative timeline. Winning bidder will work with RTI's shipping and Logistics team to coordinate logistics, pick-up, and delivery of all shipments.

Pricing

Please use either cost table as appropriate for the presentation you are proposing. If you are able to provide either or both presentations, please fill out both tables.

Item #	Quantity to be Purchased	Description of Preferred Commodity or Services Specifications	Unit of Measure	Unit Fixed Price (Each)	Total Fixed Price (Each)	Lead Time Availability (Number of Days)
1	80,000	Azithromycin pills 500 mg in blister packs, 4 pills per pack	pills			
2	80,000	Placebo pills in blister packs, 4 pills per pack	pills			
Total Count	160,000	Total Cost				

Item #	Quantity to be Purchased	Description of Preferred Commodity or Services Specifications	Unit of Measure	Unit Fixed Price (Each)	Total Fixed Price (Each)	Lead Time Availability (Number of Days)
1	80,000	Azithromycin pills in two blister packs packaged together with two (2) 500 mg pills per blister pack	pills			
2	80,000	Placebo pills in two blister packs packaged together with two (2) 500 mg pills per blister pack	pills			
Total Count	160,000	Total Cost				

Signature:

Name and Title:

Date:

By signing this attachment, the bidder confirms he has a complete understanding of the specifications and fully intends to deliver items that comply with the above listed specifications.

Attachment “B” Instructions to Bidders/Suppliers

1. **Procurement Narrative Description:** The Buyer (RTI) intends to purchase commodities and/or services identified in Attachment A. The Buyer intends to purchase the quantities (for commodities) and/or services (based on deliverables identified in a Statement of Work). The term of the Ordering Agreement shall be from Award Date to the Delivery date of the Offeror unless extended by mutual agreement of the parties. The Buyer intends to award to a single “approved” supplier based on conformance to the listed specifications, the ability to service this contract, and selling price. We reserve the right to award to more than one bidder. If an Ordering Agreement is established as a result of this RFQ/RFP, supplier understands that quantities indicated in the specifications (Attachment A) are an estimate only and RTI does not guarantee the purchase quantity of any item listed.
2. **Procuring Activity:** This procurement will be made by **Research Triangle Institute (RTI International)**, located at

3040 Cornwallis Road RTP, NC 27709 USA

who has a purchase requirement in support of a project funded by

11010704 PHS-NIH (NICHD)

RTI shall award the initial quantities and/or services and any option quantities (if exercised by RTI) to Supplier by a properly executed Purchase Order as set forth within the terms of this properly executed agreement. Supplier understands that quantities indicated in the specifications (Attachment A) are an estimate only and RTI does not guarantee the purchase quantity of any item listed. RTI does not guarantee and is not responsible for the purchase of quantities over the minimum quantity amount listed within this RFQ/P.

RTI reserves the right to extend any agreement resulting from an award of this sourcing effort for additional periods beyond the base period of award date. In addition, RTI may add or remove products and/or countries to the initial profile indicated in Attachment A as requirements may change throughout the life of the contract period

3. **Proposal Requirements.** All Suppliers will submit a quote/proposal which contains offers for all items and options included in this RFQ/RFP. All information presented in the quote/proposal will be considered during RTI’s evaluation. Failure to submit the information required in this RFQ/RFP may result in Supplier’s offer being deemed non-responsive. Suppliers are responsible for submitting offers, and any modifications, revisions, or withdrawals, to reach RTI’s office designated in the RFQ/RFP by the time and date specified in the RFQ/RFP. Any offer, modification, revision, or withdrawal of an offer received at the RTI office designated in the RFQ/RFP after the exact time specified for receipt of offers is “late” and may not be considered at the discretion of the RTI Procurement Officer. The Supplier’s proposal shall include the following:

a) The solicitation number:

b) The date and time submitted:

c) The name, address, and telephone number of the supplier (bidder) and authorized signature of same:

d) Validity period of Quote:

e) **Supplier Qualification:** Please provide:

- I. Documentation that details the procedures to review and approve suppliers/manufacturers of Azithromycin and placebo pills and other relevant documentation to attest to the quality assurance processes.
- II. Copy of the most current audit report for each pre-approved manufacturer of Azithromycin and placebo pills.
- III. Provide Good Manufacturing Practice (GMP) compliance documentation.

f) A technical description of the items being offered in enough detail to evaluate compliance with the requirements in the solicitation. This includes product literature, including the product insert, or other documents, if necessary.

g) **Lead Time Availability of the Commodity/Service.** Please provide listed availability date or acknowledgement of availability to meet the requested availability date submitted via Attachment A.

h) Terms of warranty describing what and how the warranties will be serviced.

i) Special pricing instructions: Price and any discount terms or special requirements or terms (special note: pricing must include guaranteed firm fixed prices for items requested. Note: The prices to be quoted are EX WORKS and the supplier will be expected to provide safe and controlled storage until the country requirements are known and a clear written instruction from RTI is given

to make the shipment. In the event the shipping terms for a particular are not EX WORKS, unique prices will be quoted for that order.

j) Payment address or instructions (if different from mailing address)

k) Acknowledgment of solicitation amendments (if any)

l) Past performance information, including clinical trials, when included as an evaluation factor, to include recent and relevant contracts for the same or similar items and other references (including points of contact with telephone numbers, and other relevant information)

m If RTI informs Supplier that the Commodity is intended for export and the Commodity is not classified for export under Export Classification Control Number (ECCN) "EAR99" of the U.S. Department of Commerce Export Administration Regulations (EAR), then Supplier must provide RTI the correct ECCN and the name of Supplier's representative responsible for Trade Compliance who can confirm the export classifications.

Special Note: *The Supplier, by his response to this RFQ/RFP and accompanying signatures, confirms that the terms and conditions associated with this RFQ/RFP document have been agreed to and all of its attachments have been carefully read and understood and all related questions answered.*

4. **Forms:** Suppliers (potential bidders or suppliers) must record their pricing utilizing the format found on Attachment "A". Suppliers must sign the single copy submitted and send to the email address listed on the cover page of this RFQ/RFP.
5. **Questions Concerning the Procurement.** All questions in regard to this RFQ/RFP to be directed to

Mohamed Jallow at mjallow@rti.org

6. **Notifications and Deliveries:** Time is of the essence for this procurement. Supplier shall deliver the items or services no later than the dates set forth in the contract that will be agreed by both parties as a result of this RFQ/RFP. The Supplier shall immediately contact the Buyer's Procurement Officer if the specifications, availability, or the delivery schedule(s) changes. If the delivery is delayed in excess of 4 weeks, then RTI reserves the right to cancel the order and can hold the supplier in default and liable for any additional cost.
7. **Documentation:** The following documents will be required for payment for each item:
 - (a) A detailed invoice listing Purchase Order Number, Bank information with wiring instructions (when applicable)
 - (b) Packing List
 - (c) All relevant product/service documentation (manuals, warranty doc, certificate of analysis, etc.)
8. **Payment Terms:** Refer to RTI purchase order terms and conditions found in www.rti.org/potermis, <http://www.rti.org/POterms>, http://www.rti.org/files/PO_FAR_Clauses.pdf, or http://www.rti.org/files/PO_FAR_Clauses_Commercial_Items.pdf. Payment can be made via wire transfer or other acceptable form. Suppliers may propose alternative payment terms and they will be considered in the evaluation process.
9. **Alternative Proposals:** Suppliers are permitted to offer "alternatives" should they not be able to meet the listed requirements. Any alternative proposals shall still satisfy the minimum requirements set forth in Attachment A Specifications.
10. **Inspection Process:** Each item shall be inspected prior to final acceptance of the item. All significant discrepancies, shortages, and/or faults must be satisfactorily corrected and satisfactorily documented prior to delivery and release of payment.
11. **Splitting Orders:** RTI prefers that orders ship complete and according to the specification requested in a confirmed Purchase Order. Splitting of shipments will only be entertained in emergencies and will be done so only with RTI approval.
12. **Evaluation and Award Process:** The RTI Procurement Officer will award an agreement contract resulting from this solicitation to the responsible Supplier (bidder) whose offer conforms to the RFQ/RFP will be most advantageous to RTI, price and other factors considered. The award will be made to the Supplier representing the **best value** to the project and to RTI. For the purpose of this RFQ/RFP, price, delivery, technical and past performance are of equal importance for the purposes of evaluating and selecting the "best value" awardee.

RTI intends to evaluate offers and award an Agreement without discussions with Suppliers. Therefore, the Supplier's initial offer should contain the Supplier's best terms from a price and technical standpoint. However, RTI reserves the right to conduct discussions if later determined by the RTI Procurement Officer to be necessary.

The evaluation factors will be comprised of the following criteria:

- (a) **PRICE.** Lowest evaluated ceiling price (inclusive of option quantities).
- (b) **DELIVERY.** Supplier provides the most advantageous delivery schedule.
- (c) **TECHNICAL.** Items/Services shall satisfy or exceed the specifications described in RFQ/RFP Attachment A.
- (d) **PAST PERFORMANCE** - Supplier can demonstrate his/her capability and resources to provide

the items/services requested in this solicitation in a timely and responsive manner.

(e) OTHER EVALUATION CRITERIA.

The prospective supplier is responsible and must be able to perform its obligations to demonstrate that the product that is being offered is licensed and the company is registered (or plan to be registered within 1 month of the award) in the countries requested.

13. **Award Notice.** A written notice of award or acceptance of an offer, mailed or otherwise furnished to the successful supplier within the time acceptance specified in the offer, shall result in a binding contract without further action by either party.
14. **Validity of Offer.** This RFP in no way obligates RTI to make an award, nor does it commit RTI to pay any costs incurred by the Supplier in the preparation and submission of a proposal or amendments to a proposal. Your proposal shall be considered valid for 90 days after submission.
15. **Representations and Certifications.** Winning suppliers under a US Federal Contract are required to complete and sign as part of your offer RTI Representations and Certifications for values over \$10,000.
16. **Anti- Kick Back Act of 1986.** Anti-Kickback Act of 1986 as referenced in FAR 52.203-7 is hereby incorporated into this Request for Proposal as a condition of acceptance. If you have reasonable grounds to believe that a violation, as described in Paragraph (b) of FAR 52.203-7 may have occurred, you should report this suspected violation to the RTI's Ethics Hotline at 1-877-212-7220 or by sending an e-mail to Ethics@rti.org. You may report a suspected violation anonymously.

Acceptance:

Supplier and buyer agree, as evidenced by signatures below, that the supplier's completed and signed solicitation, supplier's proposal including all required submissions and the negotiated terms contained herein, constitute the entire agreement for the services described herein.

By:
(Supplier Company Name)
Signature: Title: Date:
