

REVISED

REQUEST FOR PROPOSALS #0228A

CONSULTANT FOR DATA COLLECTION AND STUDY IMPLEMENTATION

In Support Of

ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION (“EGPAF”)

1140 Connecticut Avenue, NW

Suite 200

Washington, DC 20036

Revised Firm Deadline: March 15, 2019 5 PM EST

The Elizabeth Glaser Pediatric AIDS Foundation, a non-profit organization, is the world leader in the fight to eliminate pediatric AIDS. Our mission is to prevent pediatric HIV infection and to eliminate pediatric AIDS through research, advocacy, and prevention and treatment programs. For more information, please visit <http://www.pedaids.org>.

BACKGROUND

In response to a gap in the availability of second- and third-line treatment options for HIV-infected children and adolescents in the landscape of rapid scale-up of antiretroviral therapy (ART), Johnson & Johnson Global Public Health, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), and the Partnership for Supply Chain Management launched the *New Horizons Advancing Pediatric HIV Care Collaborative* in 2014. Since its establishment, several additional partners have joined the initiative, including Right to Care, the Relevance Network, and the Collaborative Initiative for Paediatric HIV Education and Research (CIPHER) of the International AIDS Society (IAS).

The mission of the Collaborative is to advance a holistic, integrated approach to high quality and sustainable pediatric and adolescent HIV care and treatment with a particular focus on those in need of second- and third-line medication. Key objectives of the Collaborative include: 1) addressing the gap between pediatric and adult HIV and AIDS treatment; 2) targeting challenges sustainable ART sustainability service delivery for children and adolescents; and 3) building awareness of and confronting challenges faced by adolescents concerning disclosure, adherence, psychosocial support, retention, and transition to adult care.

As a first step under the New Horizons Collaborative, a DRV/ETR *Donation Program* was launched in 2014 to increase access to pediatric HIV medicines for children experiencing ART failure. Under this program, Janssen is providing DRV (PREZISTA®) and/or ETR (INTELENCE®) free of charge to eligible national HIV/AIDS programs in sub-Saharan Africa, for use in children and adolescents up to 19 years of age. Upon turning 19 years (or before as required by the national HIV/AIDS program), patients using donated products will be transitioned into the countries' HIV treatment programs for adults as designated by the national HIV program.

PURPOSE/SCOPE OF WORK

In 2018, EGPAF began a multi-country study to collect cross-sectional demographic and clinical data at baseline and every six months for patients receiving donated products across participating

Revised 10-25-16

New Horizons donation program countries. This activity will comprise data abstraction of a key demographic, clinical, laboratory and case history indicators and outcomes on each patient who ever received DRV and/or ETR provided through the Donation Program.

This RFP seeks consultants to support this study in the following countries: Ethiopia, Nigeria, and Rwanda.

CONSULTANT RESPONSIBILITIES:

1. Ensure the safety and well-being of all study participants and scientific integrity of the study in-country.
2. Ensure the development of study-specific operating policies and standard operating procedures.
3. Responsible for completion and submission of the initial protocol package to all relevant institutional review boards/ethics committees (IRBs/IECs) according to the IRB/IEC requirements, ensuring that the same versions are approved by all IRBs/IECs prior to study implementation.
4. Responsible for ensuring that subsequent amendments and annual progress reports are submitted to all IRBs/IECs in a timely fashion.
5. Communicate directly with the local IRB/IEC, ensuring approval is received for the study and notifying the agency of research-related issues, as required.
6. Communicate directly with the local Ministry of Health stakeholders to build buy-in for the study, as required.
7. Monitor study progress with ongoing review of study implementation (timely enrollment, quality of data, follow-up rates, and overall progress in achieving study objectives). This requires conducting regular site visits, leading regular meetings with study team, and maintaining close communication with all Principal Investigators and Study Investigators.
8. Oversee all aspects of in-country data management.
9. Implement data entry and management activities, including data quality control.
10. Work closely with the Senior Biostatistician/Co-investigator to ensure high quality data collection, management, and analysis.

CONSULTANT DELIVERABLES

1. Country-specific data collection plan for the New Horizons study submitted to local IRB.
2. Initial protocol package submitted to all relevant IRBs/IECs.
3. Data collected every six months through the end of 2021 at all sites in the country receiving donated ARVs through the New Horizons donation program.

MINIMUM REQUIREMENTS:

1. Previous experience with data collection, management, and analysis (required).
2. Knowledge of local research regulations, requirements, and IRB/IEC processes (required).
3. Currently permitted to work in the country where the consultancy will be located (required).
4. Knowledge of second- and third-line antiretroviral therapy (preferred).

FOUNDATION RESPONSIBILITIES:

1. Orient consultant the study and drug donation program.

Revised 10-25-16

2. Share study-specific SOPs and other guidance.
3. Provide ongoing and routine support and communication during study implementation.

LOGISTICS:

The services will be provided at sites receiving antiretrovirals through the New Horizons drug donation program. Some annual travel and other travel (domestic and/or out of country) may be required. All travel must be specifically authorized in advanced by the Foundation.

KEY CONTRACT TERMS:

The anticipated contract type is a labor hour contract plus travel expenses in accordance with the Foundation’s travel policies. Unless stated otherwise in the statement of the work, the Consultant is responsible for providing equipment and/or supplies required to perform the services.

All deliverables provided to the Foundation must be furnished for the use of the Foundation without royalty or any additional fees.

All Materials will be owned exclusively by the Foundation. Consultant will not use or allow the use of the Materials for any purpose other than Consultant’s performance of the Contract without the prior written consent of the Foundation.

EVALUATION CRITERIA AND SUBMISSION REQUIREMENTS:

The Foundation will accept the proposal that presents the best value. All proposals will be evaluated against the following Evaluation Criteria. Each proposal must contain the items listed in the Submission Requirements column in the following chart. Please submit your Submission Requirements in the order that they appear below.

Evaluation Criteria	Submission Requirements	Weight
1. Past performance of similar work	1. Full CV including relevant and related past experience.	30%
2. Professional references	2. 2 professional references from similar past projects with phone and email contact information and one or more examples of prior similar work	20%
3. Timeframe of implementation	3. Estimated # of hours	30%
4. Total fixed price	4. Total fixed hourly rate for all activities	20%
Total		100%

All applicants are required to be registered and authorized to perform the scope of work in the place of performance. A copy of valid registration must be submitted with each proposal.

Revised 10-25-16

REVISED PROPOSED TIMELINE:

DATE: 2/26/19 – Release of Revised RFP

REVISED DUE DATE: 3/15/19 - Completed proposals must be delivered electronically by the deadline mentioned on page one to: Cathy Colbert, Senior Awards & Compliance Officer (ccolbert@pedaids.org) with a “cc” to Katie Wallner, Technical Officer (kwallner@pedaids.org).

DATE: On or about: 4/5/19 – Final decision announced and Offerors notified

DATE: On or about: 4/11/19 – Contract executed and Services begin.

Please note it is our best intent to comply with the above timeline but unavoidable delays may occur.

ADDITIONAL INFORMATION

Please include the RFP # reflected on the first page of this document on all proposals and e-mail communications.

Any proposal not addressing each of the foregoing items could be considered non-responsive. Any exceptions to the requirements or terms of the RFP must be noted in the proposal. The Foundation reserves the right to consider any exceptions to the RFP to be non-responsive.

Late proposals may be rejected without being considered.

This RFP is not an offer to enter into agreement with any party, but rather a request to receive proposals from persons interested in providing the services outlined below. Such proposals shall be considered and treated by the Foundation as offers to enter into an agreement. The Foundation reserves the right to reject all proposals, in whole or in part, enter into negotiations with any party, and/or award multiple contracts.

The Foundation shall not be obligated for the payment of any sums whatsoever to any recipient of this RFP until and unless a written contract between the parties is executed.

Equal Opportunity Notice. The Elizabeth Glaser Pediatric AIDS Foundation is an Equal Employment Opportunity employer and represents that all qualified bidders will receive consideration without regard to race, color, religion, sex, or national origin.

ETHICAL BEHAVIOR:

As a core value to help achieve our mission, the Foundation embraces a culture of honesty, integrity, and ethical business practices and expects its business partners to do the same. Specifically, our procurement processes are fair and open and allow all vendors/consultants equal opportunity to win our business. We will not tolerate fraud or corruption, including kickbacks, bribes, undisclosed familial or close personal relationships between vendors and Foundation employees, or other unethical practices. If you experience or suspect unethical behavior by a Foundation employee, please contact Doug Horner, Vice President, Awards, Compliance & International Operations, at [dhorner\[at\]pedaids.org](mailto:dhorner[at]pedaids.org) or the Foundation’s Ethics Hotline at www.reportlineweb.com/PedAids/ Any vendor/consultant who attempts to engage, or engages, in

Revised 10-25-16

corrupt practices with the Foundation will have their proposal disqualified and will not be solicited for future work.