TERMS OF REFERENCE
Request for Proposal for Adverse Drug Reaction (ADR) Monitoring Consultancy

SUMMARY	
Title	**Request for Proposal for Adverse Drug Reaction (ADR) Monitoring Consultancy**
Reference	**BZ-GF-2022-09-01**
Description *(Summary for website - 100 words max)*	Beyond Zero seeks to appoint a suitable Adverse Drug Reaction (ADR) Consultant to conduct a review of Beyond Zero operations and Improve Efficiency, Output and Value-added Services for a period of twelve (12) months.
Questions by email only to	tgf-procurement@beyondzero.org.za with the reference in the subject line. Questions may be submitted until 10 October 2022
Submission by email only to	tgf-procurement@beyondzero.org.za
Submission must include	1. CIPC Registration Documents 2. Certified ID Copies of the Directors 3. B-BBEE certificate (Failure on the part of a bidder to submit proof of B-BBEE Status level of contributor/Valid Sworn Affidavit together with the bid, will be interpreted to mean that preference points for B-BBEE status level of contribution are not claimed.) 4. Valid SARS Tax Clearance Certificate / PIN 5. VAT Registration Certificate or VAT Registration Letter (("VALUE ADDED TAX Notice of Registration") available on e-Filing for all expenditure more than R1 000 000 (where applicable) 6. Bank account verification letter 7. Signed Global Fund Code of Conduct for Suppliers of Services 8. Completed and Signed Declaration of Interest
Deadline for submission	**13h00 on Friday, 19 October 2022**

1. PURPOSE

1.1 Beyond Zero (BZ) seeks to appoint a suitable Adverse Drug Reaction (ADR) Consultant to conduct a review of BZ operations and Improve Efficiency, Output and Value-added Services for a period of twelve (12) months.

2. BACKGROUND

2.1 Since 2003, when BZ started acquiring extensive international donor grants, Adverse Drug Reaction monitoring (ADR) had been incorporated as one of its health strengthening and community service delivery activities. Adverse drug reaction (ADR) or adverse drug effect (ADE) are broad terms referring to unwanted, uncomfortable, or dangerous effects that a drug may cause. ADRs are one of the leading causes of morbidity and mortality globally.

2.2 WHO defines an ADR as any response to a drug that is noxious or unintended and that occurs at doses used in humans for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function. Adverse drug reaction reporting helps healthcare systems to detect the unwanted effects of those drugs which are already on the market, especially rare ADRs that are usually not documented by the time a drug is marketed.

2.3 ADR reporting systems are essential to a comprehensive post marketing surveillance and spontaneous reporting is the most practical. However, globally and within the BZ programs, it is well known that ADRs are not adequately reported by healthcare professionals, especially in local Primary Health Care (PHC) facilities. Factors that account for the extremely low rate or non-reporting of ADRs include lack of awareness, inadequate knowledge of pharmacovigilance, lack of time and none availability of ADR reporting tools. It is estimated that only 6–10% of all ADRs are reported world-wide according to a 2017 “British Pharmacological systemic review journal”. Thus, underreporting has been a major obstacle to spontaneous reporting of ADRs and poses a great challenge to pharmacovigilance activities as well as negatively impacting public health (Pedro Inacio, Afonso Cavaco et. al., 2017).

3. OBJECTIVE

3.1 The objective of this bid is to appoint a service provider to conduct a review and monitoring for ADR.

4. SCOPE OF WORK

4.1 To fulfil this role, BZ requires a suitable and experienced service provider to undertake the review for Adverse Drug Reaction (ADR) in the identified Provinces and operating in the sub-districts.

4.2 Each program will be undertaken in the provinces outlined in the table below, in the Eastern Cape, Free State, KwaZulu Natal, Limpopo, Mpumalanga, North West and Western Cape Province.

Table 1: Training locations and programs

PROVINCE	PROGRAMS AND SUB DISTRICT		
	MEN WHO HAVE SEX WITH MEN (MSM)	**TRANSGENDER (TG)**	**ADOLESCENT GIRLS AND YOUNG WOMEN (AGYW)**
Eastern Cape	OR Tambo		Nelson Mandela and Nyandeni
Free State	Mangaung	Mangaung	Thabo Mofutsanyane
KwaZulu Natal	Ugu		
	King Cetshwayo		
	uThukela		
Limpopo	Capricorn	Capricorn	
	Mopani		
	Greater Sekhukhune		Greater Sekhukhune
	Vhembe	Vhembe	
	Waterberg		
Mpumalanga	Gert Sibande	Gert Sibande	
North West	Bojanala Platinum	Bojanala	
Western Cape		Garden Route	

4.3 The service provider shall be expected to conduct the review for ADR in the following programs:

i. Men Who Have Sex With Men (MSM)

ii. Transgender (TG)

iii. Adolescent Girls And Young Women (AGYW)

4.4 The successful service provider shall be expected to:

i. Review BZ operational processes to identify areas of improvement in the context of Pharmacovigilance (PV).

ii. Review PV processes for BZ across all programmatic areas.

iii. Set and Implement the Community-Clinic Integrated Pharmacovigilance program in support of BZ programs.

iv. Set Community ADR reporting.

v. Carry out training on Patient-Centered PV review.

vi. Set up PV committee and training on PV clinical review and management.

vii. Capacity building and mentorship for PV coordinators.Collate ADR reports and review trending.

viii. Review ADR management approaches.

ix. Review if ADRs influence retention and adherence within the BZ program.

x. Review if medication errors and inadequate monitoring are contributing to ADRs.

xi. Review specific areas such as PrEP, (Hormone replacement therapy) HRT etc. for any specific risk drivers.

xii. Review interphase between the community and clinic for proper ADR reporting and case management.

xiii. Conduct monitoring of ADR on E-Pharmacy.

xiv. Develop at least 2 abstracts for publishing or conference presentation.

5. REQUIREMENTS

5.1 The successful service provider shall have experience and years of understanding in the development of training materials and carrying out training in pharmacovigilance.

5.2 The successful service provider must have experience in the following areas:

i. A minimum of 5 years working in HIV/AIDs especially involving Treatment Support;

ii. Medicine Regulation including Adverse Drug Reaction Monitoring;

iii. 5 years or more working in Pharmacovigilance especially HIV/AIDS program;

iv. Pharmacovigilance program design to improve on ADR monitoring;

v. Common ADR Prevention and management in the HIV/AIDs Program;

vi. Analysis and reporting on pharmacovigilance data;

vii. At least 5 years in the development of training materials and carrying out training in pharmacovigilance.

6. BID RESPONSE REQUIREMENTS

6.1 BZ will use a pre-determined evaluation criterion when considering received Proposals. The evaluation criteria will consider the commitment made for Mandatory, Functionality/Technical,

Price and B-BBEE. During the evaluation of received Proposals BZ will make an assessment on whether all of the Proposals comply with set minimum requirements. Bidders which fail to meet minimum requirements, thresholds or have not submitted required mandatory documents will be disqualified from the bid process.

6.2 The requirements at any given stage must be complied with prior to progression to the next stage. BZ reserves the right to disqualify bidders without requesting any outstanding document/information.

6.3 Bidders which meet the requirements of the TORs and the commercial and contractual conditions are invited to submit proposals. If the Consultancy finds any ambiguity, omission or internal contradictory, or any feature that is unclear or that appears restrictive, they should seek clarification before the closing date of submission.

6.4 As a minimum requirement the service provider must submit a relevant contactable reference (contact name, position, contact number and email address) supported by the appointment letters whereby they have executed similar services in the Non Profit Organisations (NPO). The appointment letters must be in the client's company letterhead and must not be older than five (5) years.

6.5 The bidder's proposed Project Lead/ Consultant is required to have experience in leading similar projects. The bidder must submit a brief CV(s) of the Project Lead(s) clearly showing the years of experience and also certified copy of their qualifications, not older than six (6) months

6.6 The Project Lead/Consultant must have relevant qualifications (Advanced qualification in Pharmaceutical Care/Pharmacy or Medicine or Public Health (MBChB or PharmD or MPH)) and / or other related fields, skills and experience in similar projects.

6.7 Bidders must provide a detailed proposal of the methodology / approach to be used to carry out the scope of work. Bidders should indicate their knowledge of the demonstration of how the bidder will deliver this project in line with the scope of work, include a detailed project plan with specific timeframes, deliverables and reporting.

6.8 Once the proposals are received and opened, bidders shall not be required nor permitted to change the substance, the key staff and so forth.

7. EVALUATION CRITERIA

The evaluation of proposals will be managed by an Evaluation Committee which will prepare a shortlist of applicants that meet the eligibility for appointment. The evaluation process will be conducted according to the following stages:

- **Stage 1:** Assessment of administrative compliance. Applications that do not comply will not be evaluated further.
- **Stage 2:** Assessment on functionality/technical evaluation criteria competency focusing on the ability to fulfil the required scope of work. Service providers need to achieve a score of at least 70 out of 100 points to progress further.
- **Stage 3:** The final stage of evaluation will be the application of the preference points system price at 80 points and B-BBEE 20 points.

7.1 Stage 1: Eligibility Evaluation

Table 2: Eligibility evaluation Stages

Criteria	Sub-Criteria	Comply / Not Comply
Eligibility	SARS Tax Clearance Status/pin	
	Certified ID Copies of the Directors	
	CIPC Registration Documents	
	In bids where consortia / joint ventures / sub-contractors are involved; each party must submit a separate proof of TCS / PIN	
	Valid B-BB-EE Certificate (from SANAS Accredited Verification Agency)	
	VAT Registration Certificate or VAT Registration Letter (("VALUE ADDED TAX Notice of Registration") available on e-Filing for all expenditure more than R1 000 000 (where applicable)	
	Completed and signed bid document	
	Signed Global Fund Code of Conduct for Suppliers of Services	
	Completed and signed Declaration of Interest	

7.2 Stage 2: Functionality/Technical Evaluation Criteria

Only service providers who score **70 points** or more in stage 2 will be evaluated further in stage 3 and therefore eligible for the award.

Table 3: Functionality/technical Evaluation

Criteria	Description	Weighting
Methodology	The service provider must provide a detailed proposal of the methodology / approach to be used to carry out the scope of work. Bidders should indicate their knowledge of the demonstration of how the bidder will deliver this project in line with the scope of work, include a detailed project plan with specific timeframes, deliverables and reporting. **Excellent:** Satisfies the requirements The response is comprehensive, unambiguous and demonstrates a thorough understanding of the requirement and provides details of how the requirement will be met in full = **30 points** **Acceptable:** Satisfies the requirement. The response shows an acceptable level of understanding of the requirement and provides some satisfactory level of details on how the requirements will be fulfilled = **20 points** **Serious Reservations:** Satisfies the requirement with serious reservations. The response addresses some elements of the requirement but contains insufficient/limited detail or explanation to demonstrate how the requirement will be fulfilled = **10 points** **Unacceptable:** Does not meet the requirement. Does not comply and/or insufficient information provided = **0 points**	30

Criteria	Description	Weighting
Reference Letters	List of References with an appointment letter from different clients as evidence of related services previously conducted. References must not be older than five (5) years, and the appointment letter must be submitted on the letterhead of the previously serviced clients and should at least reflect name of the clients, title of the related work conducted, contactable reference name and contact number and signed by the appropriate delegate. **Scoring Matrix** Three (3) and more contactable references provided with the appointment letters = **30 points** Two (2) contactable references provided with the appoiment letters = **20 points** One (1) contactable references provided with the appointment letter= **10 points** No reference letter attached = **0 points**	15
Qualifications and Experience	The **Project Lead/ Consultant** must have a qualification in Pharmaceutical Care/ Pharmacy or Medicine or Public Health (MBChB or PharmD or MPH) The bidder must provide proof of qualifications by attaching certified copies of qualifications for the **Project Lead/ Consultant**, not older than six (6) months. **Scoring Matrix:** Certified copy of **master's degree (SAQA NQF level 9)** in the fields indicated above = **20 points** Certified copy of **honour's degree (SAQA NQF level 8)** in the fields indicated above = **15 points**	20

Criteria	Description	Weighting
	Certified copy of **bachelor's degree (SAQA NQF level 7)** in the fields indicated above = **10 points** Less than a diploma or no certified qualifications submitted **= 0 points**	
	Bidder must attach a brief Curriculum Vitae (CV) for the **Project Lead/ Consultant** role indicating relevant experience and proof of master's degree in Pharmaceutical Care/ Pharmacy or Medicine or Public Health (MBChB or PharmD or MPH) **Scoring Matrix:** Fifteen (15) years' relevant experience and more = **35 points** Ten plus (10) years' relevant experience = **25 points** Seven plus (7) years' relevant experience = **15 points** Five plus (5) years' relevant experience = **5 points** Less than five (5) years' experience **= 0 points**	35
The minimum qualifying score for functionality/technical evaluation will be **70** points overall, and service providers that fail to achieve the minimum qualifying score will be disqualified.		100

Bidders obtaining a minimum of at least 70 out of 100 points of the technical competency requirements will be evaluated further on Price & BBBEE.

7.3 Stage 3: Price And B-BBEE Evaluation

Service Providers that have successfully scored 70 points and above in the Functionality/Technical evaluation stage will be evaluation on stage 3 (Price and B-BBEE). It is recognised that it is difficult for a prospective service provider to be firm about the extent of the work based solely on the terms of reference. However, to assist with assessments, a service provider will be provided with scenarios in the pricing schedule for evaluation purposes whilst a rate card will be provided and must be completed to be used during delivery of the services.

NB: Service Providers should note that the scenarios provided below are for the purposes of evaluation of the tender and a rate card unit price will be used during execution of the services. The service providers' tender response will be evaluated based on a combination of price and BBBEE in accordance with the ratios set out below:

Price and B-BBEE	Weighting
Price	80
B-BBBEE	20
Total	100

Price evaluations will be conducted using the following formula:

$$Lowest\ bid\ price = 80$$

$$Price\ under\ calculation = 80\left(1 - \frac{Price\ under\ consideration - Lowest\ bid\ price}{Lowest\ bid\ price}\right)$$

BBBEE evaluations will be conducted in accordance with the following table:

B-BBEE Status	Number of Points (80/20 system)
Level 1	20
Level 2	18
Level 3	12
Level 4	10
Level 5	8
Level 6	6
Level 7	4
Level 8	1
Non-compliant	0

PRICING SCHEDULE

Service provider to fill in the bellow table

Bidders are required to provide their Fee proposal in a following format:

Table 3

Discription	Daily rate	Hourly rate
Project Lead/ Consultant		
Sub-total		
VAT		
Total		