INVITATION TO BID

ITB-Iplus/GDF-MED/2023/3

Issue date: 20 July 2023

i+solutions, as the contracted Procurement Agent of the Stop TB Partnership/Global Drug Facility (GDF), wishes to procure bedaquiline 100mg tablets for the period until 31 December 2024.

IMPORTANT – ESSENTIAL INFORMATION

Deadline for the Request for Clarification on the ITB: **26 July 2023, 17h00 IST (India Standard Time) / 13h30 CET (Central European Time)**
Deadline for the electronic submission of Technical and Financial Bids: **7 August 2023, 17h00 IST (India Standard Time) / 13h30 CET (Central European Time)**
Public opening of Financial Bids (remotely) on **8 August 2023 at 13h30 IST (India Standard Time) / 10h00 CET (Central European Time)**

The reference **ITB-Iplus/GDF-MED/2023/3** should be shown on all correspondence related to this ITB.

This ITB document consists of the following:

LIST OF ANNEXES

Annex A. Financial Bid Response Form (Excel file)

Annex B. List and technical specifications of products requested

Annex C. List of priority countries for TB medicines registration

Annex D. i+solutions model Long-Term Agreement (LTA)

Annex E. i+solutions Code of Conduct for suppliers

Annex F. CDP technical tender submission – instructions for use

Annex G. GDF access to supplier information for WHO PQP and ERP assessed TB medicines

Annex H. Indicative non-binding estimated quantities

Annex I. GMSD address list

Annex J. GDF packaging artwork development guidelines

Annex K. Form for Requests for Clarifications or Complaints after ITB awarding

Annex L. Declaration of supply restrictions for bedaquiline 100mg tablets

SECTION 1: INTRODUCTION

1.1. GDF's mission and vision

The mission of the Global Drug Facility (GDF) is to facilitate worldwide, equitable access to tuberculosis (TB) products to help countries meet the targets set and adopted by world leaders at the United Nations High-Level Meeting on TB in 2018.
Today, GDF is the **largest supplier of quality-assured TB products** in the public sector worldwide. Since its inception, GDF has supported and increased access to critical quality-assured TB products for 158 countries.
The key added value of GDF is to offer a **full package of services** for ensuring market availability, affordability and provision of quality-assured TB products to countries in need, as well as to offer country support for facilitating access to and uptake of new medicines and diagnostic tools. GDF's services include active market-shaping, strategic procurement solutions, innovative logistics approaches, a Strategic Rotating Stockpile (SRS), pre-shipment inspection and quality control services, capacity-building and technical assistance.
As the largest public-sector purchaser, GDF is uniquely positioned to monitor and intervene in TB markets. Its market-monitoring and market-shaping work develops a transparent source of information to stakeholders and countries and provides downward pressure on the prices of TB products.

More information about GDF can be found at the following link:
https://www.stoptb.org/facilitate-access-to-tb-drugs-diagnostics/global-drug-facility-gdf

1.2. Objective of the Invitation to Bid (ITB)

The purpose of this ITB is to select a panel of suppliers who will enter into a Long-Term Agreement (LTA) with i+solutions, the contracted Procurement Agent of Stop TB Partnership/GDF, to supply bedaquiline 100mg tablets as specified in Annex B of this ITB document.

1.3. The ITB and award process

The ITB and award process consists of five (5) steps:

- Step 1: Bidders prepare and submit Bids according to the terms and conditions stated in this ITB document, particularly in sections 3.2, 3.3 and 3.4.
- Step 2: There is a public opening of the Financial Bids, as stated in section 3.6.
- Step 3: GDF/i+solutions evaluates the Technical and Financial Bids of eligible Bidders/TB medicines, as outlined in section 3.8.
- Step 4: GDF/i+solutions adjudicates the Bids, as stated in section 3.9.
- Step 5: Eligible Bidders are notified of the awards, as stated in section 3.10.

1.4. Timeline of the ITB

Activity	Scheduled Time – Deadline
ITB launch/web-publishing	**20 July** 2023
Request for Clarification on the ITB (section 3.2.8)	Deadline: **26 July** 2023, 17h00 IST (India Standard Time) or 13h30 CET (Central European Time)
GDF/i+solutions responses to Requests for Clarification on the ITB (section 3.2.9)	Deadline: by **31 July** 2023, 17h00h IST (India Standard Time) or 13h30 CET (Central European Time)
Electronic submission of Technical and Financial Bids, in separate emails (sections 3.3.4 and 3.3.5)	Deadline: **7 August** 2023, 17h00 IST (India Standard Time) or 13h30 CET (Central European Time) *Bids received after the stipulated date and time will be rejected.*
Public opening of Financial Bids (remotely) (section 3.6)	**8 August** 2023 at 13h30 IST (India Standard Time) / 10h00 CET (Central European Time)
Evaluation of Technical and Financial Bids (section 3.8)	**8 August** 2023
Adjudication of the Bids (section 3.9)	**9 August** 2023
Notification of awards to Bidders (section 3.10)	by COB **16 August** 2023

1.4.1 GDF/i+solutions reserves the right to cancel this ITB, change the scheduled times of the ITB's key activities, revise the ITB and any of its schedules, or not make any awards by issuing an amendment to this ITB. GDF/i+solutions will not be held liable for any compensation demanded by Bidders for the costs involved in Bid preparation.

1.4.2 All amendments to this ITB will be posted on the GDF website at https://www.stoptb.org/suppliers/procurement-notices and the i+solutions website at https://www.iplussolutions.org/news/.

1.4.3 It is the Bidder's responsibility to consult the GDF and i+solutions websites to ensure that they are aware of any amendments to and additional information regarding this ITB.

1.5. Contacts for the ITB

All correspondence in relation to this ITB should be sent to:

- Mr Martin Mugisha, i+solutions Senior Category Manager, at mmugisha@iplussolutions.org
- Mrs Sarah Cao, i+solutions Category Manager, at scao@iplussolutions.org
- Dr Magali Babaley, GDF Strategic Procurement and Business Intelligence Manager, at magalib@stoptb.org
- Mrs Nigorsulton Muzafarova, GDF Lead Quality Officer, at nigorsultonm@stoptb.org
- Dr Kaspars Lunte, GDF Global Sourcing Officer, at kasparsl@stoptb.org
- For CDP-related questions/queries, please contact Dr Magali Babaley, magalib@stoptb.org, and Dr Kaspars Lunte, kasparsl@stoptb.org

ATTENTION: The Bids should NOT be submitted to the above staff emails.
For Bid submission, two dedicated email addresses are used. Please refer to sections 3.3.4 and 3.3.5.

SECTION 2: SCOPE OF THE ITB

2.1. The GDF/i+solutions procurement strategy

2.1.1. The GDF/i+solutions procurement strategy for TB medicines and related products has been developed with specific key objectives to ensure uninterrupted access to quality-assured TB products at the optimum price, while simultaneously maintaining a sustainable and competitive market.

2.1.2. The GDF/i+solutions procurement strategy consolidates the results of market analysis and discussions with manufacturers, GDF clients, the Global Fund and GDF donors, and technical partners.

2.1.3. The key principles of the GDF/i+solutions procurement strategy are to support the best interests of people affected by TB implementing partners and GDF, , maximize value for money, and ensure an effective competition, with fairness, integrity and transparency. These principles have been developed with the following aims:

a. To support the introduction of new TB medicines;
b. To maintain a sustainable and predictable supply of the needed TB medicines and related products;
c. To maintain sufficient suppliers in the market through sourcing strategies, by understanding and supporting suppliers' interests and by encouraging new suppliers to enter the market;
d. To ensure affordable and competitive pricing through competitive, fair and transparent tenders, supplier engagement strategies and the minimization of supplier production costs through improved procurement planning;
e. To ensure reliable supply through improved supplier performance. In this regard, GDF uses a set of Key Performance Indicators (KPIs) and information, which cover the supplier's timely readiness of products, responsiveness, collaboration and communication with GDF/i+solutions;
f. To increase supplier engagement in sufficient production capacity in order to ensure supply security by improving demand visibility through improved GDF/i+solutions forecasts;
g. To enable supply flexibility through a reduction in supplier delivery lead times. Suppliers are encouraged to implement different approaches to decrease their delivery lead times, such as the use of consignment stock, increased production capacity, multiple sources of active pharmaceutical ingredient (API), advanced purchase of needed materials, and advanced production of API;
h. To limit the risk of expiries and write-offs by encouraging suppliers to extend product shelf life (to 60 months where applicable);
i. To reduce supply chain risks by encouraging suppliers to register their products in countries.

2.1.4. GDF and Environmental Sustainability Strategy: Environmental degradation through pollution, antimicrobial resistance and climate change are issues of concern because they disproportionately affect people in countries where TB medicines are manufactured and supplied. As a procurer of TB medicines and diagnostics, GDF relies on the environmental sustainability standards and policies of its suppliers. In its efforts to build and strengthen a sustainable supply chain, GDF will in the future embed

environmental criteria into contractual requirements to encourage environmentally sustainable and competitive markets, while ensuring uninterrupted access to TB medicines and diagnostics.

2.1.5. To this end, GDF/i+solutions suppliers are encouraged to:

a. To comply with the World Health Organization (WHO) *Global strategy on health, environmental and climate change*[1]*;*
b. Equally embed environmental sustainability requirements in their upstream sources of APIs and excipients (ensuring sustainable and environmentally respectful production processes);
c. Implement policies on environmentally sustainable waste management and energy efficiency;
d. Where possible, adopt and implement international standards on environmental sustainability, including respective third-party certifications such as ISO 14001:2015;
e. Identify areas of opportunity to redesign packaging specifications, with a view to reducing finished product waste, while maintaining the quality of the product.

2.2. Implementation of the GDF/i+solutions procurement and supply strategy

2.2.1. GDF has analysed the list of needed TB medicines and related products against its procurement strategy and has defined different priorities per product, also considering the maturity of the product versus the changing treatment guidelines. While affordability and supplier performance remain priorities for GDF/i+solutions**,** supplier production capacity, batch size, minimum order quantity (MOQ), product shelf life, number of countries in which the TB medicine is registered, and the supplier's responsiveness, collaboration and communication have also emerged as priorities. Addressing these priorities will enable GDF/i+solutions to increase supply flexibility and security, improve client satisfaction and decrease supply chain risks.

2.2.2. GS1 global supply chain standards are used for product identification, labelling and data exchange in order to enable innovation in supply chain efficiency and effectiveness. GDF/i+solutions will continue to work closely with awarded partners and stakeholders to follow up on the implementation of GS1 standards and location identification for medicines and other health products and to upload product master data attributes to the GDSN (Global GS1 network). This will improve the traceability and end-to-end visibility of health care products throughout the supply chain.

2.2.3. GDF also recognizes that it needs to further develop its supplier engagement strategy in order to improve its partnership and collaborative activities with suppliers and thus create additional value for both parties.

2.2.4. GDF's operational objectives to enhance collaboration with suppliers are:

a. To improve the GDF/i+solutions order cycle by better scheduling orders to suppliers;
b. To adapt replenishment orders and production capacity to smooth peaks in the ordering pattern;
c. To provide suppliers with more reliable and accurate forecasts and information on market evolution, especially following policy changes.

[1] WHO global strategy on health, environment and climate change: the transformation needed to improve lives and wellbeing sustainably through healthy environments. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/331959).

2.2.5. GDF/i+solutions has four categories of delivery flows and places purchase orders (POs) with suppliers accordingly:

a. Direct shipment POs: POs to purchase and directly deliver products from the supplier's premises to countries for a specific client's order, including direct shipment to India;
b. Consolidation POs: POs to purchase and deliver products from the supplier's premises to the i+solutions warehouse for consolidation of products/cross-docking before shipment to countries for a specific client's order;
c. SRS POs: POs to purchase and deliver products from the supplier's premises to the i+solutions warehouse to build the SRS or replenish products in the SRS;
d. Consignment POs: POs to purchase and deliver products from the supplier's premises to the i+solutions warehouse for consignment stock.

2.2.6. Of the 120 countries that received deliveries of TB medicines through GDF in 2022, 21 countries represented 80% of the total value of TB medicines for drug-resistant TB (second-line drugs [SLDs]) and/or drug-susceptible TB (first-line drugs [FLDs]) delivered (class A countries). Due to the small number of class A countries, variable demand and lack of seasonality, there is no stable ordering pattern per product.

2.3. Addressing market challenges

GDF is carefully monitoring market developments, specifically relating to the following:

2.3.1. The application of a fee by the WHO Prequalification Programme (PQP): This fee structure was implemented in January 2017 and applies to both first-time product applications and the maintenance of products on the WHO List of Prequalified Medicines. Thanks to joint efforts, WHO PQP has accepted a fee waiver system for many TB products in order to ensure long-term price security. The list of products eligible for fee waivers has been published at **https://extranet.who.int/pqweb/medicines/prequalification-procedures-and-fees** (and may be amended from time to time by WHO PQP). Given that manufacturers of listed products may apply for a waiver of the annual fees, GDF will not consider WHO PQP fees to be an additional cost burden for manufacturers. The supplier base for TB products is stable, and, in general, GDF anticipates trends towards sustainable and/or reduced prices. Therefore, in cases where a price is offered for a product that is higher than the previous tender price, GDF reserves the right to ask suppliers to provide a justification for the price increase. GDF will evaluate the extent to which the higher price is reasonable.

2.3.2. Product demand may change with updates to WHO recommendations, captured in the *WHO consolidated guidelines on tuberculosis*. The current consolidated guidelines for DR-TB treatment[2] recommend the use of all-oral regimens, including bedaquiline, pretomanid, linezolid and moxifloxacin (BPaLM) for 6-9 months.

2.4. Conditions/eligibility for ITB participation

2.4.1. This ITB is open to Bidders who are authorized by relevant regulatory authorities to manufacture, distribute and export medicines.

2.4.2. i+solutions and GDF reserve the right to verify the financial soundness of Bidders, unless this information has been provided within the previous 12 months; for example, the ratio of current assets/liabilities for the previous three years must be greater than 1, as substantiated by audited financial reports. GDF/i+solutions may request Bidders to submit their most recent audited financial statements, statutes, registry excerpts from the relevant chamber of commerce, and quality and

[2] WHO consolidated guidelines on tuberculosis: module 4: treatment: drug-resistant tuberculosis treatment, 2022 update. Geneva: World Health Organization; 2022 (https://apps.who.int/iris/handle/10665/365308).

environmental management system certificates. It is in the interest of the Bidders, if requested, to provide information that is as complete as possible. This information may also be used by GDF/i+solutions in the Bid adjudication process.

2.4.3. Only Bidders with products that comply with the GDF Quality Assurance Policy (https://www.stoptb.org/suppliers/quality-assurance) are eligible to participate in this ITB.

2.4.4. A Bid submitted for a product that has not received regulatory approval in accordance with the GDF Quality Assurance Policy will not be considered for the ITB evaluation.

2.4.5. Bidders who expect their product(s) to be compliant with the GDF Quality Assurance Policy at least three (3) working days before the day of the public opening of the Financial Bids must use the Centralized Data store and analysis Platform (CDP) Portal to register their product in the FPP In-Market Module (see section 3.1) and, as soon as the "Approved" status is received by GDF for the product, submit the Technical Bid for this ITB. Bidders without CDP Portal access must alert GDF on the need to receive log-in credentials to create a new product entry in the CDP Portal by writing to the contacts indicated in section 1.5 at least five (5) working days before the day of the public opening of the Financial Bids. Late submissions may be invalid.

2.4.6. This ITB should not be construed as a contract or a commitment of any kind. This ITB in no way implies the acceptance of the Bid, nor does it obligate GDF/i+solutions to award a contract, nor does it commit GDF/i+solutions to pay any costs incurred in the preparation and submission of the Bid(s).

2.4.7. Bidders shall be responsible for and bear their own costs, expenses and liabilities arising in connection with the preparation and submission of a Bid and their involvement in the ITB process. GDF/i+solutions will under no circumstances be held liable for any such costs incurred by Bidders, whether direct or indirect, regardless of the outcome of the procurement process or whether the procurement process is cancelled, altered or postponed for any reason.

2.4.8. Bidders are not required to bid for all products. However, Bidders are encouraged to bid for as many eligible products as possible.

2.4.9. By participating in this process, Bidders agree to the legal terms and conditions as stated in this ITB document. There is no arrangement or understanding between GDF/i+solutions and any Bidder with respect to this ITB other than what is outlined in this document.

2.4.10. Bidders shall comply with i+solutions purchasing general terms and conditions as stated in ***Annex D. i+solutions model Long-Term Agreement (LTA)***.

2.5. Bidder ethics requirement

2.5.1. GDF/i+solutions requires that all Bidders maintain the highest standard of ethics throughout the entire ITB process, as well as for the duration of any LTA that may be signed as a result of this process.

2.5.2. Therefore, all Bidders must represent and warrant that they:

a. Comply with the i+solutions Code of Conduct for suppliers;
b. Have not unduly obtained or attempted to unduly obtain confidential information in connection with the ITB process;
c. Have no conflict of interest that would prevent them from entering into a contract with GDF/i+solutions;
d. Have not engaged or attempted to engage in any proscribed practices in connection with this ITB process or the LTA that may be awarded as a result of this process. For the purposes of this

provision, proscribed practices are defined as corrupt, fraudulent, coercive, collusive and unethical practices, and obstruction.

2.6. List and technical specifications of products

2.6.1. Bidders are invited to submit Bids for bedaquiline 100mg tablets as specified in ***Annex B. List and technical specifications of products requested***.

2.6.2. Bedaquiline 100mg tablets will be allocated to selected suppliers based on the outcomes of this ITB.

2.7. Product quantity estimations

2.7.1. The total estimated quantity of bedaquiline 100mg to be procured in basic units (tablets) for the period 15 August 2023 to 31 December 2024 is indicated in ***Annex H. Indicative non-binding estimated quantities***. For this ITB:

a) GDF provides the estimated quantities to be procured via GDF for two (2) categories of demand (refer to Annex H, Table n°1):
   - ***Schedule 4: Bedaquiline 100mg demand for all suppliers*** – *the estimated GDF demand that is open to all eligible suppliers (all suppliers - originator and generics);*
   - ***Schedule 5: Bedaquiline 100mg demand for originator product only*** - *the estimated GDF demand that is open to originator product only.*

In addition:

b) GDF provides a projection of the quantities of bedaquiline 100mg likely to be procured via GDF per quarter for Schedules 4 and 5 for the total estimated quantities (refer to Annex H, Table n°2), and

c) GDF provides potential additional quantities of bedaquiline 100mg for the period 15 August 2023 to 31 December 2024, which may or may not be procured through GDF based on country decision (refer to Annex H, Table n°3).

2.7.2. Please note that the estimated quantities provided in Annex H are only indicative and should not be considered a volume commitment. Actual quantities to be ordered through GDF/i+solutions can vary. Therefore, GDF/i+solutions cannot make any guarantees.

2.8. Contracting

2.8.1. On behalf of GDF, i+solutions intends to sign LTAs with awarded suppliers as per the results of the ITB.

2.8.2. For contractual and technical provisions, LTAs with suppliers will be issued according to ***Annex D. i+solutions model Long-Term Agreement (LTA)*** and ***Annex E. i+solutions Code of Conduct for suppliers***.

2.8.3. Any purchases will be made against a PO issued by i+solutions in accordance with the terms and conditions of the LTA.

2.8.4. While Bids will be adjudicated on an EXW (EX-Works) basis, as stated in section 3.2.5.2, LTAs will be issued by i+solutions with three Incoterms (2020): EXW (Ex-Works), FCA (Free Carrier Alongside) and DAP (Delivered at Place) prices, including offloading of Indian supplies to the Government Medical Store Depots (GMSDs) situated in Delhi, Chennai, Hyderabad, Mumbai, Karnal, Kolkata and Guwahati. Detailed GMSD addresses are provided in ***Annex I. GMSD address list***.

2.8.5. LTAs will be valid for an initial term until 31 December 2024. They will begin on the commencement date and expire at midnight on the expiry date, unless terminated earlier in accordance with the provisions of the LTA. For Expert Review Panel (ERP)-approved products, the LTA will be subject to early termination if the product's ERP approval is not renewed or is cancelled.

2.8.6. After the initial term, i+solutions may request the supplier to renew the LTA for a consecutive term of up to 12 months, based on the same terms and conditions. i+solutions will give the supplier written notice of its intention to renew the LTA no less than sixty (60) calendar days prior to the LTA's expiry date. GDF/i+solutions may also provide the supplier with product forecast(s) for the next period. Based on the above:

d) The supplier shall notify i+solutions in writing, within forty-five (45) calendar days before the end of the initial term about price maintenance or a proposed price increase/reduction. If the supplier proposes a price increase, it must provide well-documented justification for GDF/i+solutions to consider.
e) i+solutions shall notify the supplier in writing within twenty (20) calendar days of receiving the above notice as to whether it agrees to the revised prices. In the case of a price increase, GDF/i+solutions will be entitled to revise existing market share allocations.
f) If parties agree to the revised prices, the LTA shall be amended accordingly. If the parties do not agree to the revised prices, the LTA shall not be extended.

2.9. Contract management

During the LTA period:

2.9.1. Every three months, GDF/i+solutions will monitor and report on the supplier's performance, focusing on promised delivery lead time (promised goods readiness date versus actual goods readiness date) and compliance with the guaranteed delivery lead time, as stated in the Technical Bid. Delivery lead time is defined as the length of time from when i+solutions places a PO with the supplier to when the products are available for dispatch at the supplier's premises with the full set of shipping documents (invoice, packing list, certificate of analysis and other documents) specified in the PO. This includes, but is not limited to, production planning, production/purchase of API, key starting material, packaging materials, manufacturing period and suppliers internal batch release. In addition, GDF/i+solutions will monitor the responsiveness, collaboration and communication of the suppliers with GDF/i+solutions (including the timely confirmation of POs placed by GDF/i+solutions, timely feedback on the PO status, timely provision of requested documents, compliance with the quality control and pre-shipment inspection requirements and timely communication to GDF/i+solutions of any challenges in delivering the products, along with a concrete action plan/timeline to mitigate/avoid risk of delays). Outcomes of supplier performance measurements will be used to discuss performance improvements with suppliers.

2.9.2. GDF/i+solutions may issue new tenders for specific products when:

a) Current supplier(s) are deemed unable to deliver the orders due to insufficient production capacities, or
b) A product had only one eligible Bidder at the time of the ITB, but additional quality sources have become available during the LTA period, or
c) There is a combination of a) and b), or
d) GDF/i+solutions and suppliers fail to agree on a proposed price increase, or
e) At the discretion of GDF/i+solutions to ensure the supply security of products.

2.9.3. GDF/i+solutions may conduct investigations related to any aspect of the ITB awards at any time during the term of the LTA and for a period of three years following the expiry or termination of the LTA. The supplier shall provide its full and timely cooperation with any such inspections, audits or investigations. Such cooperation includes the supplier making available its personnel and any relevant

documentation, including copies of any test results or quality control reports, at reasonable times and under reasonable conditions, and granting access to the premises used for the production, testing and packaging of the products and to its personnel. The supplier shall require its agents, including its attorneys, accountants or other advisors, to reasonably cooperate with any inspections, post-payment audits or investigations carried out by GDF/i+solutions.

SECTION 3: INSTRUCTIONS FOR BIDDERS

3.1. Submission of Technical Bids via the GDF CDP Portal

3.1.1. GDF launched its CDP Portal at the end of 2021 with the aim of improving the collection and validation of TB medicines-related data/information submitted by suppliers via the CDP Portal. The data/information collected (via Web Forms) and validated by GDF, based on supporting documentation uploaded to the CDP Portal by suppliers, are related to the finished pharmaceutical product (FPP) on the market and the country registration status of the FPP. In April 2022, GDF released a new functionality in the CDP Portal, the "GDF Tender/Technical Tender Submission" module, which enables suppliers to prepare and automatically generate the requested Technical Bid Response Form and TB medicines country registration Response Form (both in Excel format) based on the list of TB medicines required by GDF for the tender and the list of the supplier's TB medicines approved in the CDP Portal. Therefore, thanks to the CDP Portal, the Technical Bid submission is now automated for suppliers, and GDF/i+solutions will only receive Technical Bids that meet its quality assurance and technical requirements via the CDP Portal.

3.1.2. GDF is currently developing additional functionalities that will enable suppliers to also submit their Financial Bid via the CDP Portal for future GDF/i+solutions tenders.

3.2. Preparation of Bids

3.2.1. The Bidders shall complete the following forms:

3.2.1.1. For the **Technical Bid**:

a. The Bidder is requested to use the GDF CDP Portal for the preparation and submission of its Technical Bid.
The Bidder is requested to complete the Web Forms in the CDP Portal under the "**GDF Tender/Technical Tender Submission**" module. The ***Technical Bid Response Form*** and ***TB medicines country registration Response Form*** (both in an Excel file) will be automatically generated in the CDP and can be checked by the Bidder before submission. The Bidder is requested to refer to ***Annex F. CDP Technical tender submission – instructions for use*** to prepare the Technical Bid via the CDP Portal.

b. The Bidder is requested to complete, date and sign ***Annex G. GDF access to supplier information for WHO PQP and ERP assessed TB medicines*** (PDF file). If the Bidder only offers product(s) approved by a stringent regulatory authority (SRA), the Bidder is requested to send Annex G with the mention "Not applicable".

3.2.1.2. For the **Financial Bid**:

a. ***Annex A. Financial Bid Response Form*** (Excel file)
b. ***Annex L. Declaration of supply restrictions for bedaquiline 100mg tablets***

3.2.2. **GDF packaging**: GDF requests that products supplied by the supplier be in GDF packaging. For all information regarding GDF packaging requirements, the Bidder is requested to refer ***to Annex J. GDF***

packaging artwork development guidelines and sections 11 and 12 of ***Annex D. i+solutions model Long-Term Agreement (LTA).***

3.2.3. **Samples**: GDF/i+solutions reserve the right to ask the Bidder for free, non-returnable samples of products (primary and secondary packaging) for the purposes of this ITB. Failure to provide, in a timely manner, samples or documentation requested by GDF/i+solutions may lead to rejection of the Bid.

3.2.4. **Prices**: In ***Annex A. Financial Bid Response Form***, the Bidder is requested to:

3.2.4.1. Provide unit prices of the packaging offered, in US dollars only. Bids will be evaluated in US dollars only. Failure to quote in US dollars may lead to the rejection of the Bid. The Bidder must ensure that the cost of transportation packaging (shrink wrapping and palletization) is included in the price offered for the product(s). Unit prices provided will remain firm but subject to the right to review as outlined in section 2.8.6 of the ITB and in article 4 of ***Annex D. i+solutions model Long-Term Agreement (LTA).***

3.2.4.2. In case free goods[3] are offered; please provide your offer if applicable in the specific section of the ***Annex A. Financial Bid Response Form***.

3.2.4.3. The originator is requested to provide the same unit price (including free goods if applicable) for Schedule 4: Bedaquiline demand for all suppliers and Schedule 5: Bedaquiline demand for originator product only.

3.2.5. **Incoterms:**

3.2.5.1. The Bidder is requested to quote unit prices in accordance with the following delivery Incoterms (2020): EXW (Ex-Works), FCA (Free Carrier Alongside) and DAP[4] (Delivered At Place) prices, including offloading of Indian supplies to GMSDs situated in Delhi, Chennai, Hyderabad, Mumbai, Karnal, Kolkata and Guwahati. Detailed GMSD addresses are provided in ***Annex I. GMSD address list***.

3.2.5.2. The EXW prices will be used to assign the points for the Financial Bid evaluation, as stated in section 3.8.

3.2.5.3. Products for which the Bidder does not provide a DAP price for India may not be considered for Indian supply; therefore, the Bidder may not be considered for market share allocations as awarded.

3.2.5.4. Failure to quote in accordance with the requested Incoterms (EXW, FCA and DAP including offloading) may lead to rejection of the Bid.

3.2.6. **Registration of supplier's TB medicines in countries**:

3.2.6.1. As countries continue to assume increasing responsibility for the financing of TB medicines, product registration has become a key requirement for many of them. For some countries, product registration has become a mandatory requirement. The GDF/i+solutions technical evaluation of tender submissions will therefore give points per registered product according to the following:

- Products whose registration is confirmed by supporting documents (the more countries a product is registered in, the more points given).

3.2.6.2. Only country registration of a product with the quality status required for this ITB (i.e., WHO-prequalified, or SRA- or ERP-approved, and approved by GDF in the CDP Portal) will be considered for the ITB evaluation.

3.2.7. **Validity of the Bids**: Bids should be valid for a period of no less than ninety (90) days from the Bid submission date.

[3] Free goods means a number of packs offered free of charge per number of packs purchased

[4] DAP including and excluding taxes, customs clearance if applicable

3.2.8. **Bidders' Requests for Clarification related to this ITB**: Any Requests for Clarification in relation to this ITB should be sent by email to the contacts provided in section 1.5 by the deadline stated in section 1.4.

3.2.9. **GDF/i+solutions responses to requests for clarification related to this ITB**: GDF/i+solutions will respond to any Requests for Clarification received prior to the deadline stated in section 1.4 in one joint email response to all Bidders by the deadline stated in section 1.4.

3.3. Submission of Bids

3.3.1. **The Technical Bid** submitted by the Bidders shall contain the following documents:

3.3.1.1. The ***Technical Bid Response Form*** (Excel file) automatically generated by the CDP GDF Tender/Technical Tender Submission module after completion of the Web Forms by the Bidder

3.3.1.2. The ***TB medicines country registration Response Form*** (Excel file) automatically generated by the CDP GDF Tender/Technical Tender Submission module after completion of the Web Forms by the Bidder

The Technical Bid Response Form (Excel file) and TB medicines country registration Response Form (Excel file) will be automatically sent to the dedicated Technical Bid email address (see section 3.3.4 below) once the Bidder submits the Technical Bid via the CDP Portal.

3.3.1.3. ***Annex G. GDF access to supplier information for WHO PQP and ERP assessed TB medicines***, duly completed, dated and stamped by the Bidder (PDF file) and uploaded to the CDP GDF Tender/Technical Tender Submission module. If the Bidder only offers SRA-approved products, the Bidder is requested to upload Annex G with the mention "Not applicable". The Annex G will be automatically sent to the dedicated Technical Bid email address (see section 3.3.4 below) once the Bidder submits the Technical Bid via the CDP Portal.

3.3.2. **The Financial Bid** submitted by the Bidder shall contain the following documents**:**

3.3.2.1. ***Annex A. Financial Bid Response Form*** (Excel file), duly completed by the Bidder

3.3.2.2. ***Annex L. Declaration of supply restrictions for bedaquiline 100mg tablets***, duly completed by the Bidder

3.3.3. Failure to submit the above documents requested for the Technical and/or Financial Bid may result in rejection of the Bid.

3.3.4. The Technical Bid shall be sent in a separate email to ITB-GDF-Tech-Submission@iplussolutions.org by the electronic submission deadline in accordance with section 1.4. The Technical Bid is sent automatically to this email address via the CDP Portal.

3.3.5. The Financial Bid (Annex A) shall be sent by the Bidder in a separate email to ITB-GDF-Fin-Submission@iplussolutions.org by the electronic submission deadline in accordance with section 1.4. The subject of the email should be "**supplier name + ITB-Iplus/GDF-MED/2023/3 – Financial Bid**".

3.3.6. Failure to follow the instructions given in sections 3.3.4 and 3.3.5 may result in rejection of the Bid received.

3.4. Modification and withdrawal of Bids

3.4.1. The Bidder is expected to examine all schedules and instructions pertaining to the Bid. Failure to do so will be at the Bidder's own risk. The Bidder acknowledges that GDF/i+solutions and/or its staff make no representations or warranties (expressed or implied) as to the accuracy, correctness or completeness of this ITB or any other information provided to the Bidders.

3.4.2. Any changes to the Technical and/or Financial Bid must be sent by email to the relevant email addresses (refer to sections 3.3.4 and/or 3.3.5) prior to the deadline for electronic submission as stated in section 1.4. The Bidder must clearly indicate that it is a modification that supersedes the earlier Bid or clearly state the changes from the original Bid. Please refer to ***Annex F. CDP technical tender submission – instructions for use*** for modification of a Technical Bid already submitted via the CDP Portal.

3.4.3. Bidders may only withdraw their Bid prior to the deadline for electronic submission stated in section 1.4 through a written request. After the deadline, the Bid will remain valid.

3.5. Opening and screening of Technical Bids

3.5.1. The screening is done via the CDP Portal.

3.6. Public opening of Financial Bids

3.6.1. GDF/i+solutions will organize a public opening of the Financial Bids remotely via Internet connection if requested by the Bidders three working days prior to the public opening.

3.6.2. Procurement representatives of the United Nations and donor organizations may send an email request to participate in the Financial Bid opening to the contacts listed in section 1.5.

3.6.3. Bidders should note that the public opening of the Financial Bids is the only occasion on which information related to competitors' pricing per product will be publicly announced.

3.7. Minor informalities, errors or omissions

3.7.1. Provided that a Bid is substantially compliant, GDF/i+solutions may waive any minor informalities, errors or omissions in the Bid, if they are a matter of form and not substance and can be corrected or waived without being prejudicial to other Bidders.

3.7.2. Provided that a Bid is substantially compliant, GDF/i+solutions may ask the Bidder to submit the necessary information or documentation within a reasonable period of time in order to rectify minor informalities, errors or omissions in the Bid.

3.8. Evaluation of Technical and Financial Bids

3.8.1. A Bid Evaluation Committee will carry out the evaluation and assignment of scores according to the evaluation criteria for the Technical and Financial Bids. This Committee will consist of at least three members, with at least one representative from i+solutions and two representatives from GDF. The Committee will convene at the scheduled time stated in section 1.4. Additional independent parties

may be invited to observe the evaluation process under a strict confidentiality agreement with GDF/i+solutions.

3.8.2. Evaluation will be conducted based on the cumulative analysis of the Technical and Financial Bids, with a weighting of **70**% for the Financial Bid and **30**% for the Technical Bid.

3.8.3. The total maximum number of points Bidders may receive for their Bid is as follows:

- Financial Bid: **70** points
- Technical Bid: **30** points

3.8.4. The evaluation criteria and scoring methodology used to determine the total number of points that Bidders may receive for their Technical and Financial Bids are as follows:

FINANCIAL EVALUATION CRITERION (Maximum 70 points)	**Scoring methodology**
Price per basic unit (tablet) (lowest) *	*The maximum number of points will be allocated to the supplier with the lowest price offered for the product. Prices offered from other Bidders will receive points in reverse proportion according to the following formula:* *Points for the Financial Bid being evaluated =* *[Maximum number of points for Financial Bid] x [lowest price]* *[Price of Financial Bid being evaluated]*

TECHNICAL EVALUATION CRITERIA (Maximum 30 points)	**Scoring methodology**
Past delivery lead time performance (highest) **	*For these criteria, the maximum number of points will be allocated to the supplier with the highest result for the criterion being evaluated for the product. Other Bidders will receive points in reverse proportion according to the following formula:* *Points for the result of the criterion being evaluated =* *[Maximum number of points for the criterion] x [Result for the criterion being evaluated] [highest result for the criterion]*
Number of product registrations in countries (highest)	
Supplier's responsiveness, collaboration and communication score (highest) ***	

** Price per unit (tablet) offered for the EXW Incoterm. In the case free goods being offered, the unit price being evaluated will be the unit price prorated with the number of packs of free goods offered per number of packs purchased.*

**** Past delivery lead time performance: *Historical performance on delivery lead times (promised date of delivery versus actual date of delivery) will be used in the evaluation of performance in terms of delivery time. For this ITB, performance will be measured per order line, over the full period of validity of the last LTA of a duration of six months or more, including extensions, if any*.

In cases where there is no supply history for a specific product/supplier, the following methodology will be used for assigning a performance score:

- ✓ *If there is inadequate or non-existent product-specific history (i.e., the supplier has been part of GDF/Procurement Agent activities but has not previously supplied the product in question), the average performance of the supplier across all other relevant products will be considered;*
- ✓ *If there is inadequate or non-existent supplier history (i.e., the supplier is new to GDF/Procurement Agent activities or has not supplied any products during the evaluation period), a Supplier Performance Score will be assigned that reflects the average score of all eligible suppliers for that product.*

*** *Responsiveness, collaboration and communication score*

- ✓ *Responsiveness*
  - *Timely feedback on PO Status Overview: Suppliers are requested to send a response on the order status (clear and complete) within three (3) working days of the request.*
  - *Timely, complete and clear updates on delays: Delays should be communicated at least seven days before the due date with a clear explanation of the delays and mitigation plan, if any.*
- ✓ *Supplier's collaboration and communication*
  - *Supportiveness towards operational requests, with collaboration measured according to low/medium and high categories.*

3.8.5. The evaluation and scores assigned to each product offered by suppliers will be done based on the evaluation criteria and scoring methodology listed in section 3.8.4. to reach the scope of the ITB as described in section 2.

3.8.6. GDF/i+solutions will be under no obligation to reveal or discuss with any Bidder how the Technical and Financial Bids were assessed, or to provide any other information related to the selection process. GDF/i+solutions will only provide, upon the supplier's request, the total number of points allocated between the Technical and Financial Bids, as stated in section 3.8.3, concerning their Bid only. Bidders whose Bids are not selected will be notified in writing of this fact and shall have no claim whatsoever to any kind of compensation or justification.

3.8.7. The competitive range of the Bids quoted is considered to be within a maximum delta of +15% from the average price of all eligible products of the same Bid Item. Suppliers that quote a price per unit that falls outside of the competitive range may still be awarded an LTA.

3.8.8. If it is the opinion of GDF/i+solutions that the prices offered by a supplier for a particular product(s) are not reasonable, the supplier may be requested to provide proper justification along with substantiated evidence within 1–2 working days.

3.8.9. GDF/i+solutions expressly reserves the right without liability or penalty to any party to:

a) Reject any or all Bids;
b) Invalidate any Bid received from a Bidder who, in the opinion of GDF/i+solutions, is not in a position to perform the contract;
c) Accept part of a Bid.

3.9. Bid adjudication and market share allocation

3.9.1. The Bid adjudication will be carried out by a Bid Adjudication Committee. This Committee will consist of at least two members, with at least one representative from i+solutions and one representative from GDF. The Committee will convene at the scheduled time stated in section 1.4. Additional independent parties may be invited to observe the adjudication process under a strict confidentiality agreement with GDF/i+solutions.

3.9.2. The Bid Adjudication Committee will make its final decision based on the Bid evaluation outcomes presented by the Bid Evaluation Committee. The Bid Adjudication Committee will operate by consensus. If consensus cannot be reached, GDF's representative will decide the outcome.

3.9.3. Although GDF/i+solutions may make multiple awards, there is no guarantee that all eligible Bidders will be considered. .

3.9.4. **Market share allocation**:

3.9.4.1. For ***Schedule 4: Bedaquiline demand for all suppliers***. The market share allocation is indicative, based on a primary/secondary and auxiliary supplier status as per the outcomes of the ITB. It is implemented per product based on the total estimated quantities to be purchased over the contract period (see Annex H), as follows:

a. 60%/40% for primary/secondary suppliers;
b. 0% for auxiliary suppliers.

Note: Based on the total estimated quantities to be procured, GDF/i+solutions expects to award two suppliers for the market share allocation as stated above - to ensure the best price and economies of scale for the selected suppliers. Market share allocation to suppliers during the valid period of the LTA will be subject to the terms as defined in section 3.9.5 below.

3.9.4.2. For ***Schedule 5: Bedaquiline demand for originator product only.*** There is no market share. 100% of the market will be awarded to the originator (sole supplier status). It is implemented based on the total estimated quantities to be purchased over the contract period (see Annex H).

3.9.5. i+solutions, on behalf of GDF, will award LTAs based on the requirements stated in this ITB document. However, GDF/i+solutions reserves the right – at no cost to GDF/i+solutions – to adjust or cancel the orders placed for product(s) awarded to suppliers over the valid period of the LTA, and/or to suspend or terminate the LTA and reallocate quantities to other contracted suppliers at its sole discretion for any of the following reasons:

a) The supplier's inability to deliver against agreed lead times for any reason, including a force majeure event;
b) The lapse of necessary regulatory approval or certification;
c) The occurrence of any unforeseen event because of which GDF/i+solutions determines a tangible risk that the supply or price continuity cannot be maintained;
d) The supplier's failure to meet performance standards (including, but not limited to, compliance with actual lead times, responsiveness, production capacity, importation requirements, registration status). i+solutions will assess supplier performance quarterly. If a supplier is underperforming, GDF/i+solutions may issue an order for only a limited quantity until satisfactory performance can be established;
e) A change in the WHO-recommended treatment regimens, the enactment of which will materially impact the demand profile for the supplied products during the LTA period;
f) Failure in quality of the manufactured products or failure in quality of one or more of its components (API, excipients). In this case, even orders already produced can be cancelled;

g) The supplier's uncured material breach(es) of the LTA or violation of the i+solutions Code of Conduct;
h) Client preferences, including but not limited to packaging and shelf life.

3.9.6. While auxiliary suppliers will sign LTAs without market share allocation, they may receive POs based on specific country requests or as deemed otherwise necessary by GDF/i+solutions.

3.10. Notification of awards to Bidders

3.10.1. i+solutions will notify all qualified Bidders in writing of the outcomes of the ITB prior to the end of the period of Bid validity and at the scheduled time stated in section 1.4.

3.10.2. If a correction to the awards is required, this will be communicated to all awardees.

3.10.3. The awards of this ITB will supersede the awards of the previous ITBs for identical products, and new LTAs will be issued accordingly.

3.11. Requests for Clarifications or Complaints after ITB awarding

3.11.1. After the outcomes of the ITB have been communicated to the Bidders, the Bidder has the right to file a Request for Clarification or to file a Formal Complaint on the outcomes of the ITB. If a correction to the awards is published at a later stage, GDF/i+solutions may announce a shortened deadline for Requests for Clarification or Formal Complaints.

3.11.2. The Request for Clarification or the Formal Complaint should be sent only to the contacts listed in section 1.5 and should be filed within three (3) working days after the outcomes of the ITB are communicated.

3.11.3. Only ***Annex K. Form for Requests for Clarifications or Complaints after ITB awarding*** with one option clearly selected shall be used for the submission of either a Request for Clarification or a Formal Complaint.

3.11.4. If the Bidder files a Request for Clarification within the deadline, as per section 3.11.2, i+solutions shall, on behalf of GDF, provide a written response to the Bidder within three (3) working days after the submission deadline for the Request for Clarification.

3.11.5. If the Bidder files a Formal Complaint within the deadline as per section 3.11.2, GDF/i+solutions will establish a Complaint Review Committee. This Complaint Review Committee will consist of independent representatives from both GDF and i+solutions who were not members of the Bid Evaluation or Adjudication Committees. If required, the Complaint Review Committee may also include representatives from other agencies or external independent experts.

3.11.6. The Complaint Review Committee will review the complaint and provide its decision to the Bidder within five (5) working days of receiving the Formal Complaint. The decision of the Complaint Review Committee is final, and the Complaint Review Committee will be under no obligation to reveal the details of the review. If deemed necessary, GDF/i+solutions will modify the ITB awards in line with the decision of the Complaint Review Committee.

3.11.7. Formal Complaints must only be filed by Bidders. Complaints filed by third parties will not be considered.

3.12. Bidder warranties

3.12.1. If successful, the Bidder warrants that:

a. All TB medicines and related products offered are identical in all aspects of manufacturing and quality to that approved by WHO PQP and/or the relevant SRA and/or the ERP. This includes, but is not limited to, the following:
   I. FPP formulation and specifications;
   II. Method and site of manufacture;
   III. Sources and specifications of active and excipient starting ingredients;
   IV. Materials and specifications of the packaging (primary, secondary, pack size, label and package insert);
   V. Shelf life and storage conditions;
   VI. Product information;

b. It has the personnel, experience, qualifications, facilities, financial resources and all other skills and resources to perform its obligations under the LTA or PO;

c. The products supplied shall be new and factory packed, and conform to the specifications offered;

d. The products shall be free of defects in workmanship and materials;

e. The products shall be contained or packaged to ensure the integrity of the product and to fully comply with valid regulatory approvals;

f. It has not and shall not enter into any agreement or arrangement that restrains or restricts GDF/i+solutions or the ultimate recipient's rights to use, sell, dispose of or otherwise deal with any item that may be acquired through any resulting LTA or PO;

g. The Bidder and any of its affiliates shall minimize greenhouse gas emissions in their activities to the extent possible;

h. It shall obtain any export license or other governmental authorization that may be necessary. It will be the sole responsibility of the Bidder to obtain such license or authorization. GDF/i+solutions may assist upon request;

i. It will register its products including payment of the cost of registration in the countries for which it has received orders and where this registration is mandatory.

3.12.2. The successful Bidders acknowledge that:

a. GDF/i+solutions may further distribute the products supplied to its clients;

b. The benefit of any warranties provided and liabilities entered into with i+solutions shall be passed on by i+solutions to its clients.