ITB [add Reference] – LTA [add Number] [add Date]

LONG-TERM AGREEMENT

BETWEEN

Stichting Iplussolutions (hereafter refered to as i+solutions)

AND

[INSERT NAME OF SUPPLIER]

[INSERT FULL ADDRESS]

Address: [add Address]

Telephone: [add Telephone]

E-mail: [add E-mail]

FOR THE PURCHASE OF ANTI-TUBERCULOSIS (TB) MEDICINES

For i+solutions :

Ed Monchen, CEO

Queries to: wkreft@iplussolutions.org

and

For [INSERT NAME OF SUPPLIER]:

[INSERT NAME OF AUTHORISED SIGNATORY AND TITLE]

Initials of the authorised signatory of supplier:_____

Long-Term Agreement (LTA): [add LTA Reference]

LTA Validity: **From** [add Date] **To** [add Date]

Price INCOTERM (2020) Valid: EXW/FCA/DAP (including offloading and customs clearance if applicable)

Payment Currency: US DOLLARS

Payment Terms: Within 45 days after the date of invoice and Incoterm fulfilment

Delivery Terms: as agreed on with i+solutions

PRODUCT(S), SPECIFICATION(S) AND PRICE(S):

The below describes the specifications and prices of products offered and awarded during ITB process

Item No. 1:

Product Specifications:	
Primary packaging type:	
Number of units per primary packaging type:	
Secondary Packaging type:	
Number of units per secondary packaging type:	
Quality status:	
Shelf life (months)	
Storage conditions:	
Delivery Lead Time (in weeks) for regular quantity:	
Delivery Lead Time (in weeks) for high quantity:	
Minimum Order Quantity (MOQ): if applicable	

Initials of the authorised signatory of supplier:_____

Supply Price:

Price EXW in US DOLLARS (ex-Supplier)	Price FCA in US DOLLARS (named place)	Price DAP* in US DOLLARS: without tax	Price DAP* in US DOLLARS: with tax

*For India only, please refer to **Article 8.1** for details

Supply Locations:

Location EXW (city, country)	Location FCA (city, country)

TERMS OF AGREEMENT

WHEREAS the Stop TB Partnership/The Global Drug Facility (GDF) has contracted i+solutions as the Procurement Agent for procurement and delivery of anti-tuberculosis (TB) medicines and related Products on its behalf.

WHEREAS i+solutions desires to enter into a Long-Term Agreement (abbreviated to "LTA") for the supply of the referenced item(s) above (abbreviated to "Products") by order and account of the GDF and its supported clients (abbreviated to "End Users").

WHEREAS the Supplier confirms that it is qualified, ready, willing and able to supply such Products in accordance with the terms and conditions of this LTA.

1. DEFINITIONS

Adverse Event means any untoward medical occurrence in a patient or clinical-trial subject administered a human medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (e.g. an abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Affiliates means any corporation or other business entity which, directly or indirectly, is controlled by, controls, or is under common control with i+solutions or the Supplier as the case may be. For such purposes, "control" shall mean the direct or indirect ownership of more than fifty percent (50%) of the voting interest in such corporation or other entity or the power in fact to control the management directions of such entity.

Annex or Annexes means that annex or those annexes attached to and forming an integral part of the LTA.

Initials of the authorised signatory of supplier:_____

GDP means applicable current good distribution practices.

GMP means applicable current good manufacturing practices.

Code of Conduct for suppliers means the i+solutions' Code of Conduct for Suppliers, as amended from time to time and currently located on the i+solutions website at: https://www.iplussolutions.org/wp-content/uploads/2023/02/Code-of-Conduct-for-Suppliers.pdf

Commencement Date means starting date of LTA validity (From).

CoA means Certificate of Analysis.

CIS means the Consignment Inspection and Sampling.

Supplier means name of the supplier as stated in title page of the LTA .

Expiry Date means last date of LTA validity.

FPP means Finished Pharmaceutical Product.

Global Drug Facility (abbreviated: **GDF),** as part of the Stop TB Partnership, is a unique procurement mechanism for supplying quality assured and affordable anti-tuberculosis medicines and diagnostics to countries in need, as well as providing technical assistance for strengthening national medicines and diagnostics supply management systems.

Invitation to Bid (abbreviated: **ITB**) means [**ITB Reference**] from i+solutions to the Supplier to quote for the cost of supply of the products to i+solutions.

Long-Term Agreement (abbreviated: **LTA**), means this Agreement between the Parties to provide Products, including its Annexes, however with due consideration of the order of precedence among the LTA and individual Annexes, as established in Article 2.1.

Medical Export Group (abbreviated: **MEG**) means appointed partner of i+solutions for warehousing services in the Netherlands.

NOC means Notice of Concern

Parties means i+solutions and the Supplier, their permitted successors and assignees.

Pharmacovigilance Agreement means the agreement, if any, entered into between the Parties governing all pharmacovigilance obligations arising as a result of entry into and implementation of this Agreement, including but not limited to, with respect of adverse events and to any other regulatory and reporting matters set out in that agreement as relevant.

Products, in singular form **Product**, means the item(s), as described and detailed above.

PSI means Pre-shipment Inspection.

Purchase Order or **Orders** means the order(s) raised by i+solutions to purchase Products in specific quantities from the Supplier from time to time in accordance with the terms of this LTA.

QCA means Quality Control Agency.

QCL means Quality Control Laboratory.

Initials of the authorised signatory of supplier:_____

Quality Agreement means the agreement, if any, entered into between the Parties governing matters relating to quality assurance, quality control and change control with respect to the distribution and supply of the Products.

RFI form means Request for Inspection form.

Request for Quotation (Abbreviated: **RFQ)** means mini bidding competitions for specific, consolidated/bulk volume requirements.

Warranty Period means the period of duration of the warranty in respect to the Products, as described in Article 17.5.

2. LTA DOCUMENTS

2.1 The LTA between the Parties consists of the following documents:

- This LTA
- Notification of Awards dated **[add Date]**
- Invitation to Bid reference number **[ITB-Reference]**
- I+solutions code of conduct [Annex A]
- Supplier's Financial Bid dated **[add Date]**

2.2 The above documents are complementary to one another. However, in the event of any inconsistencies among them, they shall prevail in the order of their enumeration in Article 2.1 above, unless agreed otherwise in writing between the Parties.

3. PURPOSE OF LTA

3.1 The Supplier shall provide Products to i+solutions as may be required from time to time pursuant to a Purchase Order(s) and in accordance with terms and conditions of this LTA.

3.2 The LTA is awarded under the ITB mentioned in Article 2.1 above. For the Products covered by this LTA, the Supplier has been awarded the following status, together with indicative market share allocations of the estimated total Product quantities over the contract period and subject to the conditions set out in the ITB:

Product	**LTA award status** Primary/Secondary/ Tertiary/ Auxiliary/New/ Awarded	**Indicative market share allocation** *(if applicable)*
Schedule X		
Item No. X	**xx**	**xx %**

3.3 The allocation of market share, if applicable, is indicative based on the primary/ secondary/ tertiary/ auxiliary/new supplier status awarded and might be subject to change.

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3.4 i+solutions reserves the right to adjust or cancel the orders placed and/or the market share allocation for awarded product(s) 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 i+solutions determines and establishes 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 delivery lead times, responsiveness, production capacity, importation requirements, registration status). i+solutions will assess supplier performance quarterly. If a supplier is underperforming, i+solutions /GDF 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 etc.). 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 for suppliers;

h) Client preferences, including but not limited to packaging and shelf life.

3.5 For sole suppliers, i+solutions reserves the right to re-negotiate the price and terms of the LTA during the LTA period.

3.6 While auxiliary supplier has no market share allocation, i+solutions may submit purchase orders based on specific country requests or as deemed otherwise necessary by i+solutions /GDF.

3.7 Supplier performance will be measured using indicators defined by i+solutions /GDF and will be reported every three (3) months to suppliers. The market share allocation for the next period will be determined based on the performance that includes, but is not limited to, responsiveness, communication and collaboration, delivery lead time according to LTA and/or Order Confirmation, order acknowledgement with delivery date confirmation as per PO Incoterm and quality compliance.

3.8 The Supplier acknowledges that:

a) i+solutions is not obligated to order any quantity of the Product(s) from the supplier pursuant to this LTA and is not liable for any costs in the event no Purchase Orders are placed
b) this Agreement is non-exclusive, and i+solutions is entitled to procure the same or similar Products from other suppliers, as it sees fit;
c) i+solutions /GDF may issue new ITBs for specific products when:

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i. current supplier(s) are deemed unable to deliver the orders due to insufficient production capacity or insufficient current API capacities, requiring sourcing from alternative more expensive source, or
ii. 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 a combination of a) and b), or
iii. i+solutions /GDF and suppliers fail to agree on a proposed price increase, or
iv. There are other unforeseen exceptional circumstances, at the discretion of i+solutions /GDF.

d) in the event of a change of the Procurement Agent by GDF, the Supplier shall accept to have all rights and obligations pertaining to the LTA of the i+solutions, to be transferred from i+solutions to the new organization.

3.9 The Supplier undertakes to provide to i+solutions copies of the following documents upon signing of the LTA for products listed in this LTA:

a) Valid GMP certificates for the FPP manufacturing site (issued by WHO PQP/SRA/PICs, WHO Technical Report Series No 863, 1996. Earlier version is not acceptable)
b) Valid Marketing Authorization including its Annexes, issued by Stringent Regulatory Authority
c) Most recent version of the Certificate of Pharmaceutical Product (CPP/CoPP)
d) Approved API and FPP specifications from the relevant SRA or WHO PQP or ERP
e) FPP manufacturing site license with full address
f) FPP manufacturing site latest inspection report from the relevant SRA or WHO PQP
g) API manufacturing site license with full address
h) Most recently approved version of the Product information for patient (leaflet) from the relevant SRA or WHO PQP
i) Copy of the recent NOC, warning letter, injunction issued by auditing or regulating bodies, if any

4. TERM AND TERMINATION

4.1 The LTA shall commence on the Commencement Date and expire at midnight on the Expiry Date, unless terminated earlier in accordance with the provisions of this LTA (the Initial Term). 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.

4.2 i+solutions shall be entitled to request supplier (but the Supplier shall not be obliged to accept) to renew the LTA for consecutive term/s of up to 12 months, and on the same terms and conditions, unless otherwise agreed by the Parties, by giving written notice of its intention to renew the LTA and may provide the Supplier with product forecast(s) for the next period/s not less than sixty (60) calendar days prior to the LTAs Expiry Date, provided however that:

a) the Supplier: (i) shall be entitled to review its prices to apply from the end of the Initial Term; and (ii) shall, not less than within forty-five (45) calendar days before the end of the initial Term, advise i+solutions in writing as to price maintenance or proposed price increases or reductions; in case of a price increase, reasonable written explanation needs to be provided to i+solutions; and

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b) i+solutions shall notify the Supplier in writing within twenty (20) calendar days of receipt of that notice whether it agrees to the revised prices. In case of any price increase, i+solutions shall be entitled to revise the market share allocations.

4.3 If i+solutions:

a) agrees to the revised prices, then the LTA shall be amended to reflect this; or
b) rejects the revised prices, then the LTA shall be terminated in accordance with Article 4.1

4.4 In the event of:

a) a material breach of this Agreement or applicable law or regulation by one of the Parties, which is capable of remedy and that Party has failed to remedy such breach within thirty (30) calendar days from having received a written request to remedy that breach from the non-breaching Party; or any Adverse Event or any regulatory authority taking any action, or raising any objection, that prevents the Supplier from supplying the Product, then, also as referred to Article 3.4 above, the other party may terminate the LTA with immediate effect on written notice, stating the reason for the termination.

4.5 In the event of the termination or expiry of this LTA:

a) at i+solutions request, the Supplier shall deliver the outstanding Products in a prompt and orderly manner and in accordance with the terms of this LTA, and
b) the Supplier acknowledges that i+solutions shall only pay the Supplier for Products ordered pursuant to Purchase Orders placed before the date of the termination notice or LTA expiry date and satisfactorily provided in accordance with this LTA.

4.6 In case of failure by the Supplier to perform its obligations in accordance with the terms of this LTA, which may include, but is not limited to its failure to make delivery of all or part of the Products in accordance with a Purchase Order by the delivery date or dates agreed, i+solutions may, after giving the Supplier reasonable notice to perform and, without prejudice to any other rights or remedies, exercise one or more of the following rights:

a) procure all or part of the Products from other sources, in which event i+solutions may hold the Supplier responsible for any excess cost occasioned thereby. In exercising such rights i+solutions shall mitigate its damages in good faith;
b) refuse to accept delivery of all or part of the Products;
c) terminate the LTA.

5. TOTAL PRICE

5.1 i+solutions shall pay the Supplier for each delivery made in respect of a Purchase Order issued and in accordance with the terms and conditions of this LTA. The sum payable shall be based on the quantities ordered by i+solutions under that Purchase Order and delivered by the Supplier, at the prices specified in this LTA/Purchase order.

Initials of the authorised signatory of supplier:_____

5.2 The Supplier guarantees that the prices specified in this LTA are the maximum prices that shall remain firm and shall not be increased during the Initial Term. If the Supplier is able to offer i+solutions a lower unit price, the unit prices may be reduced by the Supplier, at its discretion, for specific Purchase Orders.

5.3 The Supplier shall not sell or make otherwise available the Products to third parties at lower prices than as stated in this LTA. This shall be monitored by i+solutions /GDF with reference to a Global Price Reporting Mechanism or other available information.

5.4 In the event that i+solutions /GDF becomes aware that a third party has received lower pricing for the same Products outlined in this LTA and of the same quality, i+solutions shall inform the Supplier immediately and request from the Supplier:

a) retrospective adjustment of prices for any orders placed by i+solutions since the date of the Supplier offering lower prices to that third party; and
b) reimbursement to i+solutions before any new Purchase Orders shall be placed with the Supplier.

5.5 Supplier shall direct any requests from third parties about GDF prices for the products under this LTA to the GDF with the reference to GDF product catalog under https://www.stoptb.org/global-drug-facility-gdf/gdf-product-catalog

6. PURCHASE ORDER

6.1 i+solutions reserves the right to conduct mini bidding competitions by way of Requests for Quotation (RFQ) for specific, consolidated/bulk volume requirements.

6.2 i+solutions may issue Purchase Orders to the Supplier, from time to time during the term of this LTA, referring to this LTA, and setting out the quantities required and other instructions for the delivery of the Products.

6.3 The Supplier shall acknowledge receipt of a Purchase Order by providing written confirmation by email, and/or signing and returning the Purchase Order acknowledgement with delivery/readiness date within three (3) working days of its receipt by email.

6.4 The Supplier agrees to supply Products to i+solutions pursuant to Purchase Orders received during the term of the LTA, which shall conform with the specifications and the prices specified in this LTA in addition to other instructions as specified in the Purchase Order.

6.5 Notwithstanding the obligation contained in Article 6.4, if i+solutions places a Purchase Order in accordance with the delivery Lead Time in this LTA, which the Supplier considers it cannot substantially meet, because of limited quantities of stock, production capacity, inability to meet the specifications, or any other reason, before proceeding to make a partial delivery of the Products, the Supplier shall seek further written instructions from i+solutions and shall take care of the additional costs caused by such partial deliveries as described in Article 8.7. In case i+solutions and the supplier do not find an acceptable solution, i+solutions may apply the rights stated in Article 4.6.

Initials of the authorised signatory of supplier:_____

6.6 The Supplier shall accept changes to or cancellations of Purchase Orders provided that reasonable written notice is given by i+solutions and no production or material costs have been incurred, or in the event the Supplier had not yet given confirmation for the relevant Purchase Order to i+solutions.

6.7 The Supplier undertakes to provide to i+solutions the status of open Purchase Orders twice a month along with the reason in the event of orders delayed. Also, proactive communication on delays with clear explanation and mitigation plan, if any, at least 1 week prior to the due date.

7. QUALITY CONTROL: PRE-SHIPMENT INSPECTION, TESTING AND CoA REVIEW

The quality control of Finished Pharmaceutical Products is mandatory for all GDF purchases and takes place as per the approved QA Policy and procedures of GDF, executed by the contracted Quality Control Agencies (QCA): the Consignment Inspection and Sampling (CIS) agency and the contracted Quality Control Laboratory (QCL), and coordinated by i+solutions.

7.1 Batches and/or consignments shipped to a client directly from manufacturer are subject to Pre-Shipment Inspection (PSI) and sampling executed by the contracted CIS, review of Certificate of Analysis (CoA) and testing are performed by the contracted QCL.

7.2 For this purpose, the Supplier would be required to submit the applicable documentation (approved specifications and variations of FPP) by e-mail as soon as they are approved/effective to QCA alongside with a certified copy of the original Certificate of Analysis (CoA) to ensure that the specification reference/version mentioned on the COA matches with the specification available with QCA, to avoid delay in process of COA review and deviation.

7.3 Information on goods readiness should be made available to the coordinating office of the CIS/QCL five (5) working days before the pre-shipment inspection is requested to be carried out together with duly filled in request for inspection form (RFI).

7.4 The CIS and QCL activities in no way relieve the Supplier from the performance of full contractual obligations to i+solutions.

7.5 The cost of PSI and testing are paid by clients and coordinated by i+solutions, unless additional costs for these were caused by Supplier, see Article 6.5. In this case CIS will raise invoice to supplier and supplier should pay CIS within the indicated payment term (30 days after date of invoice).

7.6 Where samples are taken for testing, the Supplier may be requested to replace the sampled quantity at Supplier's costs.

7.7 In case of any changes to approved FPP and/or its specifications from the information as provided during the ITB and/or mentioned in this LTA, the Supplier must immediately inform GDF QA of these changes.

7.8 Shipment in parallel with QC testing is authorized in emergency and/or possible supply chain interruption cases. Should the batch in the meantime fail the QC

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testing, the Supplier will be requested to recall and replace the complete batch and cover the destruction expenses at the recipient country at its own cost.

7.9 In case of the detection of Out of Specification (OoS) product, both Supplier and QCL shall investigate the OoS following their relevant internal procedures and communicate the investigation results through a full report to GDF and i+solutions QA within the agreed timelines.

7.10 In case of confirmed OoS of Product, either at PSI or QC testing stage or at time of transit/shipment or the case of shipment in parallel to QC (as specified in 7.8), the Supplier will be requested to recall and replace the complete batch at its own cost including its destruction in the country of destination.

7.11 The reference and working standards required for routine quality testing will be procured by QCA. In case of QC testing as per the in-house methods, supplier is responsible to provide reference materials and/or working standards to QCA upon request.

7.12 The activities described in the Section 7 can be also captured in separately concluded Quality Agreement if Supplier and i+solutions wish so.

8. DELIVERY

8.1 The Supplier shall make available or deliver the Products EXW (Ex-Works), or FCA (Free Carrier Alongside), or DAP (Delivered at Place) including offloading for Indian supplies to Government Medical Store Depots (GMSDs) situated in Delhi, Chennai, Hyderabad, Mumbai, Karnal, Kolkata and Guwahati (Incoterms 2020) as follows: at the Supplier's premises available for collection for EXW; at named place as quoted for FCA, and at consignee warehouse including offloading for DAP, in accordance with this LTA and the relevant Purchase Orders. All risks of loss or damage to the Products shall remain with the Supplier until collection or delivery takes place in accordance with the LTA and the Incoterms specified in the Purchase Orders.

8.2 Delivery shall not exceed the Lead Time specified for each item in the respective Purchase Order at the time of order confirmation in accordance with the terms of this LTA. Supplier acknowledges that delivery lead time is calculated from the time of issuance of a Purchase Order to Supplier to when Products are ready including QA release by supplier for PSI or dispatch (in case PSI/sampling is not required) at the premises of the supplier along with the required shipping documents as specified in the Purchase Order.

8.3 Delivery shall only be considered as completed upon the collection of the Products or their arrival at the final destination in accordance with Article 8.1 above, and verification by i+solutions personnel or representatives or consignee (if applicable) that the Products are in a satisfactory condition. Verification of the Products shall be made as soon as reasonably practicable after receipt. i+solutions personnel or representatives or consignee (if applicable) shall be entitled to reject and refuse acceptance of the Products not conforming to this LTA and the related Purchase Order. Payment for any non-conforming Products pursuant to this LTA shall not be deemed an acceptance of the Products.

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8.4 The Supplier will supply the Product in compliance with the Supplier's standard specifications for the applicable Product. i+solutions personnel or representatives or consignee (if applicable) shall inspect the Product delivered and will notify the Supplier of any defects, damage or shortage within fifteen (15) calendar days of receipt. i+solutions personnel or representatives or consignee (if applicable) shall notify the Supplier of any hidden or latent defects (i.e. not discoverable by routine quality control inspection), of which it becomes aware, within five (5) days following discovery of the defect. If i+solutions notifies the Supplier of a defect, damage or shortage within the above-mentioned timeframes and:

a) In case of quality complaints, the Supplier to undertake an investigation and provide the report to i+solutions as per the agreed timelines.
b) the Supplier agrees with i+solutions explanation of the cause of such defect, damage or shortage, the Supplier will compensate i+solutions for any defective, damaged or missing Product (unless such defect, damage or shortage is caused by the actions or omissions of i+solutions or its sub-contractors, or occurs while the Product is under the control of i+solutions); or
c) the Supplier disagrees with i+solutions explanation of the cause of such defect or damage, samples shall be submitted for QC testing to an independent laboratory, when the product quality is concerned and final decision to be taken following the outcome. For other damages mutually acceptable agreement to be sought with regards to the Product being defective or damaged shall be final and binding upon the Parties.
d) the costs arising from this process shall be borne by the party whose claim failed.

8.5 The Supplier acknowledges that any inspection and/or verification of the Products by i+solutions personnel or representatives or the contracted CSI, is without prejudice to the warranties extended by the Supplier under Article 17, which shall remain valid for the duration of the shelf life of the Product.

8.6 The Supplier shall use its reasonable endeavors to abide by the delivery dates stated in the Purchase Orders. If the Supplier is not able to meet such a delivery date or the quantities required under that Purchase Order, then the Supplier will pro-actively alert i+solutions and provide a justified reason for not meeting that date and or quantity. In case i+solutions and the supplier do not find an acceptable solution, i+solutions may apply the rights stated in art 4.6.

8.7 In the event that the Supplier is not able to ensure delivery as per the dates committed in the Purchase Order confirmation, i+solutions shall be entitled to request the Supplier to pay any additional transport costs (e.g. airlifting) and/or additional PSI cost which may reasonably be incurred as the result of i+solutions obligations to its clients to deliver the Products on time and to avoid stock-outs.

8.8 For late delivery of Products or for items which do not meet specifications and are therefore rejected by i+solutions or the consignee, i+solutions can claim liquidated damages from the Supplier and deduct 0.2% of the value of the Products pursuant to a Purchase Order per additional calendar day of delay, up to a maximum total of 10% of the value of the Purchase Order. The payment or deduction of such liquidated damages shall not relieve the Supplier from any of its other obligations or liabilities pursuant to this LTA or a Purchase Order.

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8.9 In case of delays where Supplier pays for additional transport and PSI costs and on time delivery to i+solutions /consignee can be guaranteed, the imposition of Liquidated Damages can be waived by i+solutions.

8.10 The Supplier shall cover all reasonable and documented transport and other costs related to the recall and replacement of Products, if such Products are not accepted by i+solutions, or the consignee (as applicable) due to non-conformance with the Supplier's standard specifications as set out in Article 8.4. Products returned to the Supplier shall be recorded as credits to i+solutions and replacements shall be delivered by the Supplier as soon as commercially reasonable.

8.11 The Supplier shall ensure that the quality, integrity, and shelf life of the products is maintained during storage and transport under their responsibility. For pharmaceutical products, the quality must be ensured through continuous temperature monitoring during storage and transport. Temperature monitoring during transport may be exempted based on risk assessment taking into account means of transport, transport time and prevailing temperature. The Supplier will be liable in case quality of the goods is not maintained due to unacceptable storage or transport conditions during the period wherein supplier is responsible for the logistics.

9. SHIPPING OR COLLECTION INSTRUCTIONS

9.1 Collection of products is completed in accordance with EXW or FCA INCOTERMS 2020 according to the Purchase Order issued. Suppliers should give reasonable amount of time of minimum 1 week to arrange the pick-up of the shipment after the readiness as per INCOTERM and completion of PSI, sampling, test result, as applicable. For some countries, the import license takes long time, in such case, if supplier request to pick-up the goods before import license is available then i+solutions will store the goods at nominated forwarder warehouse but in case the export is not done as per the GST deadline, then i+solutions /GDF is not responsible for the payment of GST or the reversal of the transaction and the cost therein.

9.2 The Supplier shall, in good time to meet the delivery date(s), follow i+solutions instructions on forwarding and/or instructions from the i+solutions appointed forwarding agent.

9.3 To ensure that the forwarder without undue delay can arrange dispatch of the consignment(s), it is important that the Supplier contacts the forwarder and provides them with cargo and all the necessary export clearance documents as soon as they have received green light from i+solutions in case of EXW and FCA Incoterms.

9.4 In case of DAP Incoterm (including offloading), upon receipt of green light from i+solutions, the Supplier should arrange the dispatch as soon as possible.

9.5 Any impediment to delivery must be advised in writing to i+solutions and the forwarder as soon as possible.

9.6 For shipment to i+solutions - MEG, detailed instructions are provided in the MEG warehousing SOPs. These SOPs will be shared after signing of this LTA.

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10. DOCUMENTATION AND IDENTIFICATION

10.1 The Supplier shall, at its own risk and expense, obtain any export license or other official authorization and carry out formalities necessary for the exportation of the Products.

10.2 The Supplier shall submit the following documents to the i+solutions freight forwarder in case of EXW and FCA Incoterms:

a) four (4) copies of itemized invoice;
b) four (4) copies of Packing List;
c) one (1) copy of the Clean Report of Findings (CRF) issued by the contracted Quality Control Agent (if applicable)
d) one (1) copy of the Certificate of Analysis (CoA) for each batch delivered
e) any other document/certificates required by i+solutions for export/import of the Products, e.g. DCGI (if applicable) Certificate of Origin, Certificate of Pharmaceutical Product, as specified by i+solutions in the Purchase Order.

In case of DAP Incoterm (including offloading), one set of documents as specified in the Purchase Order should be sent along with the consignment.

10.3 Invoice and Packing List should clearly indicate the i+solutions Purchase Order number, i+solutions item code, unit price and total price bifurcation between EXW and FCA/DAP in the invoice as per Purchase Order and country of destination. On a case by case basis, if needed, the Supplier may request i+solutions to solicit GDF's facilitation in the export process by available means in the scope of the procurement services agreement entered between the i+solutions and the GDF.

10.4 The Certificate of Analysis must be as per regulatory authority approved specifications (BP, Ph. Eur, Ph. Int., or USP) and issued by the manufacturer's own Quality Control Laboratory covering each batch delivered and to be submitted along with shipping documents. The Certificate of Analysis shall include all aspects of the Finished Pharmaceutical Product testing and be aligned with the module certificate as approved by the regulatory authority.

11. PACKAGING

11.1 The Supplier shall ensure that:

a) all materials used for primary, secondary and tertiary packaging must conform to the relevant edition of the BP, USP, Ph. Eur or Ph. Int. with reference to the specific active pharmaceutical ingredient in the finished pharmaceutical product and comply with the Good Manufacturing and Good Distribution Practices (GMP and GDP) as recommended by WHO;
b) all GDF deliveries in shipper boxes and pallet boxes to countries must be always shrink wrapped to ensure safe transportation and in-country distribution, and to prevent water and moisture penetration; no exception is allowed for this requirement.

Initials of the authorised signatory of supplier:_____

c) the tertiary packaging must be strong, stand stacking to a height of four (4) pallets as static storage and two (2) pallets during transportation, and be puncture resistant;
d) Cartons containing non-uniform contents and cartons containing several batches shall be clearly marked and prior approval should be taken from i+solutions.
e) For loose boxes, the supplier should use the filling materials and not the empty packs of secondary packaging. The loose box must be labeled as "Loose" and with color tape for identification.

11.2 The Supplier warrants that the cost for such packing with the shrink wrapping is included in the cost offered for the Products.

11.3 Deliveries should be packed / palletized in the most cost-effective way to minimize freight costs.

11.4 For shipment to i+solutions - MEG, detailed instructions are provided in the MEG warehousing SOPs for Air/sea and road shipments. These SOPs will be shared with supplier after signing the LTA.

12. ARTWORK AND LABELLING

12.1 The updated GDF Packaging Artwork development guidelines should be used for designing the artwork and labelling of the Product.

12.2 **Outer/shipper cartons/tertiary packaging and pallets** must be clearly labelled as follows: International Non-proprietary Name (INN) or generic name of the FPP, in a bold, clearly visible font size. INNs must not be abbreviated anywhere, including on labels and package inserts, dosage unit (like: 'tablet' etc.), strength/concentration of the Product and include the WHO PQP approval references for all prequalified Products. The label must contain the following:

a) Product name using INNs, dosage unit, pack size and quantity per outer carton (e.g 28 tabs x 24 blisters x 12 packs)
b) i+solutions item code as specified on the original/revised purchase order, (e.g.31411).
c) batch number assigned by the manufacturer;
d) date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
e) name, place and country of manufacturer and marketing authorization holder. For contract manufacture, indicate as: manufactured by company X for company Y.
f) approved storage conditions and/or special storage handling instructions, including warnings and precautions;
g) Purchase Order number;
h) The text "Supplied through the Global Drug Facility - Not for Resale";
i) gross weight;
j) cubic measurement;
k) consecutive carton numbering (e.g. 'carton 1/40')
l) GDF logo
m) GTIN code
n) NTEP logo and Schedule H1 sticker on each carton for India Programme orders only

Languages: English language.

12.3 **Secondary packaging** must be clearly labelled as follows: International Non-proprietary Name (INN) or generic name of the FPP, in a bold, clearly visible font size. INNs must not be abbreviated anywhere, including on labels and package inserts, dosage unit (like: 'tablet' etc.), strength/concentration of the Product, include the WHO PQP approval reference for all prequalified products and the following information:

a) name, strength and pharmaceutical form of the FPP;
b) pack size (i.e. 28 tablets x 24 blisters);
c) batch number as assigned by the manufacturer
d) date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
e) Storage conditions;
f) name and address of the manufacturer and/or marketing authorization holder; For contract manufacture, indicate as: manufactured by company X for company Y;
g) the secondary packaging Artwork to be developed as per the GDF Guidelines and used after the relevant approvals;
h) GTIN code;
i) NTEP logo and Schedule H1 sticker for India Programme orders only.

Languages: Multilingual, including English/French/Russian/Spanish languages.

12.4 **Primary packaging label of vial, ampoule, bottle, and sachet** must be clearly marked in languages as indicated below and should include, as a minimum the following information:

a) name, strength and pharmaceutical form of the FPP;
b) batch number as assigned by the manufacturer;
c) date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
d) name and address of the manufacturer and/or marketing authorization holder; For contract manufacture, indicate as: manufactured by company X for company Y;
e) the primary packaging Artwork to be developed as per the GDF Guidelines and used after the relevant approvals.

Languages: Multilingual, where possible (English/French/Russian/Spanish).) Where the space does not permit, labeling in English language shall be used.

12.5 **Primary packaging as Blister sheet and strip** should include, as a minimum the following information:

a) the indication on the foil, backing of the blister sheet shall be in legible printing (clearly visible color against a background);
b) the foil packing of each blister or strip shall include the following: name, strength and pharmaceutical form of the FPP;
c) batch number as assigned by the manufacturer;
d) date of manufacturing and expiry date as MM/YYYY or DD/MM/YYYY;
e) name and address of the manufacturer and/or marketing authorization holder; For contract manufacture, indicate as: manufactured by company X for company Y;
f) the primary packaging Artwork to be developed as per the GDF Guidelines and used after the relevant approvals.

Languages: Multilingual, where possible (English/French/Russian/Spanish). Where the space does not permit, labeling in English language shall be used.

Initials of the authorised signatory of supplier:_____

12.6 **The package leaflet** shall be included in each secondary packaging and must conform to the following: the latest patient information leaflet (PIL) in a format as required and endorsed by the regulatory body i.e. SRA, WHO PQP or ERP and shall be in full conformance with Summary of product characteristics (SmPC) as approved by the similar bodies and aimed at health professionals. Use of the abridged PILs based on approved version after the GDF concurrence is supported.

Languages: Multilingual, where possible (English/French/Russian/Spanish). Where the space does not permit, labeling in English language shall be used.

12.7 Latest approved version of the Summary of product characteristics (SmPC) in English language to be submitted upon signing of the LTA.

13. PAYMENT

13.1 The Supplier shall submit invoices (one invoice per attachment) to i+solutions at **e-invoices@iplussolutions.org** within 3 calendar days of date of invoice and Incoterm fulfilment for all Products delivered in accordance with this LTA.

13.2 Unless otherwise authorized by i+solutions, a separate invoice must be submitted in respect of each delivery made pursuant to this LTA and the Supplier shall ensure that all invoices:

a) are submitted in English;
b) are payable in US Dollars;
c) refer to the Purchase Order pertinent to each particular delivery of Products; and
d) provide clear and specific details of the Products that have been provided pursuant to the specified Purchase Order number

13.3 Provided that the Supplier has performed its obligations under this LTA, i+solutions shall make payment within forty-five (45) calendar days upon receipt of the invoice specified in clause 13.1 and according to 13.2

13.4 Payments for the Products shall be deposited into the Supplier's bank account as specified in the invoice(s) and in the i+solutions ERP system based on the information given by supplier without any bank transaction fees.

13.5 In case of change in bank details, supplier is required to issue a letter with supplier letterhead and on bank's letterhead to incorporate the changes in i+solutions system.

14. APPROVALS

14.1 i+solutions shall obtain and maintain, throughout the term of this LTA, all necessary permits and licenses required for the warehousing, export, importation and distribution of the Product in relevant territories and shall promptly provide copies of such to the Supplier after the Commencement Date or their receipt, as relevant.

Initials of the authorised signatory of supplier:_____

15. STORAGE CONDITIONS

15.1 The Supplier shall have the right to inspect any premises where the Products are being stored at any time during normal business hours, upon the provision of reasonably prior notice.

16. REGULATORY, ADVERSE EVENTS, PRODUCT RECALLS

16.1 The Parties shall comply with their respective obligations under the Pharmacovigilance Agreement and Quality Agreement, if so entered into between the Parties.

16.2 The Supplier shall promptly notify i+solutions in writing in case the Supplier initiates or is forced by governmental action to initiate, a quarantine, stop-sale, recall, field alert, withdrawal or field correction concerning Product supplied to i+solutions.

16.3 Actions taken on Products supplied to i+solutions shall be managed by a joint team of experts of Supplier and i+solutions in consultation with GDF QA, which shall jointly take the necessary decisions.

17. WARRANTIES AND DEFECTIVE PRODUCT

17.1 The Supplier warrants to i+solutions that:

a) at the time of their delivery to i+solutions, the Products will have been manufactured and supplied in accordance with the standards set forth in the Quality Agreement if concluded separately, or that the Products are identical in all aspects of manufacturing and quality to that approved by the WHO Prequalification Programme (WHO PQP) and/or the relevant Stringent Regulatory Authority (SRA) and/or the Expert Review Panel (ERP). This includes, but is not limited to, the following:
    i. Finished Pharmaceutical Product (FPP) formulation and specifications;
    ii. Method and site of manufacture;
    iii. Sources and specifications of active and excipient starting ingredients;
    iv. Specification of the packaging materials (primary, secondary, pack size, label and package insert);
    v. Shelf life and storage conditions;
    vi. Product information.
b) it has not and shall not enter into any agreement or arrangement that restrains or restricts i+solutions or the ultimate recipient's rights to use, sell, dispose of or otherwise deal with Product that may be acquired under this LTA during its term or purchase order;
c) it has the personnel, experience, qualifications, facilities, financial resources and all other skills and resources to perform its obligations under the LTA or purchase order;
d) the Products supplied shall be new and factory packed and shall conform to the specifications;
e) the Products shall be free from defects in workmanship and materials;
f) the products shall be contained or packaged to ensure the integrity of the Products and to fully comply with valid regulatory approvals;
g) the Supplier and any of its affiliates shall minimize greenhouse emissions in their activities to the extent possible;
h) breach of any of these warranties is a breach of a fundamental term of the LTA

Initials of the authorised signatory of supplier:_____

17.2 For Products approved with below or equal to 24 months shelf life, the Supplier shall commit to complete and submit stability studies to support minimum or beyond 30 months of shelf life either to WHO PQP or SRA depending on the mechanism which approved for the FFP.

17.3 All Products must be of fresh manufacture (except otherwise agreed with i+solutions) and must bear the manufacturing and expiry dates. The Supplier further warrants that all goods supplied will have a remaining shelf life as follows:

a) for products to be delivered to i+solutions warehouse: remaining shelf life of at least 85% upon readiness of goods and shipping documents as per committed schedule,
b) for Products to be delivered directly to GDF clients: remaining shelf life of at least 85% at the time of inspection by the CIS.

17.4 Shelf life and storage conditions: if supported stability data has been submitted, accepted and approved by the regulatory body (WHO PQP, SRA, ERP), Products can be offered with longer shelf life and approved storing conditions upon submission of the approvals to i+solutions /GDF QA responsible persons.

17.5 The Warranty Period shall commence after acceptance by the i+solutions personnel or representative of a delivery of Product is made available for collection by the Supplier under this LTA and shall end in accordance with the remaining shelf life of that Product.

17.6 If, during the Warranty Period, the Products or any part thereof purchased under this LTA are found by i+solutions to be defective or otherwise found not to conform with the LTA, i+solutions may notify the Supplier in writing and in this event, and subject to Article 8.4, the Supplier shall, promptly and at its own cost, correct the defect(s) or other non-conformity (ies) at the consignee's address. If defect(s) or other non-conformity (ies) cannot be corrected, the Supplier shall, at i+solutions discretion, either replace the defective or non-conform Products or reimburse i+solutions promptly and at no expense.

17.7 The Supplier acknowledges that:

a) i+solutions may further distribute the Products supplied to its customers;
b) i+solutions may extend the benefit of any warranties set forth in this LTA to its customers.

17.8 All Products must not have been subject to recall by the applicable National Medicines Regulatory Authority (NMRA) due to unacceptable quality or an adverse drug reaction; nor must they have been rejected at a previous inspection by the contracted Consignment Inspection and Sampling Agency (CIS) and in every other respect they must fully comply in all respects with the technical specifications required by i+solutions /GDF.

17.9 In the event of any Product recalls by the NMRA, the Supplier shall promptly notify i+solutions /GDF QA and provide details for the recall. Where the Product recall is necessitated by a failure by the Supplier or any Supplier's Affiliate to comply with its responsibilities under this LTA, the Supplier shall promptly replace, at its own cost, the recalled Product with Products that fully meet the requirements of the

Initials of the authorised signatory of supplier:_____

technical specifications and original Purchase Order(s) against which they were supplied.

17.10 Where, pursuant to Article 17.9, a Product recall is necessitated by a failure of the Supplier or the Supplier's Affiliate, the Supplier shall:

a) be responsible for transport cost, insurance, customs fees actually incurred by the Purchaser for importation of the replacement Product; and
b) arrange and bear the cost for the defective Product to be reprocessed or destroyed according to agreed written procedures.

18. INDEMNITY

18.1 The Supplier shall indemnify and hold harmless i+solutions, UNOPS/StopTB-GDF, its Clients, UNITAID and the Global Fund, and other donors of resources being used to finance and provide the Products for any loss or damage, including from any third-party product liability claim against i+solutions, UNOPS/StopTB-GDF, , its Clients, UNITAID and the Global Fund, and other donors of resources being used to finance and provide the Products which arises directly as a result of the Products not complying with the warranty provided under Article 17. Upon request by i+solutions, the Supplier shall provide confirmation of insurance covering the manufacturer's liability.

18.2 Notwithstanding anything to contrary in this LTA: (i) neither Party shall be liable under this LTA for any punitive, incidental, special or any indirect damages, or consequential damages, except as described in Article 8.8; and (ii) the total liability of the Supplier under or in connection with this LTA for all claims under or for breach of this LTA (whether under an indemnity or warranty) shall not exceed the total payments made by the i+solutions for the Products ordered under this LTA, provided that the limitation in (ii) shall not apply to fraud, wilful misconduct or gross negligence, personal injury or death, or any other liability that cannot be excluded by law.

19. ACCESS TO THE FACILITIES

19.1. The Supplier shall permit i+solutions or a duly authorized representative of i+solutions to visit to the premises where the Products are manufactured in order to verify information provided in this LTA.

20. LTA AMENDMENTS

20.1 No modification of, or change to this LTA, or waiver of any of its provisions or additional contractual relationship shall be valid and enforceable against either party unless affected by written amendment to this LTA signed by the Supplier and the i+solutions.

Initials of the authorised signatory of supplier:_____

21. MINES, CLIMATE CHANGE AND AMR

21.1 The Supplier represents and warrants that neither it nor any of its Affiliates is actively and directly engaged in patent activities, development, assembly, production, trade or manufacture of mines or in such activities in respect of components primarily utilized in the manufacture of mines. The term "mines" means those devices defined in Paragraphs 1,4 and 5 of Protocol II annexed to the Convention on Prohibitions and Restrictions on the Use of Certain Conventional Weapons Which May be Deemed to Be Excessively Injurious or to Have Indiscriminate Effects of 1980.

21.2 The Supplier is committed to establish strategies and programs to reduce the carbon footprint of its operations, supply chain, and products by improving energy and water efficiency, addressing commodity-driven deforestation, and increasing its use of renewable energy.

21.3 The Supplier is committed to contribute to the avoidance of antimicrobial resistance (AMR).

22. NOTICES

22.1 Any notice to be given to the Parties, shall be sent in writing to:

i+solutions,

Polanerbaan 11,

3447 GN, Woerden, The Netherlands

Att. Wesley Kreft

Tel: +31 348 489 630

Email: wkreft@iplussolutions.org

in the case i+solutions

and

[INSERT SUPPLIER'S NAME]

[INSERT SUPPLIER'S ADDRESS].

Attn: [INSERT NAME]

Tel: [INSERT PHONE NUMBER],

Email: [INSERT EMAIL]

in the case of the Supplier, or to such other addresses as the Parties may provide in writing from time to time. Notices shall be effective when received.

22.2 All notices and other communications under this LTA shall be in writing in the English language and shall be delivered either by: (i) personal delivery against signed receipt; (ii) recognized courier delivery service; (iii) postage prepaid, return receipt requested, certified mail; or (iv) confirmed Email transmission, addressed to the Party for whom intended at the address shown above.

23. SEVERANCE

23.1 In the event that any provision of this LTA shall be declared by any competent authority to be void or unenforceable by reason of any provision under the law of any jurisdiction, it shall be deleted and the remaining provisions of the LTA shall continue in full force and effect. The Parties shall agree to replace the invalid provision by a provision that ensures the technical and/or commercial success intended by the Parties in a suitable manner.

24. ADVERTISMENT

24.1 The Supplier agrees not to make any claims written, spoken or otherwise that misrepresent the status of any of their TB medicines with respect to the WHO Prequalification Program (WHO PQP). Where a Supplier's Product is not pre-qualified under WHO PQP and is contracted for supply by i+solutions on behalf of GDF according to the GDF's Quality Assurance Policy and Procedures, and subject to the terms and conditions of this Agreement, the Supplier shall not make any claim as to that Product having been pre-qualified by WHO. Supplier also shall not make any claim or statement as to being "WHO pre-qualified manufacturer". Only those Products listed on the WHO PQP website can be claimed as such by the Supplier.

25. REGISTRATION

25.1 The Supplier shall:

a) endeavor to register Products under this LTA in the countries for which it receives orders, with priorities to countries where registration is mandatory;
b) enter the country registration information per product in the GDF CDP Portal (FPP registration module) and submit the Web-Forms to GDF for review and approval in CDP Portal;
c) proactively use WHO Collaborative registration procedure, if applicable, or directly submit registration dossiers to countries for Products not yet registered and where commercially not unreasonable, as requested by i+solutions /GDF;
d) when such dossiers are submitted, actively follow up on the registration process and update i+solutions /GDF in the aforementioned reports. i+solutions /GDF reserves the right to issue Purchase Orders for specific countries to an LTA holder for a Product on the basis of whether the Product is registered, or the extent of demonstrable progress made towards registration completion.

25.2 The Supplier shall bear all the costs related to Product registration and renewal.

26. MISCELLANEOUS

26.1 The Supplier shall have the right to exercise its rights and perform its obligations hereunder through its Affiliates, provided that it shall be responsible for its Affiliates' performance hereunder.

26.2 The Supplier may be expected to participate, at its own expense, in GDF Manufacturers meetings, or related meetings involving GDF, i+solutions, Freight

forwarders, Consignment Inspection and Sampling Agent and Quality Control Agent, among others, on a semi-annual or annual basis.

26.3 This LTA and all details contained herein remain confidential between the Parties. Disclosure of any details of this LTA by one Party to third parties may only be made with the written consent of the other Party to this LTA, except i+solutions may disclose a copy to the GDF without seeking the consent of the Supplier. Notwithstanding the above, each Party may communicate publicly the existence of this LTA.

26.4 The Supplier may not use the name, or the logo of Stop TB Partnership, UN, UNOPS or other UN organization, or any abbreviation thereof. The Supplier may not use the name or logo of GDF, without the advance written consent of the GDF.

26.5 The Supplier is encouraged to register with the Stop TB Partnership as a registered partner (https://www.stoptb.org/joining-forces-to-endtb/how-to-become-partner); in such case, notwithstanding regulations under Article 27.4 above, the guidelines and principles on cooperation and publicity applicable to the Stop TB Partnership shall be applicable.

26.6 Nothing in or relating to this LTA with reference to UN, UNOPS, GDF, Stop TB Partnership shall be deemed a waiver, express or implied, of any of the privileges and immunities of the United Nations, including its subsidiary organs and Specialized Agencies.

27. ASSIGNMENT

27.1 This LTA and/or all rights and obligations provided herein shall not be assigned, transferred or delegated by either Party without the other Party's prior written consent not to be unreasonably withheld, except that the Supplier shall have the right to assign, transfer and sub-contract this LTA, in whole or in part, or any rights or obligations to: (i) any of its Affiliates; (ii) a purchaser of all or substantially all of its assets; or (iii) to a third party, if the Supplier divests, out-licenses or otherwise disposes of the Product, or the business or assets relating to the Product, without consent.

28.ORIGINALS

28.1 The Agreement is drawn up in two originals. i+solutions and the Supplier will each receive one signed electronic copy as pdf file. Hard copies will be provided upon request.

Initials of the authorised signatory of supplier:_____

ANNEX A

Code of Conduct for Suppliers

1. Purpose

This Code of conduct defines the basic requirements on suppliers and third party intermediaries of Stichting Iplussolutions (i+solutions) concerning how business is conducted between i+solutions employees and its suppliers, also covering suppliers acting on behalf of i+solutions. The Code of conduct is shared with Suppliers to enhance a common understanding of our business requirements.

i+solutions reserves the right to reasonably change the requirements of this Code of Conduct in line with any changes to its policies. In such event, i+solutions considers any revised versions of the Code of conduct as accepted and without requiring new signatures from the supplier. i+solutions is entitled to conduct inspections in order to verify compliance with this Code of conduct.

2. Scope and expectations

This Code of conduct applies to all bidders, suppliers, agents, intermediaries, consultants and contractors ("Supplier"), including affiliates, officers, employees, subcontractors, agents and intermediaries of suppliers.

Suppliers are expected to:

- Operate in full compliance with all applicable laws, rules, guidelines and industry codes.
- Firmly adhere to ethical principles of labor, environment, health and safety, and management systems.
- Integrate, communicate and apply these principles in a manner consistent with their own rules.
- Recognizing the importance of diversity and inclusion by strict adherence to all local laws, regulations and policies specific to equal opportunity and non-discrimination.
- Ensure the workplace is free from violations of the law including any type of prohibited discrimination.
- Be aware and respectful of cultural differences, beliefs and the challenges associated with interpreting and applying these principles globally; understand that the methods for meeting these expectations may vary and must be consistent with the local laws, values and cultural expectations of the different societies of the world.
- Integrate the principles into a continual improvement approach that improves awareness, sensitivity and inclusiveness which advances performance over time.

3. Compliance with the code of conduct

Suppliers will ensure that this Code of conduct is communicated to all their Supplier Representatives and will take reasonable steps to ensure compliance by Supplier Representatives, including by taking immediate action in cases of non-compliance. Breaches of this Code of conduct may result in a decision by i+solutions to terminate any contract with Supplier.

Initials of the authorised signatory of supplier:_____

4. Ethical business practices

Suppliers and Supplier Representatives will not, directly or indirectly, including through an agent or other intermediary, engage in corrupt, fraudulent, collusive, anti-competitive or coercive practices in bidding for, or performing, a contract or activity for i+solutions. For these purposes:

"corrupt practice" means the offering, promising, giving, receiving, or soliciting, directly or indirectly, anything of value or any other advantage to influence improperly the actions of another person or entity;
"fraudulent practice" means any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a person or entity to obtain a financial or other benefit or to avoid an obligation;

"coercive practice" means any act or attempt to influence improperly the decisions or actions of a person or entity by impairing or harming, or threatening to impair or harm, directly or indirectly, such person or entity or their property;

"collusive practice" means an arrangement between two or more persons or entities designed to achieve an improper purpose, including influencing improperly the actions of another person or entity;

"anti-competitive practice" means any agreement, decision or practice which has as its object or effect the restriction or distortion of competition in any market.

Fair competition. Suppliers and Suppliers Representatives are expected to participate in procurement processes in a manner that is transparent, fair, accountable and honest, including by complying with all applicable laws and regulations regarding fair competition as well as recognized standards of good procurement practice.

Transparency. Suppliers and Suppliers Representatives are expected to respond to solicitations in an honest, fair, and comprehensive manner, accurately reflecting their capacity to satisfy the requirements set out in the bid or contract documents. They are expected to follow all of the rules established for each procurement process, and only submit bids and enter into contracts if they can and will fulfill all obligations of the contract.

Corruption and other forms of improper payments. Suppliers and Supplier Representatives will not solicit, offer, give or receive, or promise or represent to offer, give or receive, fees, gratuities, rebates, gifts, commissions, or other payments considered as improper.

Use of information. Information, data, know-how and documents obtained in the course of performing a contract for i+solutions, must under no circumstances be made available to any third parties for the purpose of giving existing or potential Suppliers a preferential position or advantage in relation to tenders or any other procurement processes for i+solutions, without the prior written consent of i+solutions.

5. Compliance with laws

Suppliers and Supplier Representatives will comply with all applicable laws and regulations in countries where they do business, as well as the publicized rules, regulations and policies of i+solutions that apply to their areas of work and are shared with them.

Initials of the authorised signatory of supplier:_____

Suppliers and Supplier Representatives will ensure that payments received by them are not used to support, finance or promote violence, aid terrorists or terrorist-related activity or fund organizations known to support terrorism.

Suppliers and Supplier Representatives will not engage in money-laundering activities. This includes any kind of activity which hides or is intended to hide the fact that funds have been obtained illegally or are connected with the proceeds of crime, e.g. through fraud or bribery or other illegal activity.

6. Accuracy and access to business records

Accuracy of records. All financial books and records must conform to generally accepted accounting principles. Records must be accurate in all material aspects and reflect all actual transactions and payments. The records must be kept for a minimum period of seven years after the date of last payment made under the contract.

Access to records. Suppliers and Suppliers Representatives are expected to cooperate with i+solutions and comply with any reasonable request, in the opinion of i+solutions and other agents or representatives of i+solutions to allow access to relevant staff and to inspect any relevant accounts and records and other documents relating to bidding for and performing contracts with i+solutions.

Cooperation. Suppliers and Suppliers Representatives will provide at all times any assistance requested by i+solutions to enable i+solutions to comply with any legal, regulatory or statutory requirement applying to it.

7. Publicity and Advertising

Suppliers and Supplier Representatives will not, without i+solutions' prior written consent, (i) use i+solutions' name or logo in publicity or advertising; (ii) use their direct or indirect business-relationship with i+solutions to imply an endorsement by i+solutions of their products and services, and (iii) make any representation or statement for or on behalf of i+solutions.

8. Full and Open Disclosure and Conflicts of Interest

Suppliers will disclose to i+solutions prior to entering into a contract or at any time during the performance of contract whether they, or any Supplier Representatives, are subject to any sanction or temporary suspension imposed by any major international financing institution or organization, such as the UN or World Bank Group.

Suppliers will disclose to i+solutions actual, perceived, or potential conflicts of interest involving the Supplier or any Supplier Representative ("Conflict of Interest"). i+solutions considers a Conflict of Interest to be a situation in which a party has interests that could improperly influence that party's performance of official duties or responsibilities, contractual obligations, or compliance with applicable laws and regulations, and that such Conflict of Interest may contribute to or constitute a prohibited practice under this Code of conduct. To ensure that Suppliers under contracts with i+solutions observe high standards of ethics, i+solutions will take appropriate actions to manage such Conflicts of Interest if it determines that a Conflict of Interest has compromised, or risks compromising, the integrity of any procurement process.

Initials of the authorised signatory of supplier:_____

Suppliers are expected to notify i+solutions as soon as they have knowledge of any integrity concern involving or affecting i+solutions, whether or not it involves the Supplier or a Supplier Representative.

9. Product quality and supply chain integrity

Suppliers involved in the supply, manufacturing, packaging, re-packaging, testing, storage and distribution of materials/products on behalf of i+solutions will ensure compliance with applicable quality regulations and Good Manufacturing Practice, Good Distribution Practice and Good Laboratory Practice requirements for the markets in which the products are manufactured, registered and distributed. Furthermore, suppliers shall ensure the integrity of their supply chain, avoiding counterfeiting and adulterations to protect products and patients, if applicable.

10. Human rights and labor practices

Human rights. The Supplier declare to:

- Respect the protection of internationally proclaimed human rights and avoid complicity with human rights abuses.
- Refuse to tolerate any unacceptable treatment of individuals such as sexual harassment or discrimination including gestures, language and physical contact, that is sexual, coercive, threatening, abusive or exploitative.
- Promote equal opportunities and treatment of employees, irrespective of skin color, race, nationality, ethnicity, political affiliation, social background, disabilities, sexual orientation, marital status, religious conviction, gender or age.

Labor practices. The Supplier declare to:

- Avoid all forms of forced and compulsory labor and refuse to employ or make anyone work against their will.
- Employ no workers under the age of 15 or, in those countries subject to the developing country exception of the ILO Convention 138, employ no workers under the age of 14.

11. Health, safety and environment

Suppliers shall operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment. suppliers are encouraged to conserve natural resources, to avoid the use of hazardous materials where possible and to engage in activities that reuse and recycle.

The Supplier declare to:

- Act in accordance with the applicable statutory and international standards regarding the environment.
- Have systems in place for management of waste prior to release into the environment.

12. Identification of concerns.

Suppliers shall encourage all its workers and subcontractors to report concerns or illegal activities without threat of reprisal, intimidation or harassment, and shall investigate and take corrective action if needed.

Initials of the authorised signatory of supplier:_____

Signature of supplier:

For [INSERT NAME OF SUPPLIER]:

[INSERT NAME OF AUTHORISED SIGNATORY AND TITLE]

Date: [add Date]