**manufacturer COOPERATION AGREEMENT**

**This Manufacturer Cooperation Agreement** (this “**Agreement**”) is entered into as of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 2020 (the “**Effective Date**”) by and between **the Global Alliance for TB Drug Development**, a New York-based not-for-profit product development partnership with a principal address at 40 Wall Street, 24th Floor, New York, N.Y. 10005, USA (“**TB Alliance**”) and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, a \_\_\_\_\_\_\_\_\_\_ corporation having a principle place of business at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(“**Company**”). TB Alliance and Company are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

**Background**

**Whereas,** TB Alliance is a not-for-profit organization working to develop new, simpler, faster-acting regimens for the treatment of tuberculosis, including through building partnerships between the public, private, academic, and philanthropic sectors to drive the development of new products for underserved markets;

**Whereas,** TB Alliance has entered into a Subcontract Agreement with Stellenbosch University (“**SU**”) under a prime contract (“**Grant Agreement**”) between SU and Unitaid, the public health organization focused on HIV/AIDS, malaria and tuberculosis (“**TB**”) in low-income countries, relating to SU’s project entitled "Better Evidence and Formulations for Improved MDR-TB Treatment for Children" (the "Project”);

**Whereas,** Company is a pharmaceutical company with expertise, experience and technology for the development of dispersible tablets for pediatric drugs;

**Whereas,** TB Alliance and Company desire to collaborate to undertake the development, testing, manufacture and regulatory approval of certain pediatric formulations of TB drugs that are correctly dosed, properly formulated, affordable and high quality, including through the utilization of certain funding obtained from Unitaid, all under the terms and conditions contained herein; and

**Whereas,** following regulatory approval of such pediatric formulations of TB drugs Company would provide for the commercialization of such pediatric formulations of TB drugs meeting the affordability and access commitments provided for in this Agreement.

**Now Therefore**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

1. **Definitions**

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth in this Article 1. In addition, the terms “includes,” “including,” “include” and derivative forms of them shall be deemed followed by the phrase “without limitation” (regardless of whether it is actually written there (and drawing no implication from the actual inclusion of such phrase in some instances after such terms but not others)).

* 1. **“Affiliate”** means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, “control” shall mean, direct or indirect, ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby the entity or person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity. In the case of entities organized under the laws of certain countries, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity.
  2. **“Affordable Pricing”** means the lowest sustainable competitive price level for the Products. It shall cover (a) the cost of raw materials, labor and other direct manufacturing costs incurred by the Company in manufacturing a Product; (b) overhead and indirect manufacturing costs incurred by the Company in manufacturing a Product, not to exceed X% [Company to insert this percentage in response to RFP and Company and TB Alliance to negotiate the final percentage in the course of finalizing the terms of this Agreement]; (c) the actual distribution costs incurred by Company in the marketing, promotion, offering for sale, importing for sale, exporting for sale, distribution and sale of a Product as well as in procuring and maintaining the regulatory approvals necessary to undertake such activities; and (d) a reasonable net margin not to exceed Y% [Company to insert this percentage in response to RFP and Company and TB Alliance to negotiate the final percentage in the course of finalizing the terms of this Agreement ] to help ensure the economic sustainability of the production and distribution.
  3. **“Arising IP”** means any Intellectual Property generated, invented or discovered in the performance of the Project under this Agreement.
  4. **“Company Background IP”** means intellectual property including but not limited to any patented technology (including in-licensed intellectual property and technology), know-how, trade secrets, and proprietary information (including confidential information) related to the Products or any component of the Products, that was owned by the Company prior to the Effective Date, that the Company has a right to license without giving rise to a financial obligation to a third party and that is necessary to exploit the Company Foreground IP.
  5. **“Company Foreground IP”** means intellectual property including but not limited to any patented technology, know-how, trade secrets, and proprietary information (including confidential information) developed by or behalf of the Company during the course of the development of the Products, the process of manufacture of the Products or otherwise in connection with the Products, that is owned by the Company, that the Company has a right to license without giving rise to a financial obligation to a third party, and that is necessary or useful for the performance of this Agreement.
  6. **“Company Invention”** means any Arising IP that is or directly relates to an improvement, enhancement, or modification to the Product or any patented technology (including in-licensed intellectual property and technology), know-how, trade secrets, and proprietary information (including confidential information) related to the Products or any component of the Products.
  7. **“Confidential Information”** means, with respect to a Party, all proprietary and/or confidential Information of such Party that is disclosed to the other Party under this Agreement, which may include, without limitation, specifications, know-how, trade secrets, technical information, models, business information, inventions, discoveries, methods, procedures, formulae, protocols, techniques, data, and unpublished patent applications, whether disclosed in oral, written, graphic, or electronic form. All confidential Information previously disclosed by either Party pursuant to any existing confidentiality agreement shall be deemed to be the disclosing Party’s Confidential Information hereunder (with the mutual understanding and agreement that any use or disclosure thereof that is authorized under Article 7 shall not be restricted by, or be deemed a violation of, such existing confidentiality agreement).
  8. **“Executive Officer”** means, in the case of TB Alliance, CEO of TB Alliance (or an officer or employee of TB Alliance then serving in a substantially equivalent capacity) or his/her designee, and in the case of Company, [\_\_\_\_\_\_].
  9. **“Governmental Authority”** means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).
  10. **“Information”** means any data, results, and information of any type whatsoever, in any tangible or intangible form, including, without limitation, practices, business or research strategies, methods, processes, specifications, formulations, formulae, Materials, software, algorithms, marketing reports, expertise, stability, technology, test data including pharmacological, biological, chemical, biochemical, toxicological, and clinical test data, analytical and quality control data, stability data, studies and procedures, and material embodiments of the foregoing.
  11. **“Intellectual Property” or “IP”** means ideas, concepts, discoveries, inventions, developments, know-how, trade secrets, techniques, methodologies, modifications, innovations, improvements, Information, compositions of matter, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable and the Intellectual Property Rights therein.
  12. **“Intellectual Property Right”** means any patent, registered design, copyright, database right, design right, trade mark, domain name and application to register any of the aforementioned rights.
  13. **“Materials”** means biological materials, compounds or other tangible scientific materials.
  14. **“Pediatric Formulations”** means child-friendly formulations of TB drugs specified in **Exhibit A**.
  15. **“Products”** means the Pediatric Formulations.
  16. **“Project Plan”** means the Project Plan attached as **Exhibit B**, including agreed timelines for initiating and completing major Project activities.
  17. **“Project”** means the project described in the Project Plan.
  18. **“Project Countries”** means India, South Africa, Philippines and any additional countries agreed to by TB Alliance and the Company.
  19. **“Results”** means all results, Materials, data and conclusions generated, created or arising from the Project, including the specified deliverable(s) under the Project Plan.
  20. **“Stringent Regulatory Authority”** means a stringent regulatory authority which is a member of the International Conference on Harmonization of Technical Requirements of Pharmaceuticals for Human Use.
  21. **“Term”** has the meaning set forth in Section 8.1.
  22. **“Third Party”** means any entity other than Company or TB Alliance or an Affiliate of either Party.
  23. **“U.S.”** means the United States of America (including all possessions and territories thereof).
  24. **“WHO/PQ”** means the World Health Organization’s Prequalification of Medicines Programme.

1. **Project**
   1. **Performance of the Project.** Company shall perform its obligations under the Project, as set forth in the Project Plan. The Project Plan shall provide, among other things, that Company shall submit a dossier and diligently seek (a) prequalification from WHO/PQ and (b) regulatory approval from the regulatory authorities in the Project Countries for all of the Products as soon as practicable but no later than three (3) years from the Effective Date of this Agreement. Company shall promptly respond to all reasonable requests by WHO/PQ and the regulatory authorities in the Project Countries and for additional information with respect to each dossier as soon as practicable but no later than sixty (60) days after receiving such request. The Company will be solely responsible for the costs and expenses incurred by or on behalf of it in connection with its activities and responsibilities undertaken under this Agreement.
   2. **No Exclusivity.** Nothing in this Agreement will be construed to limit the freedom of any Party from engaging in similar work with other parties regarding the same therapeutic area, indication, target or application. For clarity, work performed by either Party that is independent of this Agreement shall not be implicated by the terms or conditions contained in this Agreement.
   3. **Modifications to the Project.** The Parties recognize that the Project Plan describes the Project to be conducted under this Agreement. If events occur that require modification of the Project, the Parties may amend **Exhibit B** according to Section 9.5 of this Agreement upon the written mutual consent of both Parties.
   4. **Reports and Results; Records.**
      1. Upon completion of the Project (or at such other time points as the Parties may agree or may be specified in the Project Plan), Company will provide to TB Alliance in electronic format, or other format as reasonably requested by TB Alliance, all Results generated by Company under the Project. Company shall maintain accurate, readily accessible operational information and documentation on the progress made in the implementation of the Project.
      2. Within sixty (60) days after the end of each calendar quarter, or at such other frequency as the Parties may agree, in which a Product is sold during the term of this Agreement and thereafter for a period of seven (7) years from first approval in a Project Country, Company shall provide to TB Alliance a written report in a form reasonably acceptable to TB Alliance of total net sales of the Products by country solely for the purpose of enabling TB Alliance to assess the relative impact and uptake of the Products in those countries. Such written report shall provide:(i) the number of units sold for such Products; and (ii) the net sales for such Products
      3. TB Alliance may freely disclose such data and information regarding the number of units sold to SU, Unitaid, its donors and other global health stakeholders under appropriate confidentiality provisions at least as protective of such Confidential Information as those in this Agreement. TB Alliance may publicly disclose aggregated and anonymized data extracted from such reports, where such data is aggregated with Company data across multiple jurisdictions (masking sales in any individual jurisdiction) or aggregated together with Products sold by other companies in a particular jurisdiction. Company shall maintain with TB Alliance on an ongoing basis complete, accurate copies of all such operational information and documentation. Company shall also ensure that members of Company’s personnel are available to provide information and clarifications to TB Alliance, SU, Unitaid and/or their respective representatives, upon request, on reasonable notice.
   5. **Subcontractors.** Company may not perform any of its Project obligations under this Agreement through one or more subcontractors or consultants without the prior written consent of TB Alliance, such consent not to be unreasonably withheld or delayed. If Company engages a permitted subcontractor or consultant hereunder, Company shall ensure that (a) Company remains responsible for the work allocated to, and payment to, such subcontractors and consultants as it selects to the same extent it would if it had done such work itself; and (b) Company ensures such subcontractors and consultants undertake in writing obligations on substantially the same terms and conditions hereunder to ensure the appropriate transfer of intellectual property and confidential treatment of Confidential Information, including obligations of intellectual property ownership and confidentiality and non-use regarding Confidential Information, that are substantially the same as those undertaken by the Parties pursuant to Article 7.
2. **Development Payments; Product Availability**
   1. **Development Milestone Payments.** No later than forty-five(45)days after receipt of an invoice provided by Company to TB Alliance following TB Alliance’s written confirmation of the achievement of the applicable milestone, TB Alliance shall pay, or cause to be paid, to Company the following one-time payments (“**Milestone Payment(s)**”) upon the successful achievement of each development milestone event (“**Milestone(s)**”) set forth below:

[5-6 milestones and the estimated date of achievement for each Product shall be agreed upon between TB Alliance and the Company. The following milestones are for illustrative purposes only and may vary from Product to Product.]

|  |  |
| --- | --- |
| Potential Milestone Event and Estimated Date of Achievement: | Milestone Payment: |
| Formulation Development completed including Organoleptic properties optimization | $[\_\_\_\_\_\_] |
| Analytical Method Developed & Short-Term Stability Established | $[\_\_\_\_\_\_] |
| Pivotal Bioequivalent (BE) Study Completed | $[\_\_\_\_\_\_] |
| Successful Pilot-scale Batch Manufactured | $[\_\_\_\_\_\_] |
| Successful Registration Batches Manufactured (three required) | $[\_\_\_\_\_\_] |
| Complete dossier submitted to WHO PQ | $[\_\_\_\_\_] |
| Acceptance of submission by WHO/PQ | $[\_\_\_\_\_\_] |
| Product becomes available as a result of Expert Review Panel action | $[\_\_\_\_\_\_] |
| Complete dossier submitted to regulatory authorities of the Project Countries | $[\_\_\_\_\_\_] |
| Acceptance of submission from regulatory authorities of the Project Countries | $[\_\_\_\_\_\_] |

“**Successful Completion**” shall mean achievement of the milestone event in question as determined by TB Alliance in good faith after reviewing documentation provided by the Company supporting the achievement of the milestone. TB Alliance shall provide Company with written confirmation of the completion of each of the milestones specified above in this Section 3.1 as soon as practicable. For the avoidance of doubt, each Milestone Payment shall be payable one time only and only on the first occurrence of the corresponding Milestone.

* 1. **Manner and Place of Payment; Taxes.** Payments made by TB Alliance to Company under this Agreement may be used by Company only to implement the Project activities in accordance with the Project Plan and the terms and conditions of this Agreement. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Company in the applicable invoice. Each Party will be responsible for all taxes, fees, duties, levies or similar amounts imposed on its income, assets, capital, employment, personnel, and right or license to do business. Except as otherwise stated, each Party will be responsible for its own sales tax, use tax, excise tax, Value‑Added Tax (VAT), Goods and Services Tax (GST), Consumption Tax, and similar taxes based upon its own activities under the Agreement. The Parties shall use reasonable and legal efforts to reduce or optimize tax withholding, to the extent permitted by applicable Law, on payments made pursuant to this Agreement. Each Party agrees to cooperate in good faith to provide the other Party with such documents and certifications within its possession as are reasonably necessary to enable such other Party to minimize any withholding tax obligations or liabilities. TB Alliance shall be permitted to withhold any required amount and pay it to the appropriate governmental authority to comply with applicable withholding tax obligations or liabilities. The Parties will reasonably cooperate in completing and filing documents required under the provisions of any applicable tax Laws or under any other applicable Law in connection with the making of any required tax payment or withholding payment, or in connection with any claim to a refund of or credit for any such payment. Each Party shall be responsible for its own costs and expenses incurred in connection with its performance under this Agreement.
  2. **Access and Pricing Principles.**

The Company acknowledges and agrees that

* + 1. the Pediatric Formulations shall be made available for purchase by the Project Countries and through the Stop TB Partnership’s Global Drug Facility and/or The Global Fund to Fight AIDS, Tuberculosis and Malaria (or any organizations that assumes their respective missions) (the “GDF/GF”) as quickly as possible at Affordable Pricing, and that the Company shall make reasonable efforts to make the Pediatric Formulations available for purchase outside the Project Countries and outside the GDF/GF through the Pan American Health Organization and other public sector purchasers looking to supply the Products to a Low or Middle Income Country (as defined by the World Bank from time to time) and when made available for purchase outside the Project Countries and outside the GDF/GF shall also be made available at Affordable Pricing.
    2. the Pediatric Formulations shall be developed and distributed pursuant to the quality standards set by WHO/PQ and/or relevant Stringent Regulatory Authorities, and
    3. it shall maintain its sources of supply and sufficient production capacity to ensure a continuity of supply of the Pediatric Formulations.

1. **Intellectual Property**
   1. **Company Background Intellectual Property.** Company shall retain all right, title and interest in and to all Intellectual Property owned or controlled by Company prior to the Effective Date or developed, made, conceived or acquired by Company during the Term independently of this Agreement.
   2. **Arising IP.** Inventorship of Arising IP shall be determined in accordance with U.S. patent laws. Company shall own all Arising IP and Information generated by it and its Affiliates and their respective employees, agents, investigators, consultants, advisors, collaborators and independent contractors in the course of conducting the Project under this Agreement.
   3. **Results; License to Use.** 
      1. The copyright ownership of reports, data or other documents produced as a result of this Project will remain with the creator of such document.
      2. In the event that (i) any element of the timeline set forth in the Project Plan is initiated or completed, as applicable to such timeline element, more than ninety (90) days later than is provided for in the Project Plan, (ii) at any time during the performance of the Project Plan it becomes indisputable that any element of the timeline set forth in the Project Plan cannot be initiated or completed, as applicable to such timeline element, with less than a delay of ninety (90) days, or (iii) Company materially breaches this Agreement, then without limiting any other right or remedy available to TB Alliance under this Agreement or in law or equity, the following rights and grants shall become effective upon TB Alliance giving notice to Company following such event:
         * 1. Company hereby grants to TB Alliance a worldwide, non-exclusive, irrevocable, royalty-free and sub-licensable license to use Company Background IP and Company Foreground IP for the purpose of enabling TB Alliance to develop the Pediatric Formulations, seek regulatory approvals for the Pediatric Formulations, manufacture and distribute the Pediatric Formulations;
           2. Company hereby grants a non-exclusive, irrevocable, worldwide, royalty-free, sub-licensable license to WHO on behalf of Unitaid to use the Results for non-commercial public health, education and research purposes;
           3. Company shall promptly transfer the technology and know-how developed under this Agreement, together with all documentation and data collected by Company, to TB Alliance and/or Third Party(ies) designated by TB Alliance, whether to implement the continued development of the Pediatric Formulations or seek to ensure continuity in the supplies of the Pediatric Formulations.
           4. Company shall promptly transfer all regulatory approvals and applications for regulatory approval (including prequalification and applications for prequalification with WHO/PQ) relating to the Pediatric Formulations, together with all related, correspondence, other documentation and data collected by Company relating thereto, to TB Alliance and/or Third Party(ies) designated by TB Alliance, whether to implement the continued development of the Pediatric Formulations or seek to ensure continuity in the supplies of the Pediatric Formulations.
           5. Company hereby grants to TB Alliance a “Right of Reference,” as that term is defined in 21 C.F.R. § 314.3(b) (or any analogous Law recognized outside of the United States), to all data controlled by Company or its affiliates that relate to the Pediatric Formulations or the TB drugs specified in **Exhibit A** owned or controlled by Company, and Company shall provide a signed statement to this effect, if requested by TB Alliance, in accordance with 21 C.F.R. § 314.50(g)(3) (or any analogous Law outside of the United States), for use by TB Alliance solely to support the development, manufacture, use and commercialization of the Pediatric Formulations.
   4. **No Implied Licenses.** Except as explicitly set forth in this Agreement, neither Party grants to the other Party any license, express or implied, under its Intellectual Property Rights.
2. **Representations, Warranties and Covenants**
   1. **Mutual Representations, Warranties and Covenants.** Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows:
      1. **Corporate Existence and Power.** It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder.
      2. **Authority and Binding Agreement.** As of the Effective Date: (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.
      3. **No Conflict.** It is not a party to and will not enter into any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement.
      4. **No Debarment.** In the course of performing the Project, such Party has not used prior to the Effective Date and shall not use, during the Term, any employee, agent or independent contractor who has been debarred by any regulatory authority, or, to the best of such Party’s knowledge, is the subject of debarment proceedings by a regulatory authority.
      5. **Invention Assignments.** Each employee, agent, investigator, consultant, advisor, collaborator, independent contractor or subcontractor of such Party shall be bound by invention assignment obligations which are consistent with the obligations of such Party, as appropriate, under this Agreement. It is understood and agreed that such invention assignment agreement need not reference or be specific to this Agreement. Such Party will not permit persons not bound by such obligations to work on the Project.
      6. **Anti-Bribery.** Each of the Parties agrees that it and its Affiliates and their respective employees, will comply fully with all applicable anti-corruption and anti-bribery laws, including the United States Foreign Corrupt Practices Act, the anti-corruption laws of countries where activities under this Agreement take place, and all other similar applicable laws.
   2. **Representations, Warranties and Covenants of Company.** Company hereby represents, warrants, and covenants (as applicable) to TB Alliance as follows:
      1. Company has the full right, power and authority to grant to TB Alliance the license rights that it purports to grant hereunder;
      2. Company has not granted or will not grant to any third party any of its right, license or interest in, to or under any Company Background IP or Company Foreground IP that would conflict with, limit or adversely affect the rights granted to TB Alliance or TB Alliance’s ability to exercise the license rights granted to TB Alliance under this Agreement;
      3. Company shall not infringe or misappropriate any IP owned or controlled by any Third Party in connection with Company’s performance of the activities contemplated by this Agreement, Company has not received any claim and/or been party to any proceeding of any nature by any third party claiming the existence of any such infringement, and Company shall notify TB Alliance in writing promptly upon learning of any such actual or threatened claim or proceeding;
      4. Company confirms that no official of SU, UNITAID or WHO/PQ has received or will be offered any benefit arising from this Agreement;
      5. Company represents that no payments of money or anything of value will be offered, promised or paid, directly or indirectly, to any government official: to influence any official act or decision of any government official; to induce the government official to do or omit to do an act in violation of a lawful duty; to secure any improper business advantage; or to obtain or retain business for, or otherwise direct business to Company or any other person or entity in any way related to this Agreement; and
      6. Company hereby agrees to fully comply with the ethical standards and other obligations described in the Grant Agreement as set forth in **Exhibit C** in connection with undertaking the Project.
   3. **No Other Representations or Warranties.** EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT OF THIRD-PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.
3. **Indemnification**
   1. **Indemnification.** To the full extent permitted by applicable law, each Party (an “**Indemnifying Party**”) shall indemnify the other Party (and with respect to Company such indemnification shall extend to the World Health Organization on behalf of Unitaid) and such other party’s directors, officers, employees, agents and representatives (collectively, the “**Indemnified Parties**”), from and against any and all losses, liabilities, damages, costs, and expenses whatsoever (including, without limitation, reasonable fees and disbursements of counsel) (“**Claims**”), sustained or incurred by an Indemnified Party if and to the extent resulting from Third Party claims or demands that arise from (i) any action or omission of the Indemnifying Party or any of its officers, employees, agents or representatives, other than as a result of a breach of this Agreement by the Indemnified Party, (ii) any breach of any representation, warranty, covenants or agreement of the Indemnifying Party, and (iii) in the case of Company as the Indemnifying Party, the clinical development, commercial use or sale of Pediatric Formulations, including product liability or theories of strict liability arising from such activities; except in each case of the foregoing subclauses (i) or (ii) to the extent that such Claims are covered by the indemnity provided by the Indemnified Party hereunder. Each Party shall promptly notify the other Party of any such Claims, shall reasonably cooperate in the defense of such Claims, and shall permit the Indemnifying Party to control the defense and settlement of such Claims, all at Indemnifying Party’s cost and expense.
   2. **Insurance.** Each Party shall procure and maintain insurance, including product liability insurance, with respect to its activities hereunder and which are consistent with normal business practices of prudent companies similarly situated at all times during the performance of the Project. It is understood that such insurance shall not be construed to create a limit of either Party’s liability with respect to its indemnification obligations under this Article 6 or otherwise. Each Party shall provide the other with written evidence of such insurance upon request. Each Party shall provide the other with written notice at least thirty (30) days prior to the cancellation, non‑renewal or material change in such insurance or self‑insurance which materially adversely affects the rights of the other Party hereunder.
   3. **Limitation of Liability.** EXCEPT FOR DAMAGES AVAILABLE FOR BREACHES OF CONFIDENTIALITY OBLIGATIONS UNDER SECTION 7 AND THE INDEMNIFICATION RIGHTS AND OBLIGATIONS UNDER SECTION 6, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT OR ANY TORT CLAIMS ARISING HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE MAXIMUM AMOUNT OF DAMAGES FOR WHICH either Party MAY BE LIABLE SHALL NOT EXCEED THE ACTUAL AMOUNTS PAID PURSUANT TO SECTION 3.1 (OTHER THAN FOR DAMAGES DUE TO GROSS NEGLIGENCE, DEATH OR PHYSICAL INJURY).
4. **Confidentiality**
   1. **Confidentiality.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for seven (7) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information furnished to it by or on behalf of the other Party pursuant to this Agreement except for that portion of such Confidential Information that the receiving Party can demonstrate by competent written proof:
      1. was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;
      2. was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
      3. became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;
      4. is subsequently disclosed to the receiving Party or its Affiliate by a Third Party without obligations of confidentiality with respect thereto; or
      5. is subsequently independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of Confidential Information.

**Authorized Disclosure.** Each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following situations:

* + 1. regulatory filings and other filings with Governmental Authorities (including regulatory authorities);
    2. complying with applicable laws and regulations, including regulations promulgated by securities exchanges;
    3. disclosure to its Affiliates, employees, agents, investigators, consultants, advisors, collaborators and independent contractors, and any sublicensees only on a need-to-know basis and solely in connection with the performance of this Agreement, provided that each disclosee must be bound by obligations of confidentiality and non-use at least as equivalent in scope as those set forth in this Article 7 prior to any such disclosure;
    4. disclosure of the material terms of this Agreement to any bona fide potential or actual investor, investment banker, acquirer, merger partner, or other potential or actual financial partner; provided that in connection with such disclosure, the disclosing Party shall enter into a confidentiality agreement with such partner on terms no less stringent than the terms contained herein and inform each disclosee of the confidential nature of such Confidential Information and cause each disclosee to treat such Confidential Information as confidential; and

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party’s Confidential Information pursuant to Sections 7.2(a) or 7.2(b), it will give reasonable advance notice to the other Party of such requested disclosure and use all reasonable efforts to secure confidential treatment of such information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

* 1. **Terms of Agreement; Publicity.**
     1. The Parties agree that the terms of this Agreement are the Confidential Information of both Parties and may not be disclosed without the prior written consent of the other Party; provided, however, TB Alliance shall disclose the terms of this Agreement to SU and/or UNITAID by providing to SU and/or UNITAID an unredacted copy of this Agreement as well as any future amendments to this Agreement. It is further acknowledged by Company that: (i) from time to time TB Alliance is permitted to consult with global health and key in-country stakeholders including but not limited to SU and UNITAID regarding the activities under and results of this Agreement, audits undertaken with respect to the activities under this Agreement, and any potential extensions or terminations of this Agreement; and (ii) in connection with such consultations TB Alliance shall be permitted to disclose to global health and key in-country stakeholders including but not limited to SU and UNITAID Confidential Information of Company relating to this Agreement including, without limitation, details relating to commitments set out in Section 3.3 of this Agreement.
     2. If either Party desires to make a public announcement concerning the material terms of this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and prior written approval (except as otherwise provided herein), such approval not to be unreasonably withheld, except that in the case of a press release or governmental filing required by law, the disclosing Party shall provide the other Party with such advance notice as it reasonably can and shall not be required to obtain approval therefor. A Party commenting on such a proposed press release shall provide its comments, if any, within ten (10) days of being provided advanced notice by the other Party.
     3. Except as set forth otherwise under this Section 7.3 or Section 7.4 or with the prior written approval of the other Party, under no circumstances may either Party use the name of the other Party or any of its personnel in any publication or any form of advertising without such other Party’s prior written consent. Company shall not make use of the logos or emblems of SU or UNITAID without prior written permission from SU or UNITAID respectively. Any proposed public written reference by Company to the relationship of the Project or to UNITAID’s support in connection with the Project, is subject to agreement of TB Alliance, SU and UNITAID in writing in advance; provided, it is understood that each of the Parties is entitled to refer to the Project and to their respective contributions in internal documents and annual reports. Each Party shall obligate any Affiliate, employee, agent, investigators, consultants, advisors, collaborators, independent contractor, and any sublicensee to abide by the terms of this Section 7.3(c). Under no circumstances can either Party use the name or logo of WHO in connection with the Project.
  2. **Return of Confidential Information.** Upon termination or expiration of the Agreement, or upon written request of the disclosing Party, the receiving Party shall promptly return to the disclosing Party or destroy all documents, notes and other tangible Materials representing the disclosing Party’s Confidential Information and all copies thereof; provided, however, that each Party may retain a single archival copy of the other Party’s Confidential Information in their legal files for the sole purpose of facilitating compliance with the surviving provisions of this Agreement.
  3. **Survival.** This Article 7 shall survive for a ten (10) year period of time following the expiration or termination of this Agreement.

1. **Term and Termination**
   1. **Term.** This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 8, shall expire three (3) years thereafter (the “**Term**”).
   2. **Automatic Termination.** This Agreement shall terminate automatically upon the Grant Agreement terminating for any reason at any time during the Term.
   3. **Termination by TB Alliance.** TB Alliance shall have the right to terminate this Agreement, at any time, upon ninety (90) days’ written notice to Company.
   4. **Termination by Either Party for Breach.** Either Party shall have the right to terminate this Agreement upon written notice to the other Party if such other Party materially breaches any of its representations, warranties or obligations set forth in this Agreement and, after providing written notice to such other Party identifying such material breach in reasonable detail, such other Party fails to cure such material breach within sixty (60) days from the date of such notice (or within ten (10) days from the date of such notice in the event such material breach is solely based upon the breaching Party’s failure to pay any amounts due the other Party hereunder).
   5. **Termination by Either Party for Bankruptcy.** Either Party shall have the right to terminate this Agreement upon written notice to the other Party in the event that there is (a) an assignment by the other Party for the benefit of creditors, (b) the institution of voluntary or involuntary proceedings by or against the other Party in bankruptcy, insolvency, moratorium or for a receivership, or for a winding-up or for the dissolution or reorganization of the other Party (other than a corporate reorganization not in the context of bankruptcy or insolvency), or (c) the taking of any action by the other Party under an act for relief from creditors.
   6. **Termination by Either Party Due to Continuing Force Majeure.** Either Party shall have the right to terminate this Agreement upon written notice to the other Party in the event that there is a force majeure event (as defined under Section 9.6) occurs and persists over three consecutive months.
   7. **Termination by Either Party Due to Efficacy or Safety Concern.** Either Party shall have the right to terminate this Agreement upon thirty (30) days’ written notice to the other Party in the event that the terminating Party has determined that there is a bona fide, material safety or efficacy concern calling into question the viability of each of the Pediatric Formulations.
   8. **Effects of Termination of the Agreement.** 
      1. Upon termination of this Agreement by TB Alliance under Sections 8.3 or 8.4, by either Party under Sections 8.5 or 8.6, Company shall assist TB Alliance in ensuring that TB Alliance has the freedom and ability to carry out Project activities either directly itself and/or through Third Parties, and without limiting the foregoing, or being limited thereby: (i) it is acknowledged by the Company that a material failure by Company to timely complete the transfers contemplated by Section 4.3(b) will, in addition to any other right or remedy available to TB Alliance at law or in equity, give rise to a right by TB Alliance to seek reimbursement from Company of all amounts paid by TB Alliance to the Company under Article 3; and (ii) in such event Company shall promptly pay to TB Alliance the full amount of any and all such reimbursement amounts claimed by TB Alliance.
      2. Termination or expiration of this Agreement shall not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration of this Agreement. Notwithstanding anything to the contrary, the following provisions shall survive and apply after expiration or termination of this Agreement: Sections 2.1,2.2, 2.4, 3.1,3.3, 8.8, and Articles 1, 4, 5, 6, 7 and 9.

**(c) Third-Party Beneficiaries.** Company acknowledges that Unitaid’s future non-profit grantee funded to procure or facilitate the procurement of the Products and the procurement agencies of the Project Countries are hereby designated as third-party beneficiaries of this Agreement and are entitled to enforce the terms and conditions of this Agreement in the event that TB Alliance elects not to enforce such terms and conditions whether during the term of this Agreement or following the expiration or termination of this Agreement pursuant to the survival provisions of Section 8.8 (b) above.

1. **Miscellaneous**
   1. **Governing Law.** This Agreement shall be governed by and construed under the laws of the State of New York, without giving effect to the conflicts of laws provision thereof; provided, that those matters pertaining to the validity or enforceability of patent rights shall be interpreted and enforced in accordance with the laws of the territory in which such patent rights exist.
   2. **Dispute Resolution.** Unless otherwise set forth in this Agreement, in the event of any dispute arising under this Agreement between the Parties, either Party shall have a right to refer such dispute to each Party’s respective Executive Officers, and such Executive Officers shall attempt in good faith to resolve such dispute. If the Parties are unable to resolve a given dispute pursuant to this Section 9.2 within thirty (30) days of referring such dispute to the Executive Officers, each Party may bring an action pursuant to Section 9.3.
   3. **Venue.** Each Party irrevocably submits to the exclusive jurisdiction of the United States District Court for the Southern District of New York for the purposes of any suit, action or other proceeding arising out of this Agreement. Each Party agrees to commence any such action, suit or proceeding in the United States District Court for the Southern District of New York or if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the Supreme Court of the State of New York, New York County. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any such action, suit or proceeding arising out of this Agreement in the United States District Court for the Southern District of New York, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction, at any time, in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the resolution of any dispute hereunder.
   4. **Remedy for Breach**. The Parties understand and agree that monetary damages may not be sufficient remedy for breach of this Agreement and that the injured Party will be entitled to seek equitable relief, including injunction and specific performance, for any such breach.
   5. **Entire Agreement; Amendment.** This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, including, without limitation, the Existing Confidentiality Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations pursuant to the Existing Confidentiality Agreement. In the event of any inconsistency between the Project Plan and this Agreement, the terms of this Agreement shall prevail unless the Project Plan expressly indicates the Parties’ intent to modify the terms of this Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.
   6. **Force Majeure.** Force majeure as used in this Section means acts of God, war (whether declared or not), invasion, revolution, insurrection, or other acts of a similar nature or force. In the event of and as soon as possible after the occurrence of any cause constituting force majeure, the affected Party shall give notice and full particulars in writing to the other Party, of such occurrence if that Party is thereby rendered unable, wholly or in material part, to perform its obligations and meet its responsibilities under this Agreement and that Party shall be relieved of these obligations and responsibilities for so long as such circumstances prevail. If a Party is rendered permanently unable, wholly, or in material part, by reason of force majeure to perform its obligations and meet its responsibilities under this Agreement, the other Party shall have the right to terminate this Agreement on the same terms and conditions as are provided for in Section 8.5, except that the period of notice shall be seven (7) days instead of three (3) months.
   7. **Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below delivered by hand or overnight courier with tracking capabilities or mailed postage prepaid by first class mail, addressed as set forth below unless changed by notice so given:

If to TB Alliance: The Global Alliance for TB Drug Development

40 Wall Street, 24th Floor

New York, N.Y. 10005

Attention: CEO

With a copy to: The Global Alliance for TB Drug Development

40 Wall Street, 24th Floor

New York, N.Y. 10005

Attention: Contracts Administrator

If to Company: [\_\_\_\_\_\_\_\_]

[\_\_\_\_\_\_\_\_]

[\_\_\_\_\_\_\_\_]

Attention: [\_\_\_\_\_\_\_\_]

With a copy to: [\_\_\_\_\_\_\_\_]

[\_\_\_\_\_\_\_\_]

[\_\_\_\_\_\_\_\_]

Attention: [\_\_\_\_\_\_\_\_]

Any such notice shall be deemed delivered on the date received.

* 1. **Headings.** The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.
  2. **Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer without the other Party’s consent to Affiliates or to a successor to all or substantially all of the business of such Party, whether in a merger, sale of stock, sale of assets or other transaction, provided, that the assignor shall remain liable for the performance by the assignee, of its obligations under this Agreement. Any attempted assignment in violation of this Section 9.9 shall be void and of no force and effect. The Parties’ rights and obligations hereunder will bind and inure to the benefit of their respective permitted successors, heirs, executors, administrators and assigns.
  3. **Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by an arbitrator or by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.
  4. **No Waiver.**  Any delay in enforcing a Party’s rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party’s rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.
  5. **Independent Contractors.** Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.
  6. **Compliance with Law.** Company represents and warrants that this Agreement will be performed in material compliance with all applicable laws and regulations, including without limitation, laws and regulation relating to health, safety and the environment, fair labor practices and unlawful discrimination.
  7. **Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument. Each party may execute this Agreement by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail. In addition, facsimile or PDF signatures of authorized signatories of any party will be deemed to be original signatures and will be valid and binding, and delivery of a facsimile or PDF signature by any party will constitute due execution and delivery of this Agreement.

**9.15 Records; Audit.** Company undertakes, during the Term of this Agreement and for five (5) years thereafter, to keep complete, accurate and up to date records, data and documentation recording its activities and its compliance with its obligations under this Agreement.

(a) TB Alliance may, at its cost and upon sixty (60) days’ prior written notice, carry out one (1) audit in each calendar year of this Agreement (at reasonable hours on Business Days) and for twelve (12) months after its expiry solely for the purposes of monitoring Company’s compliance with its obligations hereunder, and further including any additional “for cause” audits during the Term that TB Alliance reasonably deems appropriate in connection with a material default or suspected material default by Company of its obligations hereunder. Company may request that the audit be performed by an independent reputable audit firm acceptable to both Parties to the extent that the audit should require access to records, data and information in whatever form which the audited Party is reasonably able to demonstrate is commercially confidential, in which case the Parties shall agree on reasonable confidentiality obligations for the audit firm with regards to preparing and sharing a draft and final report. Further, to the extent the audit requires access to information that is subject to binding obligations of confidentiality to any non-affiliated Third Party, such access shall be subject to the Third Party’s consent; provided, that in such cause the audited Party shall use Commercially Reasonable Efforts to obtain the consent of the relevant Third Party.

(b) Subject to TB Alliance’s obligations of confidentiality, Company shall, on reasonable prior notice, provide TB Alliance (and/or its agents or representatives who are bound by obligations of confidentiality) with all reasonable cooperation and assistance in relation to each audit conducted in accordance with this Section 9.15(b), including by providing:

(i) all information reasonably requested by TB Alliance within the permitted scope of the audit;

(ii) reasonable access to any physical sites or data controlled or used by Company directly in connection with the performance of its obligations under this Agreement; and

(iii) reasonable access to its relevant employees and personnel within a reasonable period-of-time of the request.

To the extent Company or its Affiliates rely on Third Party sub-contractors to perform their obligations under this Agreement, Company or its relevant Affiliate shall use commercially reasonable efforts to procure the same audit rights as set out above for TB Alliance or its agents or representatives.

*[Signature Page Follows]*

**In Witness Whereof,** the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Effective Date.

|  |  |
| --- | --- |
| **The Global Alliance for TB Drug Development, INC.**  By:  Name:  Title: | **XXXXXXX**  By:  Name:  Title: |

**Exhibit A**

**TB Drugs to be Formulated for Pediatric Patients**

**Exhibit B**

**PROJECT PLAN**

**EXHIBIT C**

**Ethical Standards and Other Obligations Set Forth in the Grant Agreement Company Agrees to Comply With**

**Human Subject Research**

For the purposes of this Exhibit, the following definitions shall apply:

“**Human Subject Research**” or “**HSR**” means any social science, biomedical, behavioral, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge in which human beings: (i) are exposed to manipulation, intervention, observation or other interaction with investigators, either directly or through alteration of their environment; or (ii) become individually identifiable through investigators’ collection, preparation or use of biological material or medical or other records.

“**International HSR Standards**” means: (i) the Declaration of Helsinki (WMA 2013); (ii) International Conference on Harmonisation. ICH Topic E6(R2): ‘Guideline for Good Clinical Practice’ 2016; (iii) World Health Organisation ‘Good Clinical Laboratory Practice’ (ISBN 978-92-4-159785-2); and (iv) the last approved version of the International Ethical Guidelines for Health Related Research Involving Humans (CIOMS).

The Company shall safeguard the rights and welfare of human subjects participating in all Human Subject Research and shall ensure that all Human Subject Research is carried out in accordance with: (i) national and local laws and regulations applicable to Human Subject Research in the relevant Project Country; and (ii) International HSR Standards. In the event of any conflict between the applicable Project Country laws and International HSR Standards, the Company shall comply with whichever standard provides the greater protection for research subjects, provided that the Company shall not be in breach of any applicable Project Country laws. The Company shall ensure that appropriate terms are included in its agreements with any third party recipients of funds received from TB Alliance under the Agreement (“Project Funding”) responsible for carrying out Human Subject Research (including, without limitation, subcontractors) to ensure that the Company is able to comply with this obligation.

The Company shall not commence any Human Subject Research prior to being informed by TB Alliance that that WHO's Research Ethics Review Committee (“**WHO ERC**”) has either: (a) approved the research protocol or protocols for such Human Subject Research; or (b) issued a decision waiving the requirement for its approval. In the event that the WHO ERC has waived the requirement for its approval, the Company will nevertheless provide TB Alliance with a copy of the final research protocol or protocols, as approved by relevant ethical review boards, prior to commencing the Human Subject Research.

The Company will promptly inform TB Alliance in the event that information received by the Company with respect to adverse events occurring in research subjects in any Human Subject Research leads to a decision being made resulting in a significant impact on the HSR activities being carried out (including, without limitation, a material change to the research protocol). In the event of adverse events leading to such decision being made, the Company will also:

be permitted to take any steps it, in its sole discretion, deems necessary to protect research subjects, including but not limited to suspending the study (subject to approval and/or notification of relevant ethical review boards, including, without limitation, the WHO ERC, where required in accordance with applicable Project Country laws and/or International HSR Standards); and

submit to TB Alliance as soon as reasonably possible all information required to allow TB Alliance and/or SU the ability to submit a revised Project Plan, Budget, Logframe and/or any other relevant Annexes to the Grant Agreement, reflecting the change to the HSR activities for Unitaid’s approval.

The Company will ensure that appropriate liability insurance coverage is obtained prior to the commencement of all Human Subject Research and is maintained at all relevant times throughout the Project Term. Such insurance shall conform to all relevant standards and regulations and shall be consistent with best practices applicable in the Sponsor’s jurisdiction. It shall be taken out with a reputable international insurance provider and shall cover, as a minimum, claims brought against the Sponsor and the Principal Investigator and shall include TB Alliance, SU and WHO/Unitaid as additional insured parties. The Company will promptly provide TB Alliance with written confirmation that such insurance has been taken out, together with a copy of the certificate and policy providing evidence of such insurance, if requested by TB Alliance.

The Company acknowledges that TB Alliance, SU and WHO/Unitaid are not the Sponsor of the HSR activities to be carried out by the Company

**Disclosure of Clinical Trial Results**

For the purposes of this Exhibit, “Clinical Trial” means any clinical trial, as such term is defined by WHO (definition available at: [http://www.who.int/topics/clinical\_trials/en/).](http://www.who.int/topics/clinical_trials/en/))

The Company acknowledges and confirms that it has read WHO’s Statement on Public Disclosure of Clinical Trials (available at [http://www.who.int/ictrp/results/en/).](http://www.who.int/ictrp/results/en/))

In relation to any Clinical Trial, the Company will ensure that it complies with the requirements set out in WHO’s Statement on Public Disclosure of Clinical Trials, including through:

registering the details of the trial in a publicly available, free to access, searchable clinical trial registry complying with WHO’s international agreed standards (available at [www.who.int/ictrp),](http://www.who.int/ictrp)) prior to initiation of the trial;

posting a summary of the results of the trial on either the results section of the clinical trial registry, or, if the clinical trial registry does not have a results database, on a free-to-access, publicly available, searchable institutional website, such as the WHO website, within twelve (12) months of completion of the trial;

submitting the main findings of the trial for publication in a peer reviewed journal within twelve (12) months of completion of the trial, and publishing the main findings through an open access mechanism, or otherwise making the main findings publicly available in the event that open access cannot be used, within twenty-four

(24) months of completion of the trial;

making the trial protocol publicly available no later than the time at which the summary of results referred is posted; and

including the clinical trial ID or registry code/number in all publications and in any abstracts that may be used in bibliographic search databases.

The Company will ensure that Unitaid is acknowledged in the clinical trial registry as funder of all Clinical Trials.

The Company acknowledges that compliance (or failure to comply) with the requirements set out in this Exhibit will be monitored by WHO and the details thereof may publicly be disclosed on the WHO website.

For the avoidance of doubt, the obligations under this Exhibit are in addition to the Company’s obligations to share and disseminate the Project Results set out in the Agreement.

**Compliance with WHO Codes and Policies**

For the purposes of these Supplemental Terms and Conditions, “**WHO Policies**” means collectively:

the WHO Code of Ethics and Professional Conduct;

the WHO Policy on Sexual Exploitation and Abuse Prevention and Response;

the WHO Policy on Whistleblowing and Protection Against Retaliation; and

the UN Supplier Code of Conduct

in each case, as amended from time to time, and which are publicly available on the WHO website at the following links: [http://www.who.int/about/finances-](http://www.who.int/about/finances-accountability/procurement/en/) [accountability/procurement/en/](http://www.who.int/about/finances-accountability/procurement/en/) for the UN Supplier Code of Conduct and at <http://www.who.int/about/ethics/en/>for the other WHO Policies.

The Company acknowledges that it has read, and hereby accepts and agrees to comply with, the provisions applicable to “WHO Collaborators” (referred to as “non-staff” in the WHO Policy on Whistleblowing and “UN Suppliers” in the UN Supplier Code of Conduct) in the WHO Policies.

The Company shall take appropriate measures to prevent and respond to any violations of the standards of conduct, as described in the WHO Policies, by its employees and all third-party recipients of Project Funding.

Without limiting the foregoing, the Company shall promptly report to TB Alliance in a form designated by TB Alliance any actual or suspected violations of any WHO Policies of which the Company becomes aware.

The Company will take steps to ensure that its staff and the staff of all third-party recipients are aware of the additional mechanisms available for reporting suspected wrongdoing and/or retaliation in relation to the Project. Such mechanisms are described in the WHO Policy on Whistleblowing and Protection Against Retaliation and include the WHO whistleblowing hotline, an externally managed hotline reporting to the Office of Compliance, Risk Management and Ethics of WHO.

The Company acknowledges and agrees that in the event of any breach of the provisions set out in this Exhibit, WHO and/or Unitaid may decide to exclude the Company from participating in any ongoing or future grant applications or tenders and/or entering into any future contractual or collaborative relationships with WHO and/or Unitaid.

**Zero Tolerance for Sexual Exploitation and Abuse**

WHO (including Unitaid) has zero tolerance towards sexual exploitation and abuse. In this regard, and without limiting any other provisions contained herein, the Company warrants that it will: (i) take all reasonable and appropriate measures to prevent sexual exploitation and abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response by any of its employees and any third party recipients; and (ii) promptly report to Unitaid and respond to, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Company becomes aware.

**Anti-Terrorism and UN Sanctions; Fraud and Corruption**

The Company warrants for the duration of the Project Term that:

* + - it is not and will not be involved in, or associated with, any person or entity associated with terrorism, as designated by any UN Security Council sanctions regime, that it will not make any payment or provide any other support to any such person or entity and that it will not enter into any employment or subcontracting relationship with any such person or entity;
    - it shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the implementation of the Project; and
    - it shall take all necessary precautions to prevent the financing of terrorism and/or any illegal corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the implementation of the Project.

Any Project Funding used by the Company for the promotion of any terrorist activity or any illegal, corrupt, fraudulent, collusive or coercive practice will be deemed an ineligible expense and will be immediately reimbursed to TB Alliance.