

## Appendix 5: Access & related Terms & Conditions for the public sector & LMICs

A list of certain key terms and conditions to be addressed in any contractual agreement executed by FIND for investment and support of successful project applications to the RFP. The below language is given for guidance purposes only. Final language to be agreed between the parties to each agreement.

### 1. SOME KEY DEFINITIONS

<b>"Adequate Performance"</b>	means where (A) XYZ's performance under this Agreement complies with its responsibilities to develop and verify the Product and prepare to submit a technical dossier to an SRA, as set forth under this Agreement, including under Sections [●], as well as in the Milestones as set out in Schedules [●] (B) XYZ's commercialization of the Product is in accordance with the terms of this Agreement, including under the Global Access Section; and (C) XYZ is not in default nor commits any material breach of any covenant in this Agreement during the Term whereby FIND would have an option to terminate under Section [●];
<b>"Affordable Price"</b>	has the meaning ascribed to it under Section [●];
<b>"COGS" or "Manufacturing Cost of Goods Sold"</b>	means all of the direct costs such as labor, material, and allocated overhead costs in Product <i>production</i> ; means all of the direct costs such as labor, material, and allocated overhead costs in a Product <i>manufacture as detailed in Schedule [●] "Cost Analysis"</i> , and excluding research and development costs, sales and marketing costs, as well as selling, general, and administrative expenses;
<b>"Cost Analysis"</b>	means the Product cost information that XYZ shall provide under the format described in Schedule [●];
<b>"COVID-19"</b>	means the coronavirus disease caused by SARS-COV-2, declared by the World Health Organisation on 30 <sup>th</sup> January 2020 as a Public Health Emergency of International Concern;
<b>"Deliverable"</b>	means all reports, plans, methods, literary works, artistic works, databases, data, derivative works, and any other work product or tools to be delivered by XYZ under this Agreement, whether oral, physical, tangible, intangible or electronic, and as may be developed pursuant to the generated by the Parties pursuant to this Agreement, and shall include any financial reports as may be required;
<b>"Ex Works" or "EXW"</b>	Shall have the meaning under INCOTERMS 2020 and shall be based on XYZ COGS;
<b>"Eligible Purchasers"</b>	means any and all purchasers within the Public Health Sector and Private Health Sector;
<b>"Final Purchase Price"</b>	Means the price paid by Eligible Purchasers for the Product as detailed in Schedule [●], and includes Ex Works price, distributor's

	margin, and any service and maintenance fees (if applicable), but excludes freight costs and import fees, if any;
<b>“Global Access”</b>	means the principles according to which diagnostic products shall be available, affordable, and appropriate for use in the Territory, as further set forth in FIND's Global Access Policy available at <a href="http://www.finddx.org/policies">www.finddx.org/policies</a> , as amended from time to time;
<b>“Intellectual Property” or “IP”</b>	means patents, rights to inventions, copyright and related rights, moral rights, trademarks, trade names and domain names, rights in get-up, rights in goodwill or to sue for passing off, rights in designs, rights in computer software, database rights, rights in confidential information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which may now or in the future subsist in any part of the world. Such IP may be encompassed in part or in whole under the Deliverables;
<b>“Instrument Unit”</b>	means the specific instrument and accessories used to run a specimen that has been collected and processed with a Test Unit, and to display the result. In this Agreement, Instrument Unit refers to all of the following components: 1. .... 2. .... 3. .... ....
<b>“KfW”</b>	means the German state-owned investment and development bank, based in Frankfurt, Germany;
<b>“Know-How”</b>	means all technical and other information which is not in the public domain (other than a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, relating to but not including Foreground Intellectual Property or Intellectual Property, as previously defined in this Agreement;
<b>“Licence Agreement”</b> or <b>“Licence”</b> <b>(if applicable)</b>	Means that licence as further set out under Section [●];
<b>“LMICs”</b>	means those countries defined by the World Bank as having “low-income economies”, “lower middle-income economies” or “upper middle-income economies”, as may be amended from time to time;
<b>“Milestone”</b>	means any of the milestones set forth in Schedule [●];
<b>“Manufacturer of Record”</b> <b>(if applicable)</b>	means the named legal entity legally responsible for placing a Product on the market as recognized by the appropriate in country regulatory authority. For the purposes of this Agreement the

	Manufacturer of Record shall be the Third Party which is the recipient of the Technology Transfer.
<b>“Priority Countries”</b>	shall have the meaning set forth under Section [●];
<b>“Private Health Sector”</b>	means any non-governmental institute in the health sector which operates on a for-profit basis, and t which may have access to preferential access conditions to a Product such as set out under Global Access, and as determined on a case-by-case basis by FIND;
<b>“Product”</b>	means the XYZ assay for the POC clinical chemistry device and the materials provided with the Product as explicitly listed in the associated instructions for use, and all subsequent versions, and subsequent assays to be mutually agreed and documented as an amendment to this Agreement;
<b>“Product Requirements” or “Product Requirements Document”</b>	means the document that contains all design requirements for the Product (Test Unit and Instrument Unit);
<b>“Public Health Sector”</b>	means (i) any government in the Territory, including any government ministry of health, department or agency, or any local or regional governmental body, authority or entity, and (ii) any officially recognized, not-for-profit organization including private not-for-profit organizations, or funds, that pursue activities to relieve suffering, promote the interests of the poor, provide basic social services, or undertake community development, including, but not limited to, the World Health Organization (and other UN organizations), ICRC UNICEF, Save the Children Fund, Médecins Sans Frontières, Unitaid, PEPFAR, the Global Fund, FIND or its authorized designee, and other funding organizations;
<b>“Steering Committee”</b>	<b>shall have the meaning ascribed to it in Section [●];</b>
<b>“Stringent Regulatory Authority” or “SRA”</b>	means that definition given by WHO available at <a href="https://www.who.int/medicines/regulation/sras/en">https://www.who.int/medicines/regulation/sras/en</a> (2020);
<b>“Target Product Profile” or “TPP”</b>	means that desired ‘profile’ or characteristics of a target product that is aimed at a particular disease or diseases, including intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics, and as specifically referenced under Section [●] to this Agreement;
<b>“Technology Transfer” (if applicable)</b>	means those activities required to successfully transfer and validate such transfer of required manufacturing processes, procedures, and Know-how, to a Manufacturer of Record;
<b>“Term”</b>	has the meaning ascribed to it in Section [●];
<b>“Territory”</b>	means all of the countries classified under the LMIC definition, plus Antigua and Barbuda, the Bahamas, Barbados, Palau, Seychelles, St. Kitts and Nevis, and Trinidad and Tobago;

"Test Unit"	means the specific assay and all required ancillary reagents and other consumables to run a single test on a single human specimen;
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## 2. PROJECT: SCOPE OF PROJECT, FINANCIAL AND OPERATIONAL

### CONDITIONS 2.1 Overview

- a) With the support of KfW, FIND wishes to invest in the Project to be performed by XYZ as further set out under this Agreement and in Schedules [●], subject to the terms and conditions of this Agreement. The Project shall be conducted in accordance with the Milestones and the timelines set forth in Schedule [●].
- b) The Parties agree that the Product shall comply with the Product Requirements.
- c) ...

### 2.2 Project Implementation

- a) General. XYZ shall engage appropriately qualified and trained staff and perform any and all its duties, obligations, and responsibilities under this Agreement with all due skill and care and professional standards. XYZ shall comply with all applicable laws, regulations, and guidelines in the performance of the Project. XYZ shall (i) maintain all necessary regulatory licences, authorisations, accreditations and certifications which are necessary to complete the Project; (ii) comply with any material terms and conditions applicable to the maintenance of such licences, authorisations, accreditations and certifications; and (iii) shall ensure that any third party subcontractor complies with the same requirement.
- b) Quality Management Systems ("QMS") (if applicable). XYZ shall ensure compliance at all times with the following;
  - Ensure an appropriate QMS covering in vitro diagnostic products, is in place and compliant with SRA and/or WHO Pre-qualification ("PQ") requirements; and
  - Ensure any Product obtains and maintains appropriate SRA and/or WHO PQ authorization or approval, as appropriate, for the duration of this Agreement or its market availability in LMICs, whichever is longest.
- c) Collaboration Management and Steering Committee. The Parties shall form a collaboration management team (the "Steering Committee") consisting of a maximum of four members, two of whom shall be nominated by each Party, whose responsibilities shall include: (i) monitoring the progress of the Project under this Agreement; (ii) making recommendations to both Parties for continuation, modification or termination of the Agreement; (iii) overseeing all operational activities under the Project; and (iv) any other matter attributed to the Steering Committee under this Agreement. Steering Committee meetings shall be conducted at least every 2 months, unless otherwise agreed between the Parties. Meetings may be at a mutually agreed location or by conference call, or video conference, or any combination of these. The Steering Committee shall take all its decisions by consensus, provided however that if no consensus is reached, FIND shall have a casting vote, except for resolutions on any matter requiring additional financial commitment not provided for under this Agreement from any Party, which always require the consent of all members of the Steering Committee. At its first meeting, the Steering Committee shall agree on its operating rules and procedures such as standing agenda items, recording of minutes and action items. The Parties may mutually agree to the participation of Third Parties in the Steering Committee.
- d) Project Specific Responsibilities under this Agreement.
  - a. FIND: In addition to other obligations set forth under this Agreement, FIND shall in particular:
    - .....

- b. XYZ: In addition to other obligations as set forth under this Agreement, XYZ shall in particular perform its specific roles and responsibilities during the Term of this Agreement and as set out under Schedules, and the Global Access Section of this Agreement.

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### 3. ADDITIONAL THIRD PARTIES

XYZ may use Third Parties as subcontractors in the performance of its activities undertaken in connection with this Agreement, provided; a) FIND is informed and agrees in advance in writing to such subcontractor, and; b) XYZ must obtain each subcontractor's written agreement to comply with all the applicable terms and conditions of this Agreement. In addition, FIND may require to review the relevant sections of any agreement between XYZ and the Third Party in question, solely to ensure compliance with this Section [●]. For the sake of clarity any activity and/or obligation assigned to a Third Party under this Section [●] of this Agreement shall be considered nonetheless as being assigned to XYZ and XYZ shall be wholly held accountable for the fulfilment of such activity/obligation and any failure by the Third Party to execute their obligations shall be considered the full and direct responsibility of XYZ.

### 4. GLOBAL ACCESS AND GENERAL PRODUCT SUPPLY CONDITIONS

**4.1 General.** Each Party recognizes the requirements of Global Access and shall ensure that any Product arising from the Agreement will, subject to the terms and conditions of this Agreement and the Party's freedom to operate, be made available broadly in accordance with Global Access, including but not limited to:

- a) providing access to the Product at an Affordable Price, as defined below, including required local registrations in the Territory, and local maintenance, service, and support;
- b) results and data generated pursuant to this Agreement shall be made broadly and publicly available to any and all entities, including any Public Sector bodies, as well as for-profit and not-for-profit organizations, and research centers working in healthcare in or for LMICs.

**4.2 Eligible Purchasers and Affordable Price.** XYZ agrees to the following;

- a) XYZ will ensure that it or its manufacturing and/or commercial partner(s) sell the Product:
  - (i) at a maximum price of USD XXX (XXX United States dollars) per Test Unit (based on EXW) and a maximum price of USD XXX (XXX United States dollars) per Instrument Unit, which shall apply to Eligible Purchasers (collectively, the "Affordable Price") in the Territory;
  - (ii) at a maximum price of USD XXX (XXX United States dollars) per Test Unit (based on EXW) and a maximum price of USD XXX (XXX United States dollars) per Instrument Unit, which shall apply to Eligible Purchasers (collectively, the "Affordable Price") in the Territory;
- b) At FIND's request, XYZ shall supply the information required under the terms of Schedule [●], "Cost Analysis".
- c) The Affordable Price does not include (i) freight and insurance charges to the country destination from the XYZ site of shipment; nor (ii) import duties into the final destination

country. Regarding the freight charges, XYZ shall negotiate directly with the purchaser a mutually agreed cost, retaining at all times the requirement to minimise such a cost, in accordance with Global Access requirements.

**4.3 Priority Countries.** In general the Parties agree that the Eligible Purchasers should be the main focus for Product supply and have the right to the Global Access terms set out under this Section [●]. In addition, the following countries shall be considered as the “Priority Countries” [●]. Notwithstanding the above, XYZ shall make its commercial best efforts to ensure sufficient supply of products to the Territory which are not Priority Countries.

#### Technology Licence Agreement – in the case of a Technology Transfer (if applicable)

XYZ shall enter into a Technology License Agreement with ABC, based on the following terms, comprising the following key Definitions and “flow through” obligations:

- a. **Field** shall mean the detection of SARS-CoV-2 infection in humans, or as mutually further agreed with respect to other infectious disease agents by the Parties.
- b. **Territory** shall include all LMICs as defined by the World Bank, as amended from time to time.
- c. **Global Access** key terms regarding the Affordable Price and other key access terms to be an obligation under the Licence.
- d. **Scope of the Licence:** XYZ to be granted, a non-exclusive, non-sublicenseable (only to Affiliates), royalty-free, fully paid up and perpetual licence under the ABC IP to develop, make, or have made, use, offer for sale, sell, have sold, export or import the Product anywhere in the world for the purpose of its use in the Field and in the Territory. As per Article [●], the Field definition may be extended by mutual agreement of the Parties.
- e. **Background IP:** Such Licence shall include the right to use any pre-existing (Background) ABC IP at zero (or minimal) royalty rates as long as it is required for the commercialisation of the Product.
- f. **Technology Transfer:** Such Licence shall include appropriate technology transfer obligations under which XYZ and the Manufacturer of Record shall develop a mutually agreed plan of activities and deliverables to ensure such successful Technology Transfer (the “**Transfer Plan**”) in order to ensure that the Manufacturer of Record will be able to produce and commercialize the Product. The Transfer Plan shall be agreed within [●] weeks of the Effective Date.

As the principal funding partner under this Agreement, FIND reserves the right to participate in the licence negotiations between XYZ and ABC. The final Licence Agreement will fully reflect and incorporate the terms for such Licence as set out in this Agreement. XYZ will provide to FIND copies of such final Licence Agreement prior to execution, for FIND’s review and comments and final acceptance, and a final copy of the fully executed agreement for its records.

## **5. INDEMNIFICATION**

XYZ will be responsible for the manner in which all activities performed under or as a result of this Agreement are carried out and will indemnify and hold harmless FIND for any and all claims and liabilities (including legal fees and costs) arising or resulting from such activities carried out by XYZ, its employees, authorized agents, and subcontractors.

## **6. COMPLIANCE WITH FIND POLICIES**

Code of Conduct and Ethics: FIND has established a Code of Conduct and Ethics (the “Code”) as set forth under the FIND site at <https://www.finddx.org/policies>. By executing this Agreement, XYZ acknowledges it has read and understood the contents of the Code, has informed the appropriate personnel of the Code’s existence and agrees to abide with the Code terms and conditions, or warrants that it has its own code of conduct which is substantially equivalent and that such own code of conduct is currently applied to XYZ.

Anti-Terrorism: XYZ will not participate, directly or indirectly, in support of activities (a) related to terrorism; (b) with persons or entities that appear on the United Nations Security Council Consolidated List; or the sanctions list of donor countries including the UK, The Netherlands, Germany, USA, Canada and Australia; (c) with countries or territories against which the U.N. maintains comprehensive sanctions, under applicable law unless specifically approved by FIND in writing, at FIND’s sole discretion.

Anti-Corruption & Anti-Bribery: XYZ will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision by FIND, including by assisting any party to secure an improper advantage.

Political Activity & Advocacy: XYZ may not use funds to influence the outcome of any election for public office in any country, or to carry on any voter registration drive.

Child Safeguarding: XYZ is committed to comply with all relevant local law on child rights and welfare in order to provide what is in ‘best interest of the child’ including employment law that apply to children and shall not use any funds under this Agreement to support the contrary.

Anti-Trafficking: XYZ is committed to comply will all relevant local, national and international laws and regulations to prevent and fight against “Trafficking in Persons” including, but not limited to the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime.

Specific warranty regarding tobacco and arms. XYZ has, and currently has not had during the past four (4) years, any relations or linkages, with the tobacco or arms industry, or any subsidiary of a tobacco or arms company or commercial entity involved with the manufacture, sale, or distribution of tobacco/arms or tobacco/arms products, including, but not limited to, financial interests, controlling interests, or commercial relations resulting in licensing agreements, programmes, initiatives, research, or projects funded by the tobacco/arms industry, jointly administered with tobacco/arms-affiliated entities, or done for the tobacco/arms industry.

## **7. GOVERNING LAW AND DISPUTE RESOLUTION**

This Agreement shall be governed by and construed in accordance with the laws of Switzerland.

The Parties hereto undertake to settle any dispute concerning the validity, interpretation, and/or performance of this Agreement in an amicable manner. To the extent practical, the Parties shall continue to work under the Agreement pending the final outcome of any dispute. If the Parties fail to resolve such dispute, controversy or difference through good faith negotiations, any dispute, controversy, or claim arising under, out of, or relating to this Agreement or any task and any subsequent amendments of this Agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be submitted to mediation in accordance with the ICC Mediation Rules. The commencement of proceedings under the ICC Mediation Rules shall not prevent any disputing party from commencing arbitration in accordance with the following paragraph. All disputes arising out of or in connection with the present contract shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The number of arbitrators shall be three (3). The place of arbitration shall be Geneva, Switzerland. The language of the arbitration shall be English.



## References

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