

Accelerating the development of a point-of-care liver function tests platform adapted to low resource settings

Executive summary

FIND, the global alliance for diagnostics, is leading a Request for Proposals (RFP) **to accelerate the development of a point-of-care platform that can be used for liver function testing in low-resource settings**. Such a platform would allow liver function tests, blood tests that measure levels of biomarkers of liver injury or liver disease. We are particularly interested in platforms with the potential to measure other analytes, in addition to liver injury markers, relevant for testing for different diseases at primary healthcare facilities and enabling differential diagnosis and early intervention for patients.

- The short-term focus of this RFP is to **accelerate the development of platforms that can enable liver function testing at the point of care (POC), in low- and middle-income countries (LMICs)**
- A long-term goal of this RFP is to **expand access to point of care platforms** that allow quick and easy assessment of the most relevant blood biomarkers and thus enable effective triage and management of patients, directing those to the appropriate level of care before it is too late.
- A budget envelope of US **\$1 million** is available to selected manufacturers to support R&D expenses and device validation studies
- Manufacturers are expected to commit to **supplying an affordable product to the public sector in LMICs**
- Developers/manufacturers of platforms and assays in early development stage are in eligible to apply for this RFP. Applications for products at the technology readiness level²² three and above will be considered, and all funded activities must be completed by end of December 2022.

BACKGROUND

Low- and Middle Income Countries (LMICs) face many health care challenges, the biggest gap in the care cascade being diagnosis.^{1,2} One of the major neglected problems requiring urgent intervention is diagnosis for liver diseases.³ Causes of liver disease in LMICs include infectious agents, drug-induced injury as well as alcohol and obesity.⁶ Every year, more than 2 million deaths are attributed to liver disease globally.⁴ With timely diagnosis, many of these deaths can be avoided using appropriate treatment.⁶ Liver assessment is currently done using non-invasive methods such as ultrasound and transient elastography as well as by measuring biochemical markers in the blood.⁵ However, existing diagnostic techniques require sophisticated equipment and highly trained personnel and hence, testing is often unavailable in resource-limited settings, particularly in decentralized settings such as the primary care level.⁶ Lack of funding, lack of epidemiological data and a lack of programs that are dedicated to targeting liver disease has led to a neglect of this problem.

COVID-19 has continued to cause much death and devastation all over the world. As of the end of November 2021, there have been more than 263 million cases and more than 5 million deaths around the world.⁸ Higher COVID mortality has been linked to reduced platelet counts, reduced albumin levels and elevated alanine aminotransferase (ALT) at the time of hospital admission.⁹ Patients with chronic liver disease are at higher risk for severe COVID-19.¹⁰⁻¹⁴ Recent data has shown that patients with liver cirrhosis have particularly high rates of hepatic decompensation and death from respiratory failure following SARS-CoV-2 infection. Direct liver injury due to the SARS-CoV-2 virus has also been reported in multiple cases,^{10,15-17} In addition there has been drug-related liver injury observed in patients undergoing antiviral treatment.¹⁸ Moreover, with the introduction of lockdowns, a significant drop was noted in the number of liver tests for patients who were previously being monitored.⁷

The ability to quickly and easily assess the liver condition at the primary care will enable effective triage and management of patients, directing those to the appropriate level of care before it is too late. There is an urgent need to develop simple, effective and affordable tools that can be widely implemented in primary healthcare settings for liver function screening. While point-of-care imaging techniques are also needed, this Request for Proposals is specifically focused around the need for platforms that can measure biochemical markers in the blood, specifically ALT and AST. There are currently two FDA-approved devices for liver function clinical chemistry that are often found in LMICs: Alere Cholestech LDX and Roche Reflotron Plus. These devices are expensive, require highly trained personnel and hence, are not widely accessible.¹⁹

In order to accelerate access to liver function testing globally, **FIND is seeking to support the development of POC platforms capable of performing liver function tests.** Importantly, we are prioritizing platforms with the potential to measure other target analytes (e.g. Basic metabolic panel, Creatinine, Glucose, Platelets, TSH, T3, T4, Alpha fetoprotein, HBsAg, HBeAg, GGT, Bilirubin e.t.c) to support timely and appropriate patient triage, management and referral for a broader set of conditions.

OBJECTIVE AND SCOPE

FIND aims to **accelerate the development of point-of-care platforms** for use in LMICs. The main areas of focus for this RFP are:

- Support the development of an affordable POC device for liver function testing
- Suitability of the platform for use in decentralized healthcare facilities in LMICs, with a specific focus on high operating temperature, ruggedness, low-maintenance, and extended assay shelf-life

- Sample-to-answer systems that can be operated with minimal user training
- Products at the technology readiness level²² three and above
- Platforms with demonstrated potential to expand the assay menu to other clinical chemistry and immunoassays that could improve testing services in primary healthcare in resource-limited settings

FIND seeks platforms that closely meet the key product requirements listed in the “**Technical Assessment**” sheet within the **Assessment Matrix** (see **HOW TO APPLY** below for forms and templates). We encourage all applicants to review these product requirements.

Single applicants will be accepted, and **consortium applications are also encouraged**.

The scope of supported activities will vary according to the technology readiness level and needs of each applicant and may include, but are not limited to:

- Feasibility studies of platforms and/or assays in development
- Development of the platform/device, software, or assay, verification of performance.
- Modification of an assay or instrument to meet critical design specifications (weighted as ‘3’ in column H of the Technical Assessment)
- Validation of system performance in key LMIC markets (e.g. performance evaluation, usability studies).

FIND will not support post-launch activities such as shipping logistics, procurement, implementation, user training, distributor qualification, and post-market surveillance.

Lastly, preference will be given to applicants with interest in setting up or expanding manufacturing capacity in LMICs and platforms that are flexible for further customization and expansion of the menu.

In parallel to the activities in this RFP, FIND may decide to engage in market assessment activities to estimate the demand in the relevant market segments for specific clinical chemistry parameters, and to understand the clinical use of such a device. This information will guide further refinement of final product design specifications. Specifically, FIND’s market research may enable the definition of specific operating conditions, parameters menu and other specifications that are relevant to as many high-priority LMICs as possible. Importantly, the market assessment information generated by FIND in parallel to this RFP may also be used later to secure volume commitments and negotiate pricing in preparation for market introduction of assays and platforms developed through this RFP.

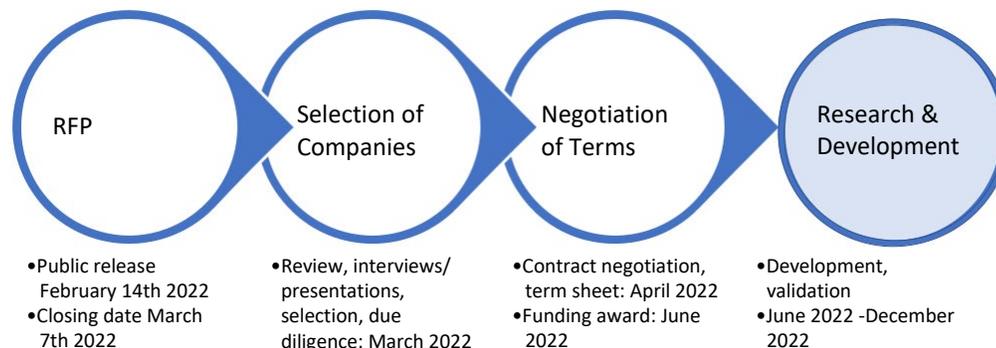
TIMELINE

The anticipated timeline for this initiative is as follows (may vary depending on applicant):

1. Project launch date: 14 February 2022
2. Selection of companies: 14 March – 15 April 2022
3. Negotiation of terms and financing: 18 April – 13 June 2022
4. R&D activities and/or clinical validations: 13 June – 15 December 2022
5. Project closure date: 31 December 2022

It is important to note that all activities funded under this RFP must be completed by **December 2022**.

Note that for companies ultimately selected for an award, costs incurred during the negotiation period will be allowable, enabling work under this RFP to begin as early as 7 June 2022.



FUNDING AWARDS

Funding for the RFP is provided through FIND from a donor grant; a **budget envelope of US\$1 million will be available to support 1-2 applications.**

AWARD CONDITIONS

For this RFP, applicants who are selected for final awards are expected to:

- Commit to undertake required product development activities to match product requirements (see **Appendix 1**)
- Commit to a pricing model that is transparent and affordable to LMICs (i.e. COGS-based pricing) (See **Appendix 2**).
- Commit to and follow [FIND Global Access Policy](#) and [FIND Code of Conduct and Ethics](#)
- See **Appendix 3** for additional information on “Grounds for Exclusion”
- Accept the Terms and Conditions of KfW Declaration of Undertaking (**Appendix 4**).

SELECTION AND AWARD PROCESS

The deadline for receipt of submissions is 11 March 2022. A commitment to a compressed timescale is required, and we anticipate funding awards and contract execution within 2 months. The selection process is designed to be objective, independent, and transparent to ensure that the most suitable technologies are supported, and potential conflicts of interest are avoided. Candidates will be evaluated by an internal review panel comprised of staff at FIND, and by an external review panel comprised of FIND and global experts with backgrounds in technical R&D, product launch, and implementation. The review panels will use information submitted in the application (see **Application Requirements** section below) as well as publicly available information. The review panels may request additional information or clarifications, if needed, in writing. Applications will be evaluated in stages, as follows:

- **Stage 0.** All applicants’ eligibility will be verified and those that are “out of scope” will be excluded. Additional grounds for exclusion of an application at this Stage 0 are detailed in **Appendix 3**. Finally, applicants should review **Appendix 4** and verify that they will be eligible to sign at the time of contract execution (please note that Appendix 4 is only provided at this time for informational purposes; signing is not requested at the time of application). Eligible candidates will advance to Stage 1.

- **Stage 1.** This first evaluation will down-select the long list of candidates to a short list of up to 10 candidates. An internal review panel will evaluate long-listed candidates using the submitted application materials (See **Application Requirements**). More specifically, candidates will be evaluated on:
 - o Existing product specifications, scored in the sheet titled “**Technical Assessment**” in the **Assessment Matrix**.
 - o Organizational criteria, scored in the sheet titled “**Business Assessment**” in the **Assessment Matrix**.
 - o **Applicant Presentation**, which details specific topics described in the **Application Requirements**.

The internal review panel will then score the candidate’s alignment to the goals of the RFP (see sheet titled “**Alignment Criteria**” in the **Assessment Matrix**). The **Applicant’s Total Score** will then be calculated as a weighted sum of the normalized scores from the Technical Assessment (25%), Business Assessment (25%), and Alignment Criteria (50%).

Early stage technologies (platform and/or assay TRL 3-TRL 6) and late stage technologies (TRL6 and above) will be assessed separately and proposals within each category will be shortlisted. Final set of short-listed candidates will include both early stage and late stage technologies and will be selected in a consensus call of reviewers. Shortlisted proposals will be advanced to Stage 2.

- **Stage 2.** This second evaluation will down-select short-listed candidates to a list of finalists. Candidates will be evaluated using:
 - o **Follow-up Live Presentation** (by teleconference): Short-listed candidates will be invited to make a follow-up presentation to address a set of questions provided to the candidates in advance.
 - o **Applicant Presentation**, which details specific topics described in the Application Requirements.
 - o Scores from the Technical Assessment and Business Assessment (completed in Stage 1) will also be provided to the external review panel.

The external review panel will score the candidate’s alignment to the goals of the RFP (see sheet titled “**Alignment Criteria**” in the **Assessment Matrix**) – this scoring will be conducted *independently of the candidate’s score in the Alignment Criteria from the internal review panel during Stage 1*. Lastly, the **Applicant’s Total Score** will be calculated. Finalists will be selected in a consensus call of reviewers and will advance to contract negotiation. Final funding awards and contract execution is expected to be completed by the end of March 2022. Note: Applicants not selected will be notified; however, the details regarding non-selection will not be provided for every applicant.

- **Due diligence:** Given the tight timelines for this RFP, due diligence (DD) to verify the applicant submissions and claims will proceed in parallel with contract negotiations. The DD process may include site visits and/or phone/video conferencing, as well as requests for additional information. Should the DD reveal any unresolvable inconsistencies with this RFP and/or donor requirements and restrictions, applicant exclusion at this late stage is still possible. FIND may outsource conduct of DD to an independent third party, following FIND procedures.

APPLICATION REQUIREMENTS

Applications should include the following:

1. **Applicant Presentation**

- Applicants shall provide a slide deck of **no more than 20 slides** that must include the following information, and must use the provided PowerPoint template (see **HOW TO APPLY** for templates and forms):
 - Overview of the platform and assay.
 - Current performance of the platform: evidence of the system (or prototype system) performance, including but not limited to data from any existing feasibility, verification and/or validation studies (published or internal).
 - Alignment with Product Requirements. Provide evidence to support claims, particularly for requirements denoted with a Weight of '3' in the sheet titled "Technical Assessment" in the **Assessment Matrix**.
 - Roadmap, including current stage of development and proposed activities to meet the Product Requirements, where data are not available yet or the existing specification does not meet either the Optimal or Acceptable specification (in sheet titled "Technical Assessment" in the **Assessment Matrix**).
 - Description and timeline of activities proposed under this award. Please also include estimated funding need, and other support required to meet product requirements and/or pricing and supply in LMICs.
 - Describe commercialization plans. See **Appendix 2** for additional considerations.
 - Proposed strategy for roll out in LMICs.
 - Organizational strength: Evidence of institutional commitment and/or track record of the organization or key personnel with experience in in vitro diagnostics (IVD), and/or LMIC markets.

2. Assessment Matrix

- Applicants are to complete noted sections of the provided spreadsheet titled "Assessment Matrix" (see **HOW TO APPLY** for templates and forms), specifically:
 - Technical Assessment
 - Please describe the **existing** Design Specifications (column D) of the system (or prototype system), and provide supporting evidence and/or data (column E) to support the claims in column D. If data are not available, please enter "No data" and provide the projections/assumptions in the Applicant Presentation file.
 - If the Existing Specification does not fall within the Acceptable and Optimal Specifications, please use the Applicant Presentation to briefly describe the plan or expected activities required to modify the existing specification into a proposed acceptable specification.
 - Business Assessment
 - Please provide evidence and supporting information (column C) regarding each of the criteria. Applicant responses to be supported by/verifiable through corporate documentation and due diligence.

3. Supporting Documents

- Aside from the 2 forms listed above, the only additional documents allowed for submission are registration/regulatory certificates, QMS/ISO certificates, instructions for use/product inserts for existing or relevant products, if available, and CVs from relevant team members and management.
- There will not be public opening of awards, or separate technical and financial bidding documents.

HOW TO APPLY

Submit applications via the FIND's [Technology Scouting Submission Webform](#). Please, select 'Liver function' as the 'Disease Area' and 'RFP: POC liver function device' as the 'Disease Area Subtype' and proceed with the online submission. Templates for the Applicant Presentation and Assessment Matrix can be downloaded from the submission portal. Please upload your completed **Applicant Presentation** and **Assessment Matrix**, along with any supporting documents by **7 March 2022**.

FIND intends to use the information on technologies submitted in response to this RFP to update the community's understanding of the POC clinical chemistry pipeline. All tests submitted to this RFP will automatically be included in the clinical chemistry technologies pipeline tracker which may be published on FIND's website. If you do not want your product to be included, please mention it in the application or at poc_lft@finddx.org.

QUESTIONS & FURTHER INFORMATION

Please email questions to: poc_lft@finddx.org. Questions will be accepted and responded to expediently until end of 11 March 2022. Submitted questions (and corresponding answers) will be publicly available at: <https://www.finddx.org/calls-for-partners/>

CONFIDENTIALITY

All information supplied to the applicant by FIND, including the RFP and all other documents relating to the RFP process, must be treated as confidential, and not disclosed to any third party unless the information is already in the public domain or is required to be disclosed and vice versa. FIND considers any application and supporting documents received under the RFP as confidential. If required, FIND can sign a Confidentiality Disclosure Agreement with interested applicants prior to proposal submission. FIND shall not disclose the proposal to third parties without the prior written agreement of the proposal submitter. All members of the review panel shall also be under confidentiality and shall be recused if found to have a potential conflict of interest (which they are obliged to disclose). Any specific questions concerning confidentiality should be addressed to the FIND team.

CONTRACTUAL TERMS AND CONDITIONS

FIND will use a commercial level contractual mechanism where the standard Terms and Conditions address the requirements of supplying a product for public health particularly in LMICs, as set forth under **Appendix 5**.

COMPLAINTS

Applicants who consider that actions or decisions taken in the course of the RFP result in an unfair dis/advantage may file a related complaint. Such a complaint shall be addressed in writing to FIND (at poc_lft@finddx.org), detailing the grounds for the complaint and making reference to the applicable provisions in the RFP or other applicable regulations. The complainant may also use FIND's [Ethics Hotline](#) as a channel for raising complaints anonymously. FIND shall acknowledge the complaint within three (3)

days of receipt, and respond with results of the complaint handling within ten (10) working days thereafter.

Appendix 1: Product Requirements

Characteristic	Minimal Requirements	Optimal Requirements
General		
Target use setting	Level 2 healthcare facility	Level 1 healthcare facility (primary care) defined as having a rudimentary equipped laboratory, water, electricity with intermittent surges and/or outages, limited climate control, dusty environment; medical staff onsite
Intended user	Healthcare worker with minimal training	Healthcare worker or lab technician with limited training (e.g. basic laboratory training, able to operate an integrated test system with minimal additional steps)
Device		
Device design	Device(s) with a single port capable of interfacing with one cartridge design; one or more connectable instruments can be used to cover the minimal test menu (must be centrally managed)	Single integrated device with universal port(s) capable of interfacing with one or more cartridge designs for simultaneous, independent detection of multiple analytes
Size	Bench-top device	Handheld device
Weight	≤ 10 kg	≤ 3 kg
Power requirements	Local 110–220 V AC mains power, plus uninterruptible power supply (UPS) to complete current cycle; UPS and circuit protector must be integrated within the system	Same as minimal, with rechargeable battery back-up (8-hour operation) or single-use battery (for hand-held)
Throughput	Throughput processing of one sample at a time; minimum of 10 samples per hour when individual analytes are tested or 4 samples per hour when analyte panels are tested	More than one sample at a time with random access and the ability to test different analytes simultaneously
Environmental stability: operating range of the device	Operation at 10–35°C and up to 90% non-condensing humidity at an altitude up to 2,500 meters	Operation at 5–45°C and up to 98% non-condensing humidity at an altitude up to 3,000 meters; able to function in direct sunlight; able to withstand dusty conditions

Biosafety	Closed, self-contained system with unprocessed sample transfer; no open handling of biohazardous material; easy decontamination of instrument surfaces	Same as minimal
Training time needed	Below 1 day for untrained healthcare worker	Below 2 hours for untrained healthcare worker
Service maintenance and calibration	Daily maintenance (<30 minutes, with hands on time <10 minutes); mean time between failures of at least 24 months or 10,000 tests; self-check alerting operator to instrument errors or warnings; operator calibration per new lot or at set time intervals	Weekly maintenance (<30 minutes, with hands on time <10 minutes); mean time between failures of at least 36 months or 30,000 tests; self-check alerting operator to instrument errors or warnings; ability to be calibrated remotely or no calibration needed (factory calibrated)
Patient identification capability	Manual entry of alphanumeric patient identifier via keypad, touchscreen or connected result management device (e.g. smartphone)	Same as minimal, plus bar code, radio frequency identification (RFID) or other reader
Result output	Quantitative based on the analytes of detection; qualitative where this is sufficient to inform clinical decision making	Quantitative plus option of qualitative readout where that result is sufficient to inform clinical decision-making; ability to select which test results are reported to the user based on the intended use in the regional context in which the test is used
Result display	On-device visual readout with ability to function in various lighting conditions ranging from bright to low ambient light conditions	Same as minimal, with option to add custom result ranges and alerts to support clinical decision making
Data extraction & Connectivity	Possibility to export data via USB and ideally LAN, or no connectivity.	Same as minimal, plus 3G/4G/Wi-Fi/Bluetooth
Data export and protection	Secured data export with end-to-end encryption connectivity to external printer; passcode-protected machine access	Same as minimal, plus scheduled/automatic data export using interoperable standards; support of any or all of the following formats: HL7, FHIR, ASTM, JSON; passcode-protected individual user access
Data storage	No integrated data storage	Expandable memory and cloud connectivity
Manufacturing	International Organization for Standardization (ISO) 13485:2016 compliant	Same as minimal
List price of the device	≤5,000\$ (USD) (Estimate at full scale)	≤500\$ (USD) (Estimate at full scale)

Device regulatory status	Approval through at least one Stringent Regulatory Authority	Same as minimal plus CLIA-waived; WHO-PQ approval if requirements are in place
Test cartridge		
Analytes/test menu	AST, ALT	ALT, AST + plus other parameters*, including basic metabolic panel and at least any two of the following: HBsAg, HBeAg, AlkP, Bilirubin, GGT, Total protein, Creatinine, Glucose, Platelets, HbA1c, TSH, T3, T4. Alpha Fetoprotein *List of relevant analytes may be refined based on outcomes of key stakeholders' survey conducted in January 2022
Description of test cartridge	A maximum of two separate reagents provided separately (without including controls), as part of the kit. The rest of the reagents, if required, shall be embedded in the cartridge/cuvette	No additional reagents required. All reagents integrated in the cartridge/cuvette
Throughput	Throughput processing of one sample at a time; minimum of 10 samples per hour when individual analytes are tested or 4 samples per hour when analyte panels are tested	More than one sample at a time with random access and the ability to test different analytes simultaneously
Additional third party consumables	None, except for sample collection	None; manufacturer-provided kits contain all required items for sample collection and testing
Sample type	Ability to accept venous whole blood and/or serum/plasma	Same as minimum, plus ability to accept fingerstick whole blood
Limit of detection	Equivalent to state-of-the-art reference assays for the same target analytes; where applicable, clinically relevant LODs are to be met	Same as minimal;
Interfering substances	Level of interference established for samples; level of interference established for exogenous and therapeutical substances	Same as minimal
Standardization and traceability	Test should be standardized based on established methods and traceable to internationally recognized reference materials (where available)	Same as minimal
Quantitation	Quantitative result based on the analytes of detection. Qualitative result available to user where that result is sufficient to inform clinical decision making	Same as minimal

Total Error Allowable (TEa)	Test performance criteria must fall within acceptable Total Error Allowable (TEa) targets for each test as set by the stringent regulatory authority in which the device is approved.	Same as minimal
Quality Control & Proficiency Testing	The frequency of quality control and proficiency testing shall follow the frequency set by the stringent regulatory authority in which the device and assay are approved.	Same as minimal
Environmental stability: transport	No cold chain required; should be able to tolerate stress during transport (cycles of temperature of 30 to 50°C) without affecting the labelled expiry date	Same as minimal
Environmental stability: Reagent shelf life and storage conditions	12 months at 2–35 °C (including 3 months at 40°C); up to 90% relative humidity	24 months at 2–40 °C; up to 98% relative humidity
Operating conditions	Operation at 10–35°C and up to 90% non-condensing humidity at an altitude up to 2,500 meters; able to function in direct sunlight; able to withstand dusty conditions	Operation at 5–45°C and up to 98% non-condensing humidity at an altitude up to 3,000 meters; able to function in direct sunlight; able to withstand dusty conditions
In-use stability (for open cartridge package)	15 minutes at maximum operating temperature and humidity	1 hour at maximum operating temperature and humidity
Waste/disposal Requirements	No components that are classified with a GHS[1] classification – H(2) that would require waste disposal with high temperature incinerator (or more than a De Monfort type incinerator)	Same as minimal
Manufacturing	International Organization for Standardization (ISO) 13485:2016 compliant	Same as minimal
Reagent regulatory status	Approval through at least one Stringent Regulatory Authority	Same as minimal plus CLIA-waived; WHO-PQ approval if requirements are in place
List price of assay	≤3\$ (USD) per analyte (individual or as part of a panel) *List price may be refined based on outcomes of national stakeholders' survey conducted in January 2022	≤1\$ (USD) per analyte (individual or as part of a panel) *List price may be refined based on outcomes of national stakeholders' survey conducted in January 2022

Appendix 2: Pricing considerations

FIND is committed to assisting research and development for innovative diagnostics that have the potential to ultimately be delivered to LMICs. Special consideration will be given to applicants who are able to demonstrate their **commitment to marketing their system in LMICs** – this includes an emphasis on the cost of goods sold (COGS) and the marketed price of the system.

Transparency

FIND recognizes not only the urgent market need for an affordable point-of-care system, but also the need for a sustainable business model. In the spirit of collaboration, FIND aims to strike a balance where the needs of both the market and the applicant are met. In the context of confidential discussions, FIND expects applicants to provide transparency around the COGS-based price. This price should allow companies to cover their expenses and enable long term support and supply of the product, while also remain accessible to the public sector in LMICs. Ultimately, applicants are encouraged to **explore pricing models that will enable them to sustain a long-term commitment to supply in LMICs**. Pricing models include, but are not limited to, a capital purchase agreement (upfront payment for the instrument with contracted price per test), or a “reagent-rental” model, which is an all-inclusive price that includes an amortized instrument cost, all necessary reagents or consumables, and service and maintenance.

Appendix 3: Grounds for exclusion

Country of origin is not an exclusion criterion for this call, except where an international embargo or sanction by the United Nations, the European Union or the German Government applies.

Applicants/Bidders shall not be awarded a Contract if, on the date of proposal submission or the intended date of award, they:

- are bankrupt, being wound up or ceasing their activities, are having their activities administered by courts, have entered into receivership, or are in any analogous situation;
- have been:
 - convicted by a final judgement or a final administrative decision or subject to financial sanctions by the United Nations, the European Union and/or Germany for involvement in a criminal organization, money laundering, terrorist-related offenses, child labour or trafficking in human beings; this criterion of exclusion is also applicable to legal Persons, whose majority of shares are held or factually controlled by natural or legal Persons who themselves are subject to such convictions or sanctions;
 - convicted by a final court decision or a final administrative decision by a court, the European Union or national authorities in the Partner Country or in Germany for sanctionable practice during any Tender Process or the performance of any Contract or for an irregularity affecting the EU's financial interests;
- have been subject, within the last five years to a Contract termination fully settled against them for significant or persistent failure to comply with their contractual obligations during Contract performance, unless (i) this termination was challenged and (ii) dispute resolution is still pending or has not confirmed a full settlement against them;
- have not fulfilled applicable fiscal obligations regarding payments of taxes either in the country where they are constituted or in Switzerland (governing law will be Switzerland);
- are subject to an exclusion decision of the World Bank, or any other multilateral development bank, and are listed in the respective table with debarred and cross-debarred firms and individuals available on the World Bank's website or any other multilateral development bank, and cannot demonstrate, with supporting information along with their DoU, that the exclusion is irrelevant in the context of this RFP;
- have given a misrepresentation in supplying the information requested by FIND as a condition to participate in this RFP.

Appendix 4: Declaration of Undertaking

Accelerating the development of a point-of-care liver function tests platform adapted to low resource settings (the "Contract")

1. We recognize and accept that KfW only finances projects of the Foundation for Innovative New Diagnostics ("FIND") subject to its own conditions, which are set out in the Funding Agreement it has entered with FIND. As a matter of consequence, no legal relationship exists between KfW and our company, our Joint Venture¹ or our Subcontractors under the Contract. FIND retains exclusive responsibility for the preparation and implementation of the RFP and the performance of the Contract.
2. We hereby certify that neither we nor any of our board members or legal representatives nor any other member of our Joint Venture, including Subcontractors under the Contract, are in any of the following situations:
 - 2.1) being bankrupt, wound up or ceasing our activities, having our activities administered by courts, having entered receivership, reorganization or being in any analogous situation;
 - 2.2) convicted by a final judgement or a final administrative decision or subject to financial sanctions by the United Nations, the European Union or Germany for involvement in a criminal organization, money laundering, terrorist-related offenses, child labour or trafficking in human beings; this criterion of exclusion is also applicable to legal Persons, whose majority of shares are held or factually controlled by natural or legal Persons who themselves are subject to such convictions or sanctions;
 - 2.3) having been convicted by a final court decision or a final administrative decision by a court, the European Union, national authorities in Switzerland or in Germany for Sanctionable Practice in connection with a Tender Process or the performance of a Contract or for an irregularity affecting the EU's financial interests (*in the event of such a conviction, the Applicant or Bidder shall attach to this Declaration of Undertaking supporting information showing that this conviction is not relevant in the context of this Contract and that adequate compliance measures have been taken in response*);
 - 2.4) having been subject, within the past five years to a contract termination fully settled against us for significant or persistent failure to comply with our contractual obligations during such Contract performance, unless this termination was challenged, and dispute resolution is still pending or has not confirmed a full settlement against us;
 - 2.5) not having fulfilled applicable fiscal obligations regarding payments of taxes either in the country where we are constituted or in Switzerland;
 - 2.6) being subject to an exclusion decision of the World Bank or any other multilateral development bank and being listed on the website <http://www.worldbank.org/debarr> or respectively on the relevant list of any other multilateral development bank (*in the event of such exclusion, the Applicant or Bidder shall attach to this Declaration of Undertaking supporting information showing that this exclusion is not relevant in the context of this Contract and that adequate compliance measures have been taken in reaction*); or
 - 2.7) being guilty of misrepresentation in supplying the information required as a condition to participation in this Request for Proposals (RFP).

¹ In the context of this "Declaration of Undertaking", Joint Venture is given to mean collaboration between parties. For clarity, it is not intended in the common contractual sense where two parties share assets and benefits, in addition to risks, in a defined business venture.

3. We hereby certify that neither we, nor any of the members of our Joint Venture or any of our Subcontractors under the Contract are in any of the following situations of conflict of interest:
 - 3.1) being an affiliate controlled by FIND or a shareholder controlling FIND, unless the stemming conflict of interest has been brought to the attention of KfW and resolved to its satisfaction;
 - 3.2) having a business or family relationship with FIND's staff involved in the RFP or the supervision of the resulting Contract, unless the stemming conflict of interest has been brought to the attention of KfW and resolved to its satisfaction;
 - 3.3) being controlled by or controlling another Applicant or Bidder, or being under common control with another Applicant or Bidder, or receiving from or granting subsidies directly or indirectly to another Applicant or Bidder, having the same legal representative as another Applicant or Bidder, maintaining direct or indirect contact with another Applicant or Bidder which allows us to have or give access to information contained in the respective Applications or Offers, influencing them or influencing the decisions of FIND;
 - 3.4) being engaged in a Consulting Services activity, which, by its nature, may be in conflict with the assignments that we would carry out for FIND;
 - 3.5) in the case of procurement of Works, Plant or Goods:
 - i. having prepared or having been associated with a Person who prepared specifications, drawings, calculations and other documentation to be used in the Tender Process of this Contract;
 - ii. having been recruited (or being proposed to be recruited) ourselves or any of our affiliates, to carry out works supervision or inspection for this Contract.
4. If we are a state-owned entity, and compete in a Tender Process, we certify that we have legal and financial autonomy and that we operate under commercial laws and regulations.
5. We undertake to bring to the attention of FIND, which will inform KfW, of any change in the situation with regard to points 2 to 4 above.
6. In the context of the RFP and performance of the corresponding Contract:
 - 6.1) neither we nor any of the members of our Joint Venture, nor any of our Subcontractors under the Contract, have engaged or will engage in any sanctionable practice during the RFP process and, in the case of being awarded a Contract, will not engage in any sanctionable practice during the performance of the Contract;
 - 6.2) neither we nor any of the members of our Joint Venture or any of our Subcontractors under the Contract shall acquire or supply any equipment nor operate in any sectors under an embargo of the United Nations, the European Union or Germany; and
 - 6.3) we commit ourselves to complying with and ensuring that our Subcontractors and major suppliers under the Contract comply with international environmental and labour standards, consistent with laws and regulations applicable in the country of implementation of the Contract and the fundamental conventions of the International Labour Organization² (ILO) and

²In case ILO conventions have not been fully ratified or implemented in the Employer's country, the Applicant/Bidder/Contractor shall, to the satisfaction of the Employer and KfW, propose and implement appropriate measures in the spirit of the said ILO conventions with respect to a) worker grievances on working conditions and terms of employment, b) child labour, c) forced labour, d) worker's organizations and e) non-discrimination.

international environmental treaties. Moreover, we shall implement environmental and social risks mitigation measures when specified in the relevant environmental and social management plans or other similar documents provided by FIND and, in any case, implement measures to prevent sexual exploitation and abuse and gender-based violence.

In the case of being awarded a Contract, we, as well as all members of our Joint Venture partners and Subcontractors under the Contract, will (i) upon request, provide information relating to the RFP application and the performance of the Contract, and (ii) permit FIND and KfW or an auditor appointed by either or both of them, and in the case of financing by the European Union also to European institutions having competence under European Union laws, to inspect the respective accounts, records and documents, to permit on the spot checks and to ensure access to sites and the respective project.

7. In the case of being awarded a Contract, we, as well as all our Joint Venture partners and Subcontractors under the Contract, undertake to preserve the above-mentioned records and documents in accordance with applicable laws, but in any case, for at least six years from the date of fulfillment or termination of the Contract. Our financial transactions and financial statements shall be subject to auditing procedures in accordance with applicable laws. Furthermore, we accept that all data (including personal data) generated in connection with the preparation and implementation of the RFP and the performance of the Contract are stored and processed according to the applicable law by FIND and KfW.

Name: _____ In the capacity of: _____

Duly empowered to sign in the name and on behalf of³: _____

Signature: _____ Dated: _____

³ In the case of a Joint Venture, insert the name of the JV. The person who will sign the application, bid or proposal on behalf of the Applicant/Bidder shall attach a power of attorney from the Applicant/Bidder.

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

"Adequate Performance"	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 [●];
"Affordable Price"	has the meaning ascribed to it under Section [●];
"COGS" or "Manufacturing Cost of Goods Sold"	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;
"Cost Analysis"	means the Product cost information that XYZ shall provide under the format described in Schedule [●];
"COVID-19"	means the coronavirus disease caused by SARS-COV-2, declared by the World Health Organisation on 30 th January 2020 as a Public Health Emergency of International Concern;
"Deliverable"	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;
"Ex Works" or "EXW"	Shall have the meaning under INCOTERMS 2020 and shall be based on XYZ COGS;
"Eligible Purchasers"	means any and all purchasers within the Public Health Sector and Private Health Sector;
"Final Purchase Price"	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;
“Global Access”	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 www.finddx.org/policies , as amended from time to time;
“Intellectual Property” or “IP”	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;
“Instrument Unit”	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.
“KfW”	means the German state-owned investment and development bank, based in Frankfurt, Germany;
“Know-How”	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;
“Licence Agreement” or “Licence” (if applicable)	Means that licence as further set out under Section [●];
“LMICs”	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;
“Milestone”	means any of the milestones set forth in Schedule [●];
“Manufacturer of Record” (if applicable)	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.
“Priority Countries”	shall have the meaning set forth under Section [●];
“Private Health Sector”	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;
“Product”	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;
“Product Requirements” or “Product Requirements Document”	means the document that contains all design requirements for the Product (Test Unit and Instrument Unit);
“Public Health Sector”	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;
“Steering Committee”	shall have the meaning ascribed to it in Section [●];
“Stringent Regulatory Authority” or “SRA”	means that definition given by WHO available at https://www.who.int/medicines/regulation/sras/en (2020);
“Target Product Profile” or “TPP”	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;
“Technology Transfer” (if applicable)	means those activities required to successfully transfer and validate such transfer of required manufacturing processes, procedures, and Know-how, to a Manufacturer of Record;
“Term”	has the meaning ascribed to it in Section [●];
“Territory”	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.

.....

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.

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