

Request for Proposals

Seeking a manufacturing and commercialization partner for an antigen-based rapid diagnostic test for schistosomiasis infection with a focus in low- and middle-income countries

Executive summary

- ◆ FIND, a non-profit diagnostic initiative, is leading a Request for Proposals (RFP) to **find a manufacturing and commercialization partner to whom transfer an antigen-based rapid diagnostic test for schistosomiasis infection (SCH RDT)** for use in low- and middle-income countries (LMICs) to support national control programmes in measuring the impact of mass drug administration campaigns. The target populations are school-aged children and other high-risk groups.
- ◆ The short-term focus of this RFP is to identify partners with interest in transfer of the technology for manufacture.
- ◆ Selected applicants will be required to commit to undertake activities that enable product launch (local registration, service, and distribution activities) and supply to the public sector in LMICs (volume and details to be negotiated), based on FIND's global access policy.
- ◆ FIND will facilitate the introductions between the manufacturer and test developer, as well as provide access to well-characterised samples for lab verification and validation, as well as provide funding and developing the study protocols to undertake the clinical trials of the manufactured product.

BACKGROUND

Schistosomiasis (SCH) is a major neglected tropical disease, affecting over 240 million people, primarily in Africa. The World Health Organization (WHO) SCH control strategy focuses on large-scale targeted treatment campaigns. Whilst these successfully reduce the global burden of disease, lack of adequate diagnostic tools for precision mapping has limited their efficiency and effectiveness.

To address this gap, FIND and its partners have developed a simple, accurate and affordable SCH rapid diagnostic test (SCH RDT) that meets the TPP requirements developed by the SCH subgroup of the Diagnostic Technical Advisory Group (DTAG) following ISO 13485. It detects the circulating anodic antigen (CAA), which is an antigen secreted by all living schistosome species that are of public health importance. The intended use case for this RDT is to support national control programmes in measuring the impact of mass drug administration campaigns. The target populations are school-aged children and other high-risk groups. Lab data using stored plasma samples have shown that the performance criteria set out in the WHO-published TPP (1) have been met. Field evaluations are currently underway in Kenya and the Philippines (1'556 individuals enrolled across both countries) to demonstrate the feasibility of using finger-prick blood to determine infection status as well as confirm performance in the field. The current SCH CAA RDT is in late-stage development and will be ready for technology transfer to manufacturing after the field evaluations have been completed.

FIND is seeking a manufacturer and commercialization partner who will commit to obtaining regulatory approval for the deployment of the test with the use case described above in LMICs. Through the support of our key donors, FIND has funding to cover the transfer to the manufacturer as well as the lab verification and validation and the clinical trials (data required as part of the dossier for approval by a regulatory authority). In addition, preliminary performance data, cost-effectiveness of such a tool and market size estimates are available.

FINAL PRODUCT SPECIFICATIONS AND RATIONALE

The key product requirements are shown in Appendix 1.

The SCH CAA RDT developed by FIND and its partners meets the TPP requirements for an RDT for use with finger prick blood. Laboratory performance shows optimal clinical sensitivity and specificity for the detection of *S.mansoni*, *S.haematobium* and *S.japonicum*. Testing of additional clinical samples is currently ongoing at study sites in Kenya and the Philippines, with results expected in March 2024.

The test is easy to use, requires 40µl of finger prick blood with a time to result of 20 min, and an LMIC-appropriate shelf life. Results are colorimetric based and can be read by the naked eye.

MARKET OPPORTUNITIES

During 2021, Market Access Africa conducted a market landscape of SCH diagnostics for FIND. There are currently four different types of diagnostic tests available: antibody-based methods, microscopy, antigen-based methods, and DNA-based methods. At the time of writing, there are two commercially available antigen-based tests – which look at the circulating cathodic antigen (CCA) (2). However, both tests detect *S.mansoni* only and are reliable in moderate to high prevalence areas. Whilst a highly sensitive laboratory-based test currently exists for CAA and meet the required sensitivity and specificity requirements per WHO TPP, it is not commercially available and is limited in routine setting due to cost and difficulty to deploy at the point of care. Thus, the SCH CAA RDT is believed to be the first in the market and thus will have very little competition at launch.

Through stakeholders' interviews, the SCH RDT was described as a big value add to improve SCH diagnostics, emphasizing on the need for better performance (compared to microscopy-based methods), ease-of-use and

affordability – all of which are fulfilled by the SCH CAA RDT. However, uptake by national control programs and partners is linked to receiving endorsement by WHO. Through the WHO DTAG, guidance to a clear evaluation pathway to a formal submission to the Expert Review Panel for Diagnostics (ERPD) ([additional information](#)) is under discussion. The ERPD is a new WHO pathway to procurement- aimed at reviewing the risks and benefits associated with procurement and use of IVDs that may have a high public health impact without having pre-qualification nor have yet undergone stringent regulatory assessment. Furthermore, with information available on the cost-effectiveness of implementing the SCH CAA RDT at scale, this will serve as an advocacy tool to drive uptake by in-country programs.

In parallel, deep-dive market studies in Nigeria and Ghana were conducted. Results indicate that updating national guidelines which include the use of the SCH CAA RDT was not necessarily a pre-condition for utilizing the test, however, pilot studies or field evaluations in the country were strongly encouraged. For the SCH CAA RDT to rise in importance among national stakeholders, the priority next steps include raising awareness and building the evidence to support and inform national policy-making and funding decisions for SCH testing to align with the newly launched WHO SCH guidelines.

Some preliminary market sizing models (prior to the new SCH guidelines in February 2022) and estimate forecast needs across 29 countries were also calculated. The best-case scenario of the global need for the next 4 years is 1.5 million tests, with Ethiopia, DRC and Kenya being the top three countries where the demand is the highest. However, accurate and available data is lacking, making these estimates unreliable and likely an underestimation of the need. Through work funded by the Bill and Melinda Gates Foundation, more data is becoming available as we write, which will help to refine the need and potentially increase the market size.

The market is currently in its early stage. However, this new tool represents an urgent market opportunity to contribute to the global efforts to eliminate SCH as a public health problem by 2030.

OBJECTIVE AND SCOPE

FIND invites companies with capacity to manufacture quality-assured IVDs (manufacturing can also be offered in collaboration with an appropriate partner) with a global sales, marketing and distribution network in the IVD market, including a commercial presence in LMICs, to submit a proposal for the commercialization of the new SCH CAA RDT.

The project objectives are designed to enable a partner to commercialize the SCH CAA RDT within a 2-3 year timeframe. The partner would engage to:

- ✓ conduct a technology transfer from FIND's development partners at the end of the product development phase (expected to end by 2024).
- ✓ manufacture the product using their own facilities or in collaboration with an appropriate third party for testing in clinical trials and to scale up to meet market projections while following the necessary quality standards (ISO 13485).
- ✓ complete appropriate performance studies and submissions for registration in selected target markets (for example early adopter countries) as well as for WHO ERPD assessment (expected to end by November 2025).
- ✓ provide product demand creation, commercial sales, marketing, and distribution in select LMIC target markets.

TIMELINE

The product is expected to be available for technology transfer from FIND Development Partner to the selected manufacturer by Q2 2024. The selected manufacturer is expected to complete the following steps: manufacturing processes defined, pilot manufacturing established, and lab verification and validation testing completed by the end of Q4 2024.

SUPPORT PROVIDED

- A **design-locked SCH CAA RDT** ready to be transferred to a manufacturer with access to antibodies under an Agreement with FIND including Global Access terms.
- Access to clinical samples for further development, if needed.
- Funding to support design-lock, transfer to manufacturing and lab verification and validation up to USD 700'000.
- Funding (secured) to conduct clinical trials (estimated enrolled participants of 6000 individuals) of the successfully transferred SCH CAA RDT in Kenya and the Philippines, with partners already identified (the sites will be recipients of the funding). FIND would draft the study protocol as well as work with our in-country partners to secure ethical approval.
- Within the context of the MOU with WHO and other key stakeholders, FIND will advocate with donors to accelerate the deployment and access of the test in the most affected countries, and work closely with WHO to update the testing guidelines for SCH.
- Access to FIND's market assessment for countries where a fast introduction of the SCH CAA RDT would be possible.

ELIGIBILITY CRITERIA

Companies responding to this RFP must meet the following two criteria for their proposals to be considered:

- Have gained WHO Prequalification or other stringent regulatory body (e.g. FDA or CE mark) approval for at least one IVD product,
- Be willing to commit to an affordable selling price for LMICs, together with other access conditions, to be negotiated as part of the commercialization agreement.

Proposals are welcome from organizations with existing in-house capacity for large-scale manufacturing, distribution, and marketing, as well as from consortiums of entities with established relationships offering to jointly undertake the work. In the latter case, proposals shall be submitted by the lead organization which will be the main point of contact and responsible for further negotiations. We also strongly encourage applications from LMICs.

COMMERCIAL PARTNER INVESTMENT

The following typical commercialization investments will be needed from the selected commercial partner to bring the product to market:

- Fully support the investment required to implement and scale up manufacturing operations (including setting up the manufacturing system, if required).
- Run clinical trials and other performance studies to obtain regulatory approval in target markets (target

- markets will be agreed on during contract negotiation process), in addition to WHO ERPD approval.
- Ensure adequate manufacturing capacity to meet demand.
- Commit to a pricing model that is transparent and affordable by providing relevant COGS for lowest sustainable pricing for LMICs (i.e., COGS-based pricing)
- Maintain and manage adequate inventories to meet demand and distribute the product to fulfill orders.
- Provide after-sale support, customer training, complaint management.

SELECTION CONDITIONS

For this RFP, applicants who are part of the final selection are expected to:

- Commit to undertake activities that enable product launch (e.g., local registration, service, and distribution activities) and to supply to the public sector in LMICs (volume and details to be negotiated).
- Commit to a pricing model that is transparent and affordable for 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".

SELECTION PROCESS

The deadline for receipt of submissions is 6th November 2023 by 23h59 CET. The selection process is designed to be objective, independent, and transparent to ensure that the most suitable partner is selected, and potential conflicts of interest avoided. Candidates will be evaluated by an internal review panel comprised of staff at FIND, and by an external review panel comprised of specialists with backgrounds in technical R&D, product launch, and implementation. The review panels will use information submitted in the application (see **Application Requirements** 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" or incomplete will be excluded. Additional grounds for exclusion of an application at this stage are detailed in **Appendix 3**. The list of eligible candidates will advance to Stage 1.
- **Stage 1.** This first evaluation will short list 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 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 Business Assessment (50%), and Alignment Criteria (50%). Short-listed candidates will be selected in a consensus call of reviewers and will advance to Stage 2.

- **Stage 2.** This second evaluation will define the 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.

Note: Applicants not selected will be notified; however, the details regarding non-selection will not be provided for every applicant.

- **Due diligence:** The 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 the conduct of DD to an independent third party, following FIND procedures.

Stage 0	Stage 1	Stage 2
<i>Initial screening of all applicants to a set of long-listed candidates</i>	<i>First evaluation to short-list candidates (up to 10)</i>	<i>Second evaluation to define a list of finalists</i>
<ul style="list-style-type: none"> • Verification that the contents of the application are in-scope. Applicants that are “out of scope” will be excluded. • Verification of applicant eligibility. Applicants that are not eligible will be excluded. 	<ul style="list-style-type: none"> • Evaluation of long-listed candidates will be performed by an internal review panel. • Candidates will be evaluated based on: <ol style="list-style-type: none"> 1. Score on the “Business Assessment” within the Assessment Matrix 2. Applicant Presentation • The internal review panel will score the candidate’s overall alignment with the goals of the RFP (see sheet titled “Alignment Criteria” within the Assessment Matrix). 	<p>Evaluation of the finalists will be evaluated based on:</p> <ol style="list-style-type: none"> 1. Scores on the “Business Assessment” completed in Stage 1. 2. Applicant Presentation 3. Follow-up questions and Live Presentation <ul style="list-style-type: none"> • The review panel will score the candidate’s overall alignment with the goals of the RFP (see sheet titled “Alignment Criteria” within the Assessment Matrix).

SUMMARY OF SELECTION TIMELINE

RFP Issued	11 th September 2023
Deadline for questions	13 th October 2023 by 5 pm CET
Application deadline	6 th November 2023 by 23h59 CET
Notification of short-listed candidates (end of Stage 1)	30 th November 2023 by 5 pm CET
Start of due diligence and contract negotiation	8 th January 2024
Start of project	1 st April 2024

APPLICATION REQUIREMENTS

Applications should include the following:

- **Applicant presentation**
 - Applicants shall provide a slide deck of **no more than 10 slides** and must use the provided PowerPoint template (see **HOW TO APPLY** for templates and forms).
- **Assessment matrix**
 - Applicants are to complete noted sections of the provided spreadsheet titled “Assessment Matrix” (see **HOW TO APPLY** for templates and forms), specifically:
 - Business assessment: Please provide evidence (column C) and supporting information (column D) regarding each of the criteria. Applicant responses are to be supported by/verifiable through corporate documentation and due diligence.
- **Self-declaration**
 - Applicants are to complete the self-declaration form (see Appendix 3)

- **Supporting documents**

- Aside from the two 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.

HOW TO APPLY

Submit applications via the FIND [Technology Scouting Submission Webform](#). Please select '**RFP: Antigen-based RDTs for Schistosomiasis Infection**' as the 'Purpose of submission' and proceed with the online submission. Templates for the Applicant Presentation, Assessment Matrix and self-declaration can be downloaded from the submission portal. Please upload your completed **Applicant Presentation, Assessment Matrix and a completed self-declaration**, along with any supporting documents by **6th November 2023 by 23h59 CET**.

QUESTIONS & FURTHER INFORMATION

Please email questions to ntdteam@finddx.org with the subject line: "SCH RDT manufacturing RFP". Questions will be accepted and responded to expediently up to and including **13 October 2023**. Submitted questions (and corresponding answers) will be publicly available on the [Calls for Partners](#) page.

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 binding agreements containing commercial-level contractual clauses and FIND standard Terms and Conditions to address the requirements of supplying a product for public health particularly in LMICs, as set forth under **Appendix 4**.

COMPLAINTS

Applicants who disagree with any actions or decisions taken in the course of the RFP evaluation may file a complaint in writing to FIND (ntdteam@finddx.org), detailing the grounds for the complaint and making reference to the applicable provisions in the RFP or other 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 within ten (10) working days thereafter.

Appendix 1: Target product profile for a diagnostic test for schistosomiasis to support monitoring and evaluation

Product use summary	Minimum requirements	Ideal requirements	Currently available lab data
Intended use	An <i>in vitro</i> point-of-care test for the detection of analyte specific to <i>Sm</i> or <i>Sh</i> to aid in monitoring and evaluation of SCH control efforts.	An <i>in vitro</i> point-of-care test for the detection of analyte specific to <i>Sm</i> and <i>Sh</i> to aid in monitoring and evaluation of SCH control efforts.	
Target population	School-aged children resident in the defined geographical area and other high-risk groups	Same as minimum	
Target distribution	All countries that are endemic to <i>Sm</i> or <i>Sh</i>	All countries that are endemic to <i>Sm</i> and <i>Sh</i>	
Sample type/collection method	Whole blood from finger stick	Same as minimum	
Sample volume	1-100µl	1-10µl	
Type of analysis	Qualitative	Semi-quantitative	
Detection	High contrast, clear result for naked eye	Provides some indication of infection intensity	
Quality control	Internal process control indicator	-Internal process control indicator. -Stable signal for independent evaluation - Colourimetric or other indicator to identify excessive heat/humidity exposure	
Clinical sensitivity	>60%	>75%	73%-86% for <i>Sm</i> , <i>Sh</i> and <i>Sj</i>
Clinical specificity	>95%	>96.5%	95%-100% for <i>Sm</i> , <i>Sh</i> and <i>Sj</i>
Species detection	<i>S.mansoni</i> and/or <i>S.haematobium</i>	<i>S.mansoni</i> and <i>S.haematobium</i>	
Time to results	<2 h to develop test result	<0.5 h to develop test result	
Required supplies	All reagents and supplies included in test kit, with minimal import restrictions	Same as minimum	
Ease of use	≤ 3 timed steps; ≤ 10 user steps, instructions for use should include diagram of	1 timed steps; ≤ 5 user steps, instructions for use should	

	method and results interpretation	include diagram of method and results interpretation	
Target shelf-life/stability	≥ 18 months, 2-40°C, 75% RH (no cold chain required); temperature excursion/prolonged deviation of 50°C for 2 weeks acceptable	≥ 24 months, 2-40°C, 75% RH (no cold chain required); temperature excursion/prolonged deviation of 50°C for 2 weeks acceptable	
Operating temperature	15-40°C, 75% RH	Same as minimum	
Storage conditions	Ambient storage conditions, 2-40°C; no cold storage required	Same as minimum	
Target price (ex-works)	< US\$ 3	< US\$ 1	
Product lead times	<6 weeks	<4 weeks	

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**.

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 remaining 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.

$$\text{Ex works Price to LMIC markets} = (\text{manufacturing cost}) + (\text{mark-up}) + (\text{royalties, if applicable}) + (\text{distributor mark-up, if applicable})$$

Please note that due to the existence of third-party Intellectual Property rights, for the distribution of the SCH CAA RDT into High-Income Countries, a royalty of up to 2% of the Ex-works Price (Incoterms 2020) will apply.

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 applies.

Applicants/Bidders shall not be selected for 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 judgment or a final administrative decision or subject to financial sanctions by the United Nations, the European Union and/or Switzerland for involvement in a criminal organization, money laundering, terrorist-related offences, 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 Switzerland 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.

Kindly complete the self-declaration form provided in the submission portal (see HOW TO APPLY). To note: "yes" answers to these questions should indicate, preferably with accompanying evidence, what remedial measures have been taken by the entity to resolve the issue in question. FIND will not exclude Applicants where we consider the measures to be sufficient and appropriate, and where Applicant reliability can be clearly demonstrated.

Appendix 4: Related Terms & Conditions for LMIC public sector

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 this agreement.

1. SOME KEY DEFINITIONS

TERM	DEFINITION
“Ex Works” or “EXW”	shall have the meaning as set out under INCOTERMS 2020 and on XYZ COGS;
“Eligible Purchasers”	means all Public Health Sectors in LMICs and other private (ie non-governmental) health care providers not defined under the Public Health Sector but which may have access to preferential access conditions to a Product for use in a public health setting, and as further set out under Global Access Article [●], and as determined on a case-by-case basis by FIND;
“Global Access”	means the principles according to which diagnostic products shall be available, affordable and appropriate for use in Territory, as further set forth in FIND's Global Access Policy available at FIND Policy - Global Access - July 2021 (finddx.org) , 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 IPR may be encompassed in part or in whole under the deliverables and/or Product;
“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)	based on Article [●];
“LMICs” or the “Territory”	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;
“Manufacturing Cost of Goods Sold” or “COGS”	means all the direct costs such as labour, material, and allocated overhead costs in Product <i>production</i> ;

“Manufacturer of Record” <i>(if applicable)</i>	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”	based on Article [●];
“Private Health Sector”	any non-governmental institute which operates on a for-profit basis but 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;
“Public Health Sector”	means (i) any government in the LMICs, 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, UNICEF, Save the Children Fund, and Médecins Sans Frontières, Unitaid, PEPFAR, the Global Fund, FIND or its authorised designee and other funding organizations;
“Technology Transfer” <i>(if applicable)</i>	those activities required to successfully transfer and validate such transfer of required manufacturing processes, procedures, and Know-how, to a Manufacturer of Record;
“Technology Licence” or “Licence” <i>(if applicable)</i>	the licence to use ABC IP and Know-how required to commercialise a Product, and as further set out under the Article [●];
“Target Product Profile” or “TPP”	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 the Article [●] to this Agreement;
“Test Unit”	the specific assay and all required ancillary reagents and other consumables to run a single test on a single human specimen.

2. QUALITY REQUIREMENTS *(if applicable)*

Quality Management Systems (“QMS”). XYZ shall ensure compliance at all times with the following;

- a) Ensure an appropriate QMS covering *in vitro* diagnostic products, is in place and compliant with Stringent Regulatory Authority (SRA) and/or WHO Pre-qualification (“PQ”) requirements; and
- b) 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.

3. ADDITIONAL THIRD PARTIES

General. 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 reviewing the relevant sections of any agreement between XYZ and the Third Party in question, solely to ensure compliance with this Article [●]. For the sake of clarity any activity and/or obligation assigned

to a Third Party under this Article [●] 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

General. Each Party recognizes the requirements in accordance with the Global Access to ensure that any Product arising from the Agreement, will be made accessible and affordable to people living in the LMICs. Both Parties will take all reasonable and diligent actions necessary, within their scope and freedom to operate, that any Product arising from the Agreement will be made available broadly in a manner that meets their respective Global Access requirements, including but not limited to; a) provide access to the Product on an affordable basis, and including required in-country registrations as agreed with FIND, and local service and support. In addition, the Parties subscribe to the concept and implementation of Global Access as set out under the FIND policy at www.finddx.org/policies whereby, subject to the terms and conditions of this Agreement, specified results, 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, resource-limited settings.

Eligible Purchasers and Affordable Price. XYZ agrees to the following:

- a. In particular, with respect to pricing, under the TPP, the Affordable Price shall be determined as an EXW price, currently as a target of US\$ per Test Unit, including sample preparation or results reader (if required);
- b. Affordable Price to be available to Eligible Purchasers looking to supply Product to LMICs, including the Private Sector.
- c. Other Countries. Notwithstanding the above, XYZ shall make its commercial best efforts to ensure a sufficient supply of products to LMICs that are not Priority Countries.

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 Article [●]. In addition, the following countries shall be considered as the "Priority Countries" [●].

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 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

1. Diagnostic target product profiles for monitoring, evaluation and surveillance of schistosomiasis control programmes 2021, WHO website, accessed on 7 February 2023; <https://www.who.int/publications/i/item/9789240031104>
2. GSA Communication piece: commercially available diagnostic tests 2021, GSA website, accessed on 7 February 2023; [Communication piece available diagnostics 09.04.2021 English.pdf \(eliminateschisto.org\)](#)