



**REQUEST FOR PROPOSALS (RFP)**  
**TECHNOLOGY PLATFORM FOR HOSTING CLINICAL DATA**  
**FOR VALIDATING DIGITAL HEALTH PRODUCTS**

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## 1. LIST OF ACRONYMS AND DEFINITIONS

CDA	Confidential Disclosure Agreement
CAD	Computer-aided detection
LMICs	Low- and middle-income countries
RFP	Request for Proposal
TPP	Target product profile
WHO	World Health Organization

## 2. BACKGROUND INFORMATION

FIND, the global alliance for diagnostics, was established in 2003 as a global non-profit organization dedicated to accelerating the development, evaluation, and delivery of high-quality, affordable diagnostic tests for poverty-related diseases, including tuberculosis, malaria, HIV/AIDS, Ebola virus disease, sleeping sickness, hepatitis C, leishmaniasis, Chagas disease, Buruli ulcer, and acute febrile illnesses. FIND functions as a global health product development partnership, engaging in active collaboration with over 150 partners. FIND’s headquarters are in Geneva, Switzerland, with country offices in India, South Africa, Kenya, and Vietnam. More about FIND and our programmes can be found on [www.finddx.org](http://www.finddx.org).

## 3. STATEMENT OF PURPOSE

FIND is seeking to collaborate with an organization to develop a technology platform for the validation of digital diagnostics. The technology platform is expected to host various types of clinical data (images, videos, audio files, etc.) presented in multiple formats including text files, XLS files, other (.wav, .jpg, dicom, etc.). As an early phase of the project, FIND will work with the identified organization to set up a technology platform that allows for database hosting and performance assessment of computer-aided detection (CAD) software (see Appendix I).

This Request for Proposals (RFP) describes the Background, Scope, Objectives, and Deliverables related to the project. This document also provides Instructions to Applicants, Proposal Requirements, a summary of Selection Criteria, and the RFP Schedule.

## 4. SCOPE OF WORK AND DELIVERABLES

The objective of this scope of work is to produce a technology platform that meets the needs described in the **product vision document**, provided in Appendix I. FIND is requesting proposals to establish a partnership with an organization capable of creating and maintaining this technology platform.

The scope of the project includes creating a technology platform which allows upload and use of various types of clinical data and digital diagnostic software. It includes developing and implementing data hosting and security measures, identifying infrastructure requirements, and creating client interfaces for evaluation and analysis.

FIND will be responsible for:

- Defining high-level needs in the product vision document (as per Appendix 1), some revisions may be made early in the project)
- Providing a list of digital diagnostic tools that will need validation and the data types that would be collected for that exercise
- Establishing relationships for ethical and transparent data collection in collaboration with various partners
- Establishing study design and oversight on operations
- Project and partner coordination
- Funding to support human resources and material expenses incurred by the technology platform provider in this project
- Conducting statistical analysis or validation of selected digital diagnostic tools and related reporting

The technical partner will be responsible for:

- Technology platform development, verification, maintenance, and all other activities necessary to meet the project goals and schedule.
- Create the hosting platform and adhering to EU General Data Protection Regulation (GDPR). Ensure data integration, allow FIND's data science team to conduct analysis on the server and integrate data visualization tools/dashboards, as required. Finally, define infrastructural needs, build client interfaces for multiple users, and resolve technical issues during the project.
- Conduct capacity building sessions for FIND internal users and partners, where appropriate, to explain the usage of the developed technology platform.
- Integration of all required tools to the technology platform – data acquisition, annotation, analysis, visualization, etc.
- Develop interfaces that allow multiple users to monitor and visualize (aggregated) information on selected subsets of the data (e.g. by study site, geographical regions, gender, or subpopulation).
- In collaboration with FIND's data science team, develop a standardized validation report for digital health solutions.
- Set up a secure cloud-based hosting environment for the installation of digital diagnostic software like CAD applications, while ensuring that access to this software after installation can be restricted. Also, in collaboration with the product developers, install identified digital health tools on the technology platform in a secure manner.

The minimum deliverables of the project are:

- Technical requirements (Software Requirements Document or similar)
- Early versions of the technological architecture
- Test plans for the platform
- A platform that can hosting multiple data types and clinical information
- Examples of user interfaces and dashboards
- A final report summarizing the work performed, the product, the outcomes, and lessons learned after each digital diagnostic validation exercise

The proposal should describe the applicant's full set of deliverables.

## 5. PERFORMANCE STANDARDS

FIND expects the selected applicant to bring demonstrated expertise in the following:

### Must have –

- Database architecture development and maintenance expertise, including designing a scalable database both for transactional and analytical use cases.
- Technology platform development and maintenance, including cloud hosting.
- Data integration and implementation of interoperable systems.

### Good to have –

- Understanding of different data management and exchange/interoperability standards in healthcare such as HL7, FHIR, etc.
- Understanding data annotation, tools, and requirements for creating datasets for AI.
- Understanding of the requirements for evaluation and validation of AI-based diagnostic tools, from data collection to reporting of the results.

If several entities from a consortium plan to apply to this RFP (for example, a database management company and a cloud space provider), a primary applicant must be identified for the purpose of this application. This primary applicant must have the ability to develop and provide technical support for the technology platform during and after this project.

Organizations that would like help to form a consortium should contact FIND immediately with an explanation of the type or types of partners required. FIND, at its sole discretion, may facilitate introductions with other potential RFP respondents. Once established, any consortium applying to this RFP should submit a single, unified proposal.

FIND also proposes weekly calls to track project progress, define action items, review risks, and identify and address challenges. Additional meetings will be held to review milestones defined after execution of the contract.

## 6. APPLICATION GUIDELINES

This RFP is an invitation for a suitable establishment to submit a proposal for the project described above. Therefore, this RFP must not be construed, interpreted, or relied upon, whether expressly or implicitly, as an offer of acceptance by any person, or as creating any form of contractual, promissory, or other rights.

Please follow the PowerPoint presentation template to provide the required information. Recommended length: Not more than 20 slides (including appendices). Supplementary information can be included as appendices.

In addition, please fill the following information as a part of the proposal.

- **Appendix 1:** Self-assessment against the 'Product vision outline': For each product vision document item, state whether it is "not met", "minimally met" or "optimally met" with an explanation and supporting data.
- **Appendix 2:** Provide relevant information in the 'Organization Assessment Criteria'.

These appendices are in the format of an excel spreadsheet and should be filled and attached with the PowerPoint presentation when submitting the proposal.

Applicants should use the following outline:

- 1. Executive summary**
- 2. Organization**
  - 2.1. Brief history of the organization and key achievements in the context of the project
  - 2.2. Leadership team
  - 2.3. Total number of employees
  - 2.4. Annual financial turnover
- 3. Business & operations**
  - 3.1. Geographic presence
  - 3.2. Outsourced activities relevant to the project
- 4. Technology & product**
  - 4.1. Describe how the technology platform will be developed with a user-oriented approach
- 5. Project**
  - 5.1. Proposed approaches for key project issues, including:
    - 5.1.1. Ensuring database uptime and performance
    - 5.1.2. FIND users should be able to conduct data cleaning and analysis in a functional intuitive manner while restricting access based on user function. Creating user profiles and access restrictions as provided by the FIND team.
    - 5.1.3. Training all users on the technology platform usage – How to: login; upload data; access, analyse, and download data; understand secure flow of data, and how the technology platform functions in general. In addition, there should be a provision of a user-manual for guidance/ an access to user support when indicated.
    - 5.1.4. Providing a good user experience and delivering timely, useful insights on which tools need to be integrated for data cleaning, analysis, annotation, and verification.
    - 5.1.5. Any other items considered significant or challenging
  - 5.2. Workplan and timeline
  - 5.3. Deliverables
  - 5.4. Budget
  - 5.5. Risks
  - 5.6. List of key personnel planned to be involved in the project and their expertise

A budget should be submitted as part of the proposal. The final contract will provide additional details on the financial terms. Proposals and any other correspondence are to be sent in English by e-mail to [DHvalidation@finddx.org](mailto:DHvalidation@finddx.org).

## **7. AWARD CONDITIONS (EXCLUSION CRITERIA)**

Applicants/Bidders that are selected for final awards are required to:

- Be legally permitted to perform work in the country where the contract will be performed.
- 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**).

## 8. HOW TO APPLY

Submit applications via the FIND Technology Scouting Submission Webform. Please, select '**Outbreak**' as the 'Disease Area' and '[RFP: technology platform for hosting clinical data for validating digital health products](#)' 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 **24 January 2022**. Any correspondences are to be sent in English by e-mail to [DHvalidation@finddx.org](mailto:DHvalidation@finddx.org).

## 9. EVALUATION AND AWARD PROCESS

Proposals will be assessed, and partners selected, through a systematic process, which is described in detail in the KfW Procurement guide. A first pass evaluation of all applications will be performed for an assessment of scope of work and clarification of essential technical and partner-specific details. Those applications deemed suitable for a potential collaboration will then undergo an in-depth second pass evaluation that grades the potential partner organization (Appendix II of this document) and capacity to achieve the current product vision outlined in Appendix I of this document. A framework for these scoring criteria is outlined in pages 14-16 of the [Technology and Partner Selection Guidelines](#). Applicants will be notified of FIND's decision after the final partner selection. Details of FIND approach to engagement with private sector partners is outlined in our [Policy & Guidelines for Working with Private Sector Partners](#). A particular focus will be put on the following during the partner selection process:

- Technology and product:
  - Current capability with respect to the product vision document's criteria listed in **Appendix 1**
  - Future likelihood of meeting product vision documents optimal criteria
  - Approach to addressing key project issues listed in 'Section 5.1' in the application guidelines
- Partnership opportunity:
  - Organizational assessment listed in **Appendix 2**
  - Cost of the project

## 10. 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**.

## 11. TERMS OF CONTRACT

The scope of this project is until **31 December 2022** with a potential for extension.

## 12. CONFIDENTIALITY

FIND considers any proposal received under the RFP as confidential. If required, FIND can sign a CDA with interested Applicants/Bidders prior to proposal submission. FIND will not disclose the proposal to third parties without the prior written agreement of the proposal submitter. Review of proposals will be carried out by an internal FIND

team as well as a team of external experts (which may or may not include members of FIND’s independent Scientific Advisory Committee), all of whom are under confidentiality and are 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.

### 13. TIMELINES

The solution should be fully developed and implemented by Q2 or Q3 2022.

Activity	Dates	RFP week number
RFP issued	6 Dec 2021	0
Deadline for email notification regarding intention to respond to RFP and for any requests for FIND to facilitate introductions to form a consortium	20 Dec 2021	2
Deadline for any questions to be submitted to FIND (responses will be sent to all registered applicants)	10 Jan 2022	5
<b>Deadline for submission of proposals</b> [18h00 Geneva time]	24Jan 2022	<b>8</b>
Proposal reviews and discussions with applicants	24 Jan – 7 Feb 2022	8–10
Notification of decision	7 Feb 2022	10

### 14. QUESTIONS AND COMMUNICATIONS PROTOCOL

Please email any questions in English by e-mail to [DHvalidation@finddx.org](mailto:DHvalidation@finddx.org). Questions will be accepted and responded to expediently until **10 January 2022**.

## 15. APPENDICES

### APPENDIX 1: PRODUCT VISION DOCUMENT

### APPENDIX 2: ORGANIZATIONAL ASSESSMENT CRITERIA

### 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 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 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 DoJ, 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

Technology platform for hosting clinical data for validating digital health products (the "**Contract**")

1. We recognize and accept that KfW only finances projects of 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 Venture<sup>1</sup> 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 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;
  - 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/debar> 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).
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 Organization<sup>2</sup> (ILO) and 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 of <sup>3</sup>: \_\_\_\_\_

Signature:

Dated:

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<sup>1</sup> 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.

<sup>2</sup> In 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.

<sup>3</sup> 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 AND RELATED TERMS AND CONDITIONS FOR THE PUBLIC SECTOR IN 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 (“XYZ” and FIND) to each agreement denoted by [●].*

### 1. SOME KEY DEFINITIONS

<b>Manufacturing Cost of Goods Sold (COGS)</b>	All direct costs such as labour, material, and allocated overhead costs in Product production;
<b>COVID-19</b>	Coronavirus disease caused by SARS-CoV-2, declared as a Public Health Emergency of International Concern by WHO on 30 January 2020;
<b>Ex Works (EXW)</b>	Defined under INCOTERMS 2020 and based on COGS;
<b>Eligible purchasers</b>	All public health sectors (PHS) in LMICs and other private (i.e. non-governmental) healthcare providers not defined under PHS, 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 the Global Access Article [●], and as determined on a case-by-case basis by FIND;
<b>Global access</b>	Meaning set forth under the Article [●].
<b>Intellectual property (IP)</b>	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;
<b>Know-how</b>	All technical and other information which is not in the public domain (other than a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications, and techniques, laboratory records, relating to but not including Foreground Intellectual Property or Intellectual Property, as previously defined in this Agreement;

<b>Licence Agreement (Licence)</b>	The licence, as further set forth under the Article [●];
<b>LMICs (Territory)</b>	Those countries defined by the World Bank as having “low-income economies”, “lower middle-income economies” or “upper middle-income economies”, and may be amended from time to time;
<b>Manufacturer of Record</b>	The named legal entity legally responsible for placing a Product on the market as recognized by the appropriate in country regulatory authority. For the purposes of this Agreement the Manufacturer of Record shall be the Third Party which is the recipient of the Technology Transfer.
<b>Priority countries</b>	Meaning set forth under the Article [●];
<b>Product</b>	The Technology Platform and the materials provided with the Product as explicitly listed in the associated instructions for use, and all subsequent versions, and subsequent assays to be mutually agreed and documented as an amendment to this Agreement;
<b>Private Health Sector</b>	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;
<b>Public Health Sector (PHS)</b>	(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;
<b>Stringent Regulatory Authority (SRA)</b>	Defined by WHO here: <a href="https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs">https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs</a> , and may be updated from time to time;
<b>Technology transfer</b>	Those activities required to successfully transfer and validate such transfer of required manufacturing processes, procedures, and Know-how, to a Manufacturer of Record;
<b>Technology Licence (Licence)</b>	The licence to use ABC IP and Know-how required to commercialize a Product, and as further set out under the Article [●];

<b>Target Product Profile (TPP)</b>	The 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 the Article to this Agreement;
<b>Test Unit</b>	The specific assay and all required ancillary reagents and other consumables to run a single test on a single human specimen.

## 2. QUALITY REQUIREMENTS

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 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 providing access to the Product on an affordable basis, including the required in-country registrations as agreed with FIND, and to 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](http://www.finddx.org/policies) whereby, subject to the terms and conditions of this Agreement, specified 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 centres 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, which may include consumables used for sample preparation or instrument (if required);
- b. Affordable Price to be available to Eligible Purchasers looking to supply Product to LMICs
- c. Other Countries. Notwithstanding the above, XYZ shall make its commercial best efforts to ensure sufficient supply of products to LMICs which are not Priority Countries.

Priority Countries and Volume Commitments. 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” [●].

Technology Licence Agreement – in the case of a Technology Transfer, if applicable

XYZ shall enter into a Technology Licence 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-sublicensable (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.

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.