FIND	**GL 03-06-01** **TECHNOLOGY AND PARTNER SELECTION GUIDE**	
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1. PURPOSE

FIND works with partners to:

i) Catalyse development of essential *in vitro* diagnostic (IVD) products for diseases prevalent in low- and middle-income countries (LMICs);
ii) Guide the use of these products and the policies for their uptake; and
iii) Accelerate access to diagnostic technologies that meet defined and agreed-upon needs.

In the field of infectious diseases, neglected tropical diseases, and other diseases of poverty, new diagnostic technology platforms are needed to accurately identify these infections. As new technologies are constantly emerging from research laboratories, a clear process is required to select those tools that meet pre-defined specifications, and that have demonstrable potential to make an impact on global health outcomes.

Most new IVD products are developed by for-profit manufacturing companies, often with support from academic or other groups that conduct research and development (R&D) activities. As such, FIND works directly with the for-profit sector to serve the needs of patients in the non-profit and public sectors in LMICs. This, in turn, requires that FIND adopt an objective, transparent approach to technology and partner selection to ensure that the most suitable technologies are supported, that potential conflicts of interest are avoided, that the partner is able to meet Global Access requirements, and that the global community understands and has access to the selection process and its outputs.

In our Private Sector Partners Policy, which is published online[1], we have outlined our philosophy and approach to selecting technologies and industry partners with whom we work based on each of FIND's four strategic pillars. **The purpose of this guideline document is to describe the processes that FIND staff and consultants shall follow in selecting technologies and partners to ensure that practices and decision-making are objective, transparent, and appropriately documented.**

2. SCOPE

FIND works with many different types of partners, and the criteria for their selection and the processes by which they are selected vary depending on the nature of the relationship. The processes described in this document are to be applied for the selection of new technologies and of potential partners who have products on the market or under development that are of interest to FIND (collectively, the "Partnership Opportunities"). **This document is specifically intended to be used at all points at which decisions need to be made regarding a Partnership Opportunity that is being supported by (a) a for-profit IVD company, (b) and academic group, and/or (c) any other group that is actively involved in R&D work, and which could lead to a commercial product or service.**

2.1 Decision points

The process for partner and technology selection described here will be applied at four specific decision points:

2.1.1 when FIND initiates a Project that involves material support for product development;
2.1.2 when FIND enters into a strategic alliance with a manufacturer of *in vitro* diagnostic products, with the intention to explore product-focused collaborations;
2.1.3 when a product enters into independent clinical validation studies as part of a FIND Project; and
2.1.4 when FIND initiates a Project that involves implementation support for a commercial product.

[1] Private Sector Partners Policy

2.2 Out of scope

The process for partner and technology selection described here does not apply to the selection of:

2.2.1 Suppliers, either of goods or services
2.2.2 Clinical trial sites
2.2.3 Implementing partners

3. RESPONSIBILITIES AND GOVERNANCE

All FIND staff and consultants will be expected to follow the processes described herein. Overall responsibility lies with the FIND senior management team, while the technology team will coordinate the overall technology and partner selection process.

A dossier will be created for each Partnership Opportunity, and one member of the technology team will be designated Owner of the dossier; responsibility for the dossier remains with the Owner until the dossier has been closed or has transitioned to a FIND disease portfolio project.

Disease programme heads have an essential role in the tiered decision-making process and are responsible for providing target product profiles (TPPs) which describe the set of target product specifications that guide diagnostic solution searches and Partnership Opportunity assessments. Furthermore, product requirement documents (PRDs) are used to guide the search for disease cross-cutting technology solutions. PRDs are developed by the technology team in collaboration with the disease programme heads.

Technology and partner selection is linked to FIND's Scientific Advisory Committee (SAC) in instances where candidates for engagement have been identified within the Partnership Opportunities, and for which the implications of such an engagement (e.g. financial, strategic, resource commitment, risk) is considered significant and meets the thresholds defined in this document for review and recommendation by the SAC.

4. TECHNOLOGY AND PARTNER SELECTION PROCESS

FIND's Technology and Partner Selection Process[2] is depicted in Figure 1.

There are two possible entry points, one passive and one active. Through either pathway, the FIND technology team will execute an *initial analysis* (referred to interchangeably as a "1st Pass Analysis"), as detailed below. The technologies, products, or companies involved in certain Partnership Opportunities will merit an *in-depth analysis* (or "2nd Pass Analysis"), as further detailed below. The outcomes of either level of analysis may be used to drive decision-making on technologies and choice of partners which, once made, feed into FIND's project management process (see Figure 1 and Figure 2).

The selection process is supported by a custom web-based tool and database, both of which are accessible through the FIND website[2]. Archiving of all assessments and support documentation is done in the Salesforce® database.

4.1 Passive Input

External parties, as well as any FIND staff or consultants, who identify promising Partnership Opportunities, can submit information on the technology of interest using an on-line "Webform"[3]. This is the external portal to the database. The Webform is self-explanatory, user-friendly (it includes examples), and is designed to capture the information needed for the initial analysis. FIND provides TPP/PRD-based submission templates on its website for the passive input pathway.

4.2 Active Input

The active pathway is the usual process resulting from one of FIND's own targeted, strategy-driven analyses, such as a technology landscape assessment and/or request for proposal (RFP). To trigger the active input pathway, FIND staff will be expected to follow the Landscape Development Guidelines provided in Appendix 1 and/or the RFP development guide. Potential technologies that enter the Partner and Technology Selection process through the active input pathway will more than likely have been "pre-screened" during the landscape analysis, using the same standardized criteria as in the passive input

[2] Technology Review & Support https://www.finddx.org/technology-review/
[3] Technology Scouting Submission Webform: https://www.finddx.org/technology-review/webform/

pathway. As a result, information on a targeted set of candidate partner organizations is entered into the database.

4.3 Initial Analysis (1st Pass Analysis)

Each 1st Pass Analysis will evaluate the Partnership Opportunity on the following set of criteria, as compared against the appropriate WHO-endorsed target product profile (TPP) or, where TPPs are not yet available, a Product Requirements Document (PRD):

- Cost
- Analytical and system performance (actual or projected)
- Usability
- Fit with FIND strategy
- Probability of success

This last criterion encompasses a broad assessment of the various nonperformance-related factors that would impact on operational delivery and uptake of a product/technology, including a potential partner's organizational strengths and weaknesses (see Appendix 2).

The 1st Pass Analysis is carried out by at least two members of the FIND technology team, using a standardized template. RFP submissions are further assessed by external reviewers. Selection of reviewers will be done on the basis of the following criteria as relevant:

1. Expertise in disease area
2. Expertise in technology platform
3. Expertise in IVD product development (regulatory, quality, manufacturing)
4. Experience in assessing IVD companies
5. Expertise in IVD for LMICs
6. No declared conflict of interest

The output of the 1st Pass Analysis is reviewed and approved by the relevant disease programme head.

As a result of the Initial Analysis, the Partnership Opportunity is classified as:

- Out of scope (rejected);
- In need of more information from applicant/partner organization;
- In need of further technical analysis, with possible access to basic FIND support resources (such as provision of specimens; S4S programme support; rapid feasibility study) before re- evaluation;
- Suitable for a potential collaboration, and cleared to proceed to 2nd Pass Analysis.

In the latter case, a Project Concept document is prepared for review by the disease programme head as one of two gates to the 2nd Pass Analysis. The Project Concept includes the information gathered from the Initial Analysis, as well as an estimate of overall funding requirements and timelines for full development and delivery of the proposed project.

The decision to move from 1st Pass to 2nd Pass Analysis is made by the disease programme head, based on approval of the project concept, and on whether the criteria for 2nd Pass Analysis are met (see 4.4 below). Input from FIND's Senior Management Team is taken into account where appropriate, particularly if there are cross-functional or cross-disease impacts to the Partnership Opportunity.

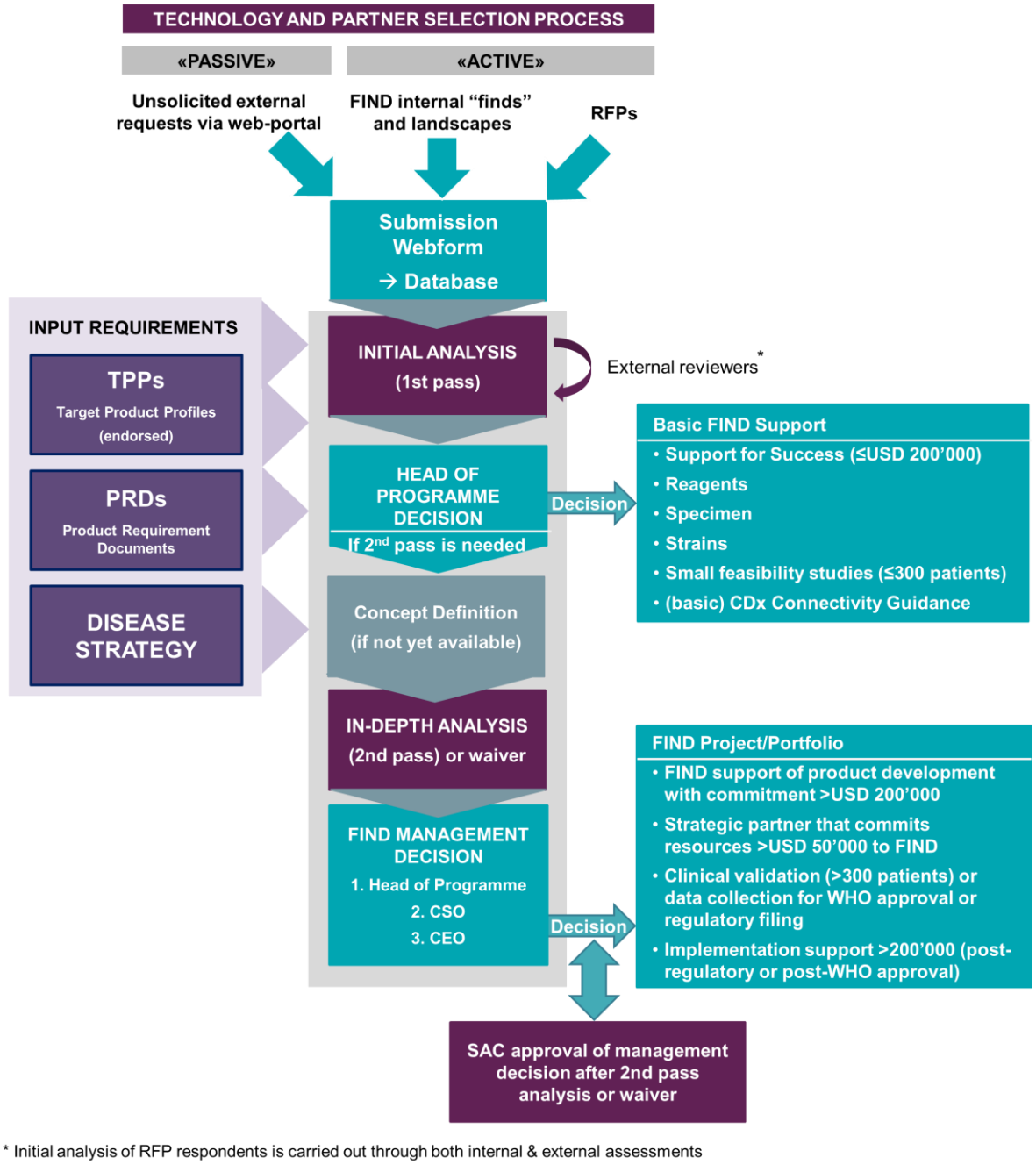

Figure 1: FIND technology and partner selection process

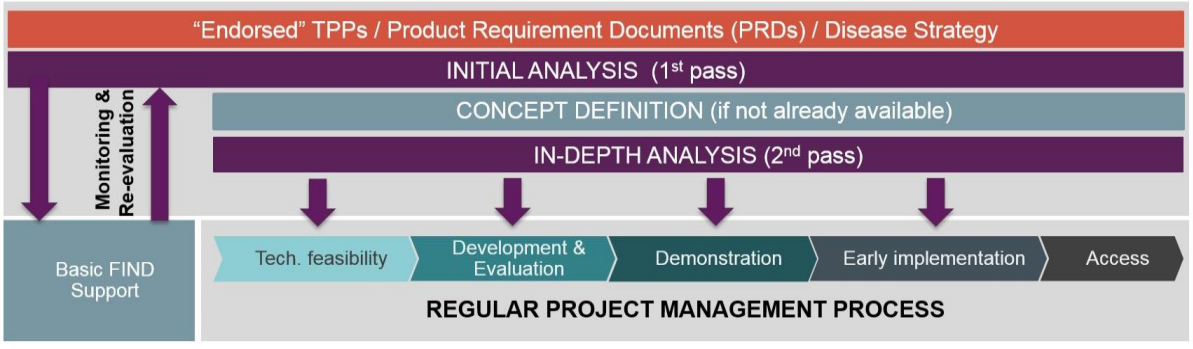

Figure 2: Linking technology and partner selection with the FIND project portfolio

4.4 In-depth analysis (2nd Pass Analysis)

The purpose of the 2nd Pass Analysis is to assess comprehensively the strength of the Partnership Opportunity where a technology or product is of interest to FIND in order to provide the information needed to construct a solid business case and to support a specific project.

4.4.1 Criteria for 2nd Pass Analysis

A 2nd Pass Analysis is mandatory for the following cases:

- FIND support of product development requiring a commitment of >USD 200'000, in cash or in- kind (i.e., for products that are pre-regulatory approval)
- A strategic partnership that commits resources to FIND of >USD 50'000, in cash or in-kind
- An independent clinical validation study of a prototype or product that involves >300 patients
- A project that includes data collection for WHO Pre-Qualification, for a WHO policy recommendation, or for submission of a technical file to a recognized regulatory authority
- FIND support of an implementation Project requiring a commitment of >USD 200'000 (i.e., for products that are post-regulatory or post-WHO approval)

The above criteria will trigger an automatic 2nd Pass Analysis.

In the absence of the above criteria, a disease programme head can request that a 2nd Pass Analysis be executed.

4.4.2 Scope of 2nd Pass Analysis

Depending on the level of the planned collaboration and the extent/quality of the available data and information, the 2nd Pass Analysis will include (see template in Appendix 3):

- Updated technology status and performance data (if available)
- A detailed assessment of the product or technology concept, including basic market and competitive analysis
- A detailed risk assessment
- A partner due diligence (financial, management team, track record)
- An assessment of the level of partner commitment to Global Access principles
- A detailed assessment of fit with FIND's portfolio and strategy

As a result of the 2nd Pass Analysis, the Partnership Opportunity may lead to an approved Project within the FIND portfolio. This final approval process includes the following steps:

- Review and approval of the 2nd Pass Analysis by the disease programme head.
- Review and approval of the 2nd Pass Analysis by at least one member of the FIND Senior Management Team.

Review and recommendation of the 2nd Pass Analysis by two members of the SAC with the involvement of the Chair of the SAC. SAC members will be selected as reviewers by the disease programme head based on relevant expertise (disease, clinical, technological, market, lab and health system, product and business development, regulatory, etc.) and confirmed by the SAC chair. During this SAC review, the two selected SAC members can:

(i) Recommend approval of the 2nd Pass Analysis;
(ii) Request the involvement of other SAC members or the whole SAC;
(iii) Request further information and analysis;
(iv) Request an extended discussion with the FIND team;
(v) Reject the 2nd Pass Analysis; or
(vi) Decline to review the 2nd Pass Analysis in the event that: a) they cannot provide a review within 10 business days, or b) have conflicting interests.

The relevant Owner on the FIND technology team will request review of and a recommendation on the 2nd Pass Analysis from respective SAC members via e-mail, and capture responses in the database. 2nd Pass Analysis reports may also be reviewed during formal SAC meetings.

4.4.3 Waiver of full 2nd Pass Analysis

In select circumstances, the full 2nd Pass Analysis can be waived, if the following criteria are met:

- For partners for whom FIND has done a 2nd Pass Analysis in the previous 5 years, the FIND technology team has the option of conducting an abbreviated analysis, limited to

- an assessment of the Partnership Opportunity's strategic fit within the FIND portfolio
- a risk assessment

These assessments will be provided to two members of the SAC and the Chair of the SAC, along with the original 2nd Pass Analysis. During this SAC review, the two selected SAC members can:

(i) Recommend approval the abbreviated 2nd Pass Analysis;
(ii) Request a full 2nd Pass Analysis; or
(iii) Decline to review the 2nd Pass Analysis in the event that: a) they cannot provide a review within 10 business days, or b) there is a conflict interest.

The appropriate Owner on the FIND technology team will request a review of and recommendation on the 2nd Pass Analysis from respective SAC members via e-mail, and identify the 2nd Pass Analysis waiver in the executive summary.

4.5 Conflict of interest

Any and all potential conflicts of interest (COIs)—of reviewers and SAC members—are to be declared via FIND's COI and Confidentiality Agreement for each review separately. Reviewers are recused in instances where a possibility of conflict has been identified.

5. Definitions

1st Pass Analysis/Initial Analysis	An analysis of the cost, performance, usability, and fit with the FIND strategy of a diagnostic technology—as well as the probability of success—as measured against a TPP or PRD.
2nd Pass Analysis/In-depth Analysis	A comprehensive analysis of the technology concept, all available performance data, market, competitive technologies, risk, fit with the FIND strategy, and partner due diligence.
Clinical validation studies	Independent evaluations of prototype or product performance in a target population of use, measured against the performance of at least one reference method, with statistically valid data appropriate for inclusion in an IVD product technical file.
Disease programme head	A staff member responsible for one of FIND's designated disease programmes.
Dossier	A file created for each Partnership Opportunity that contains basic information on the opportunity as well as the 1st Pass Analysis and 2nd Pass Analysis, as warranted. Currently, d ossiers are maintained in a custom Salesforce database.
Owner	A member of the technology team with assigned responsibility for a specific Partnership Opportunity.
Landscape development guidelines	Procedures for FIND staff members performing an evaluation of a new concept, technology, or identified product need.
Partnership Opportunity	An opportunity to partner on a future project. Projects can included development, validation, commercialization, or implementation of a diagnostic technology, product, or service offering.
Product requirements document	A detailed set of technical specifications for an *in vitro* diagnostics product.
Project	A discrete endeavour focused on IVD product development, validation or implementation and undertaken toward a defined endpoint. Projects have a defined scope, budget, resource allocation and set of deliverables, and are linked to a TPP or approved product.
Scientific Advisory Committee	A group of scientific and technical experts chartered at FIND to

	provide advice to the FIND Board of Directors on technology and disease portfolio options, to assist FIND in strategy development, and to review scientific management process of FIND Projects.
Senior management team	FIND staff with organizational responsibility for policies and procedures, comprised of at a minimum the Chief Executive Officer, Chief Access Officer, Chief Medical Officer, Head of Finance, Head of Operations, and any additional staff members so designated.
Target product profile	A set of target product specifications that guide product developers in meeting diagnostic solution needs.
Technology team	The team comprised of FIND staff members with expertise in diagnostic technologies and their assessment, and empowered to manage the Partner and Technology Selection process.

APPENDIX 1: LANDSCAPE DEVELOPMENT GUIDELINES

Technology and partner landscapes may be performed as part of strategy-driven analyses to identify platforms with the highest potential of meeting TPPs, and to identify partners with the highest probability of success. The same assessment criteria apply as for the 1st Pass Analysis.

Landscapes will be initiated by the head of programme on an as need basis, and will be performed by the technology team, in close collaboration with FIND disease teams.

A typical landscape includes the following steps:

1. Define the scope of the landscape and any relevant TPPs and/or PRDs.
2. Define the assessment criteria (typically 20-30) based on the TPP and/or PRD - refer to the standardised criteria that are used for the 1st Pass Analysis of the passive input pathway.
3. Long list: Comprehensive search of technologies (an initial list of candidates (~30) with some information on these platforms that is already available.)
4. Short list: Define and apply 1 to 3 exclusion criteria to come up with a short list of candidates (e.g. approximately 5 to 10).
5. Perform a detailed assessment including all criteria from 2 for the entities on the short list. Use publicly available information (e.g. internet search, publications, and patents), information from the FIND technology database, and direct contact with listed organizations to obtain all relevant information.
6. Lead candidates: Identify 2 to 5 lead candidates (if possible; there may be fewer).
7. Initiate business discussions with the most promising partner candidates to explore a potential collaboration and to understand a partner's interest.
8. Summarize the landscape in a written report, and the detailed assessment from 5. in a spreadsheet
9. Summarize the landscape in a PowerPoint presentation.
10. Log the short list (e.g. 5-10) candidates in the FIND technology database.

APPENDIX 2: INITIAL ANALYSIS (1ST PASS) CRITERIA

First Pass Analysis criteria. “Affordability”, “Usability” and “Performance” are usually defined in the PRD/TPP. “Probability of Success” includes factors that impact on operational delivery and uptake of a product/technology.

CRITERIA	DESCRIPTION	RATING (1: not met/low | 2: promising/middle | 3: met/high)
Affordability		
Cost per test	Cost per test (ex-works)	Based on TPP/PRD: 1: not met | 2: promising | 3: met
Instrument cost	Cost of instrumentation required (if any); including accessories that may be required (ex-works)	Based on TPP/PRD: 1: not met | 2: promising | 3: met (irrelevant for tests that don’t required an instrument)
Usability		
System integration	To what degree is the system one unit for full sample to result?	Based on TPP/PRD: 1: not met | 2: promising | 3: met
Infrastructural requirements	What additional requirements are placed upon the laboratory or site in order to obtain a result for the sample (e.g. Biosafety Cabinet, power supply, etc.)?	Based on TPP/PRD: 1: not met | 2: promising | 3: met
Environmental stability	Stability in relationship to environmental factors; temperature, humidity, handling and storage conditions	Based on TPP/PRD: 1: not met | 2: promising | 3: met
Ease of use (targeted end user)	Based on a combination of the complexity of the solution versus the level within the healthcare system where the solution needs to reside	Based on TPP/PRD: 1: not met | 2: promising | 3: met
Performance		
Analytical Sensitivity	Represents the smallest amount of analyte in the sample that can accurately be measured by an assay (Limit of Detection)	Based on TPP/PRD: 1: not met | 2: promising | 3: met
Analytical Specificity	Refers to the ability of an assay to measure one particular analyte (organism or substance), rather than others, in a sample. An assay's analytical sensitivity and analytical specificity are distinct from that assay's clinical diagnostic sensitivity and diagnostic specificity.	Based on TPP/PRD: 1: not met | 2: promising | 3: met
Clinical Diagnostic Sensitivity	The frequency of positive test results of a diagnostic in patients with the disease (true positive rate)	Based on TPP/PRD: 1: not met | 2: promising | 3: met
Clinical Diagnostic Specificity	The probability that, given the absence of disease, the test will exclude the disease (1-false positive rate)	Based on TPP/PRD: 1: not met | 2: promising | 3: met
Throughput	Maximum number of samples that can be processed in a given timeframe (usually per 6 hours working day)	Based on TPP/PRD: 1: not met | 2: promising | 3: met
Time-to-result	The time required from acceptance of the first sample to first result being	Based on TPP/PRD:

	generated	1: not met | 2: promising | 3: met
Hands-on-time	Cumulated total amount of time required for manual manipulation or interventions (e.g. pipetting, key strokes, etc.) per sample, hour, or workday	Based on TPP/PRD: 1: not met | 2: promising | 3: met
Probability for Success		
Strength of data	Based on submitted or publicly available data and data exchanged under a non-disclosure agreement	1: (low) no data available 2: (middle) data obtained, questions answered but data short for specific analyte of interest 3: (high) strong data for the relevant analyte
Strength of team	Based on the experience of the management team as well as key positions within R&D, manufacturing, product realization, quality	1: (low) team has no experience and no track record
		2: (middle) adequately experienced, complementary team but limited track record for this specific company 3: (high) highly experienced, complementary team with track record in IVD development
Product development capabilities	Current capacity for product development, in-house expertise of experts in relevant fields and track-record	1: (low) no capacity or capabilities 2: (middle) capacity and experience in all relevant development fields, including written operating procedures and phase-gate milestone review process 3: (high) Highly experienced product development in all relevant fields that resulted in marketable products, written operating procedures and phase gate milestone review process
Distribution capacity	Based on the current system for distribution and the extent of current capabilities	1: (low) no capacity or capabilities 2: (middle) distribution channels exist in the three most relevant markets 3: (high) distribution channels exist in all countries of interest Not relevant: this criteria may not be relevant for all proposals
Manufacturing expertise/capacities	Current capacity of manufacturing lines, infrastructure for expansion; how close is the proposed solution to current commercialized products	1: (low) no capacity or capabilities 2: (middle) capacity and experience but would have to expand production capabilities to meet projections beyond the study phase 3: (high) capacity to meet needs for the next projected 3 years for the product target Not relevant: this criteria may not be relevant for all proposals
Quality and regulatory strength	Certifications, extent of quality systems and experience in regulatory requirements	1: (low) no quality system or regulatory experience 2: (middle) quality system in place with documented evidence of utilization, audits by competent authorities (CE marking) 3: (high) full FDA compliant Quality System Regulation (QSR) with FDA audit experience and experience in product registration worldwide (e.g. BRICS)

		Not relevant: this criteria may not be relevant for all proposals
Technology readiness and time to market	Technology maturity and length of time it takes until the product is available.	1: (low) time to market >5 years, early concept phase 2: (middle) time to market 3-5 years, proof-of-concept done and validated and initial clinical studies 3: (high) time to market for the target product < 3 years, clinical studies with the target product
Strategic fit		
Fit with FINDs strategy	How well does the proposed activity, product or service coincide with FIND's strategy/priorities?	1: no fit 2: neutral 3: fit
Strategic aspects	Additional considerations (availability of FIND funding/resources, important strategic/political partner, relevance for resources mobilization)	1: mostly negative aspects 2: neutral 3: mostly positive aspects

Note: For RFPs, criteria can be modified (removed or added) to fit a specific need. A weighting factor for each criteria may also be added

APPENDIX 3: IN-DEPTH ANALYISIS (2ND PASS) TEMPLATE

FIND TECHNOLOGY AND PARTNER SELECTION: 2nd Pass In-depth Analysis
Summary and Recommendation for FIND management and SAC

Company or Institution

Company or Inst. Name:	**<Please complete form>**
Lead Contact:	
Title of the collaboration:	

Results summary of the due diligence and recommendation to the management board

Executive summary of the Concept Definition	
Proposed collaboration:	☐ 1: Clinical trial (describe size of the trial and details below) ☐ 2: S4S; (specify level of support and nature of support below) ☐ 3: Investment to support product development (describe amount and detail below) ☐ 4: Strategic partnership: (describe details below) ☐ 5: Early Implementation: (describe details below) ☐ 6: Access: (describe details below) ☐ 7: Other (describe details below)
Details of proposed collaborations	
Value of collaboration in US$	
Funding source:	**<Project Number and Grant>**
Lead Reviewer:	
Recommendation:	☐ Pass ☐ Reject ☐ Conditional (please specific conditions in executive summary)
Partner classification:	☐ 1: Pre-Company ☐ 2: Seed company or institution ☐ 3: Early SME ☐ 4: Mature SME ☐ 5: Small-cap ☐ 6: Large-cap
Executive Summary of results, conclusions of the assessment and recommendation	
Associated risks	

Risk	***Likelihood***	***Impact***	***Mitigation***
<Please copy key risks and mitigation strategy from the checklist below>			

	 *very low* | *low* | *middle* | *high* | *very high*

Approval

This analysis was approved by the

1. Head of programme
2. CSO
3. CEO

prior to SAC review. Approvals are captured electronically in FIND's technology database.

FIND TECHNOLOGY AND PARTNER SELECTION:
2nd Pass In-depth Analysis CHECKLIST for FIND internal use

Strategic fit and technical analysis

Area of review	Question	Score (upper row) and Answer / Comments /Source /Reference				Risk/Weaknesses Likelihood and Impact for every risk	Mitigation
Alignment with FIND strategy and priorities	How well does the proposed activity, product or service coincide with FIND's strategy/priorities?	☐ 1: No fit	☐ 2: Fits, but the partners' key priorities are different from those of FIND	☐ 3: Excellent fit	☐ Not relevant (explain)	<Please describe risks and weaknesses, i.e. for low scores ≤2>	<Please describe mitigation strategy for the identified risks>
		<Please add comments for each Area of review>					
Initial First Pass Analysis & Appropriateness	What was the resulting score from the initial first pass analysis (summarize comments from first pass, fit to TPP & likelihood of target population needs in terms of Global Access, being met). Do first pass analysis if not available	☐ 0...1.5 Not met	☐ 1.5...2.5 promising	☐ 2.5...3.0 Mostly met	☐ Not relevant (explain)		
FIND project/ Fundability	Is the collaboration related to a FIND project or already funded activity?	☐ 1: No funds available	☐ 2: Partnership in grant application planned, and/or initial funding available	☐ 3: Planned activity is fully funded	☐ Not relevant (explain)		
Added value	Does the proposed activity, product or service advance the field and help FIND achieving its strategic goals?	☐ 1: No relevant advance-ment expected	☐ 2: The planned activity will lead to some innovation	☐ 3: Transforma-tional, will likely result in innovative products or services	☐ Not relevant (explain)		

Relative merits	How does it compare to other Partnership Opportunities?	☐ 1: There is a better partner /activity in the pipeline that adds more value for the investment	☐ 2: This partnership is comparable to others in terms of expected outcome	☐ 3: Unique partnership. It would be hard to find a similar partner	☐ Not relevant (explain)		
Global Access Requirements - Availability	Did the partner present a plan that shows that the product will be brought to LMIC markets? This includes supply and service as needed.	☐ 1: No plan and no commitment to make the product available in LMIC	☐ 2: Committed but no or basic plan	☐ 3: Full commitment and plan in place	☐ Not relevant (explain)		
Global Access Requirements – Affordable COGS	Did the partner present a COGS analysis? Example: COGS (indicating labour, fix cost, material, etc.) vs. volume. Is the partner committed to minimizing cost to maximize affordability? See checklist in Key Financials.	☐ 1: No plan and no commitment to make the product affordable in LMIC	☐ 2: Committed but no or only basic COGS understanding	☐ 3: Full commitment and plan in place	☐ Not relevant (explain)		
Global Access Requirements - Affordable IP, Royalties, and Freedom to operate	Is the partner managing intellectual property (patents, copyrights, trademarks, trade secrets and data rights) sufficiently to ensure freedom to operate and to minimize royalty burden?	☐ 1: No IP management and freedom to operate is unclear leading to major risks	☐ 2: Freedom to operate but only basic IP management	☐ 3: Comprehensive understanding of Global Access, solid IP management, full freedom to operate and minimal royalties	☐ Not relevant (explain)		
Other strategic aspects	Are there additional considerations (availability of FIND	☐ 1: mostly negative	☐ 2: neutral	☐ 3: mostly positive aspects	☐ Not relevant (explain)		

	funding/resources, important strategic/political partner, relevance for resources mobilization)	aspects					

Organizational history and track record

Area of review	Question	Answer / Comments				Risk/Weaknesses Likelihood and Impact for every risk	Mitigation
History	Has FIND worked successfully with the organization/company before?	☐ 1: No	☐ 2: No, but the partner has references	☐ 3: FIND already has established, successful collaboration	☐ Not relevant (explain)		
	What is the history of the organization and what have been the key milestones and accomplishments (of the past 3-5 years)	☐ 1: No convincing history in the last 3-5 years visible	☐ 2: Well-established org. with a history of success in the last 3-5 years	☐ 3: The organization has a multi-year success story and key achievements in the field in the last 3-5 years	☐ Not relevant (explain)		
	Are past accomplishments relevant in the context of the planned activity/project?	☐ 1: Past accomplishments (if any) are from a different field	☐ 2: Past accomplishments in a different field but a clear plan how to leverage into the new field	☐ 3: Past accomplishments are from the same field/topic like the planned activity.	☐ Not relevant (comment why?)		
	Has the partner been active in the Global Health Arena or shown strong interest to become active?	☐ 1: No interest in Global Health	☐ 2: Not active in the past but has indicated strong interest to become active in Global Health	☐ 3: Active in Global Health	☐ Not relevant (comment why?)		

Executive Leadership Team and Board

Area of review	Question	Answer / Comments:				Risk/Weaknesses Likelihood and Impact for every risk	Mitigation
Executive Leadership	Does the organization have a full-time management team as well as key positions within R&D, manufacturing, product realization and quality? Provide detailed org charts.	☐ 1: Fully dedicated team could not be identified	☐ 2: Management team could be identified but further key positions need to be filled (list key positions and positions that should be filled to enable success)	☐ 3: Organization has all key position filled (including management, development, manufacturing, regulatory approval and commerciali-zation	☐ Not relevant (comment why?)		
	What are the backgrounds, qualifications and experiences of the management team members?	☐ 1: Team members have limited (IVD) experience and/or limited track record	☐ 2: Team has adequate experience in the key positions	☐ 3: Highly experienced team and extensive track record.	☐ Not relevant (comment why?)		

Resources, assets and competencies

Area of review	Question	Answer / Comments:				Risk/Weaknesses Likelihood and Impact for every risk	Mitigation
Infrastructure	Does the company have its own assets, facilities, labs, offices, etc., or does it share these with a university or other company? Is the company in an "incubator"?	☐ 1: No own premises	☐ 2: Own premises but some key activities are outsourced	☐ 3: All major competencies to understand and manage the required parts of the value chain (whether in-house or outsourced)	☐ Not relevant (comment why?)		
Outsourcing	Does the company take responsibility for its key activities (including management of outsourced activities)?	☐ 1: no ownership of key activities. Mainly "uncontrolled" outsourcing	☐ 2: Only few key activities in-house. Some control over outsourced activities.	☐ 3: key activities in-house. Clear supplier management for outsourced activities	☐ Not relevant (comment why?)		
Manufacturing	If relevant for the planned activity: has the company manufacturing capabilities (in-house or external) to meet the demands. Has the company established an effective QMS?	☐ 1: No	☐ 2: Rather no	☐ 3: Yes	☐ Not relevant (comment why?)		
Distribution	If relevant for the planned activity/collaboration: Does the organization have its own logistics chain and "order to delivery" process?	☐ 1: No	☐ 2: Not yet, but the organization has a clear plan for distribution	☐ 3: Yes	☐ Not relevant (comment why?)		

Financial health: See additional checklist in Key Financials

Area of review	Question				Risk/Weaknesses Likelihood and Impact for every risk	Mitigation
Financial audits	Has the organization been financially audited in the last 12 months? Please attach and review the latest financial report if available.	☐ 1: No	☐ 2: Yes	☐ 3: Not relevant (explain)		
Short-term demands	Does the organization have enough cash to meet short-term demands?	☐ 1: no	☐ 2: Yes	☐ Not relevant (explain)		
Financial health	Could red flags (e.g. risk of solvency over 3 years) based on the key financial metrics (if available) be identified?	☐ 1: Red flags	☐ 3: No	☐ Not relevant (explain)		
Acquisition plans	Are there acquisition plans/exit strategies over the duration of the planned activity that can lead to a major strategy change?	☐ 1: Red flags	☐ 3: No	☐ Not relevant (explain)		

Partner classification of commercial stage and development

Area of review	Question	Answer	Brief comment	Risk/Weaknesses Likelihood and Impact for every risk	Mitigation
1. Stock Market	Is the company listed on the stock market? If yes skip questions 2-11 and go directly to 12.	☐ Yes ☐ No If yes, go to 12			
2. Legal entity (AG, Inc)	Is the company a legal entity? Please outline fully, country, state (if applicable), etc.	☐ Yes ☐ No			
3. Separate premises	Does the company have its own assets, facilities, labs, offices, etc.?	☐ Yes ☐ No			
4. Complete, experienced full time management team	Does an experienced management team work full-time with the company?	☐ Yes ☐ No			
5. Quality management system	Does the company have: i) a Quality Management System; ii) a dedicated Quality Manager/Regulatory Affairs officer (for product development and/or manufacturing, whichever is relevant for the planned FIND activity); iii) a quality certification from a notified body or equivalent (e.g. ISO 13485 or FDA CFR Part 820 compliance) in place? Please provide copies of all current certifications and details on Quality and Regulatory staff e.g. org chart and job descriptions.	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No			
6. Products on local markets	Does the company sell its own products in local markets (own distribution, subsidiaries or distributors for the same country or region)?	☐ Yes ☐ No			
7. Supplier control	Can the company provide documentation of supplier control? Is the documented supplier controls adequate to protect the supply of product?	☐ Yes ☐ No			
8. Affiliates	Does the company have affiliates in other countries (not distributors)	☐ Yes ☐ No			
9. External investors	Does the company have external investors? Provide a list and if possible the percentage of holdings for each majority investor (>5%)	☐ Yes ☐ No			
10. Own distribution chain	Does the organization have its own logistics chain and “order to delivery” process?	☐ Yes ☐ No			
11. Customer service strategy	Has the company a system in place to deal with customer service issues like training, complaint handling, and on-site service?	☐ Yes ☐ No			
12. Products on market outside home base	Does the company sell products outside of its home country/region (own distribution, subsidiaries or distributors)?	☐ Yes ☐ No			

"Classification key"

Elements*	**Pre-Company**	**Seed company or institution***	**Early SME** (small-to-medium enterprise)	**Mature SME**	**Small-capital**	**Large-capital**
	No or minimal legal structure, minimal independent assets/people ("garage" type operation).	A company with "seed" capital investment. A legal & financial structure, identifiable premises, employees & perhaps external money.	Same as Seed, plus make and sell products. Can be with OEMs and/or distributors. Have some QA system / ISO.	Same as SME and is probably certified to main standards. Fully integrated company. Regional sales.	Fully integrated company. On the stock market or privately owned with a small market capitalization value.	Global player. On the stock market, or privately owned with a large market capitalization value.
1. Stock market	No	No	No	No	Yes	Yes
2. Legal entity (AG, Inc)	No	Yes	Yes	Yes	Yes	Yes
3. Separate premises	Yes/No	Yes	Yes	Yes	Yes	Yes
4. Complete, experienced full-time management team	Yes/No	Yes/No	Yes	Yes	Yes	Yes
5. Quality management system	No	Yes/No	Yes/No	Yes	Yes	Yes
6. Products on local markets	No	No	Yes/No	Yes	Yes	Yes
7. Supplier Control	No	No	Yes/No	Yes/No	Yes	Yes
8. Affiliates	No	No	No	Yes/No	Yes	Yes
9. External investors	Yes/No	Yes/No	Yes/No	Yes/No	Yes	Yes
10. Own distribution chain	No	No	Yes/No	Yes/No	Yes	Yes
11. Customer service strategy	No	No	Yes/No	Yes	Yes	Yes
12. Products on market outside home base	No	No	No	Yes/No	Yes/No	Yes

Key Financials checklist

“Financial Due Diligence” checklist for inspection of financial status

Sources of information for this Report:

Source		Details/Commentary
Company annual reports	Y/N	
SEC “type” filings	Y/N	
Company presentations	Y/N	
Interview with senior company manager(s) and/or Visits and/or on-the-spot audits	Y/N	
Financial analyst reports	Y/N	
Other (please describe)	Y/N	

Key Financials

Financial Metric	**Value (latest Report date) (millions £/$/¥/ Other)**	**Value (Previous Report date) (millions £/$/¥/ other)**	**Commentary on YoY**
Sales			
Cost of goods			
Gross margin			
Profit/loss			
Change on sales YoY			
Shareholder capital			
Accumulated profit/loss brought forward			
Cash generated by operations			
Net cash flow			
Cash/liquid assets			
Share price 52 week Hi/Lo & current			
Market capitalization			
Annual burn rate			
Key ratios (define)			
OTHER			

Manufacturing Costs Analysis

a) Provide BOM[4] typical of the Product Technology
   - Main material costs to 80% COGS
   - Highlight volume-sensitive elements and volume cut-offs

b) Summarize Basic COGS/Manufacturing Costs Elements and opportunities for cost savings

Element	% of COGS	Cost saving opportunities (e.g. automation, batch size, OEM partners….)	Impact of Cost Savings on Cost Element (%)
From BOM – direct materials			
Direct Labour			
Direct manufacturing overhead			
Other direct allocations Manufacturing equipment usage/amortization Facility/manufacturing personnel allocations			
Indirect allocations			

c) External OEM[5] costs (Country source)

Company Operations

a) Provide organizational chart.
b) Provide Quality Certification forms from a notified body or equivalent (e.g. ISO 13485 or FDA CFR Part 820 compliance) if a QMS is in place.
c) Provide copies of all current certifications and details on Quality and Regulatory staff e.g. org chart and job descriptions.

[4] Bill of materials
[5] Original equipment manufacturers