REQUEST FOR PROPOSAL (RFP)
REGULATORY AFFAIRS SPECIALIST CONSULTANCY

PUBLICATION REFERENCE:
RP25-0019

PUBLICATION DATE
22/10/2025

CONTENTS

1. Background Information:

FIND, established in 2003 and headquartered in Geneva, Switzerland, is a global nonprofit dedicated to equitable access to diagnostics. With regional offices in India, Kenya, South Africa, and Viet Nam, FIND partners with countries, funders, healthcare providers, and developers to drive diagnostic innovation and strengthen health systems. As a WHO Collaborating Centre, FIND leads efforts in pandemic preparedness and access to essential diagnostic tools.

2. Statement of Purpose:

FIND is currently supporting the verification, validation, and commercialization of regionally manufactured Yellow Fever NS1 Ag Rapid Diagnostic Test (RDT). To ensure successful regulatory submission and market entry, FIND seeks a Regulatory Affairs Specialist with deep expertise in in vitro diagnostics (IVDs), WHO processes, and African regulatory pathways, particularly for manufacturers based in Africa.

3. Scope of Work and Deliverables:

- Provide regulatory strategy guidance for the Yellow Fever RDT, including a roadmap to WHO Prequalification (PQ) and/or ERPD assessment.
- Build, review, and advise on product dossier preparation, ensuring compliance with WHO requirements.
- Advise on risk management documentation in line with ISO 14971 and specific requirements for IVD products.
- Ensure compliance of labels, Instructions for Use (IFUs), and user materials with WHO PQ requirements.
- Provide input on verification & validation protocols and clinical evaluation plans from a regulatory perspective.
- Support the project team in preparing for WHO audits/inspections, including guidance on common pitfalls and mitigation strategies.
- Advise on African regulatory approval pathways for IVD registration, with a focus on priority markets in West Africa.
- Provide recommendations on regulatory implications of any changes in product design, manufacturing, or supply chain during the project.

Deliverables:

- Regulatory roadmap and timeline for Yellow Fever RDT PQ/ERPD submission.
- Gap analysis of dossier requirements vs. current documentation.
- Review of draft dossier sections and related documentation.
- Recommendations on risk management files, labeling, and IFUs.
- Advisory notes on African regulatory submissions.
- Audit readiness pack for WHO PQ site inspection

4. REQUIRE COMPETENCIES:

Core Competencies

- In-depth knowledge of IVD regulation and WHO Prequalification requirements.
- Experience with WHO ERPD process and dossier preparation.
- Strong understanding of risk management (ISO 14971) for IVDs.
- Knowledge of compliance requirements for labeling, IFUs, and end-user materials.
- Familiarity with Emergency Diagnostic Listing for African CDC EDL.

Additional Competencies

- Familiarity with African IVD regulatory landscapes and registration processes.
- Experience supporting LMIC manufacturers in regulatory submissions.
- Excellent communication skills, able to translate technical requirements into practical guidance.

5. QUALIFICATION & EXPERIENCE:

- Graduate or postgraduate degree in life sciences, biomedical engineering, or related field.
- Minimum 7–10 years' experience in regulatory affairs for IVDs.
- Demonstrated track record of successful WHO PQ submissions or ERPD reviews.
- Experience working with African or LMIC-based manufacturers preferred.
- Fluent in written and spoken English; French is an advantage.

6. APPLICATION GUIDELINES:

Interested candidates are invited to submit:

- Their professional profile/CV, highlighting relevant experience.
- Financial proposal - A proposed budget for the consultancy, detailing daily rates and total expected costs.
- A brief cover letter outlining their approach to supporting West African based diagnostic manufacturers and their availability for the assignment.

Please note: The position will remain open for two weeks to collect profiles. Candidates are encouraged to respond promptly and include all requested information in their application.

7. Evaluation and Award Process:

Proposals will be evaluated based on the following criteria:

Criteria	Weighting
Technical Expertise & Experience	40%
Understanding of Assignment & Approach	20%
Qualifications & Education	20%
Financial Proposal	20%

- **Technical Expertise & Experience (40%) –** Strength of relevant expertise, certifications, and prior project experience.
- **Understanding of Assignment & Approach (20%) –** Quality of proposed methodology and alignment with FIND Objectives.
- **Qualifications & Education (20%) –** Academic and professional background.
- **Financial Proposal (20%) –** Cost effectiveness and clarity of daily rates and expected costs.

8. Timelines:

	Activity	Expected date
1	Publication of RFP	22nd October 2025
2	Closing date for submission of proposals	5th November 2025
3	Evaluation of applications	6th to 14th November 2025
4	Communication on Award/s of Contract	From 17th till 21st November 2025
5	Contract/s signed with selected Bidder	First week of December 2025
6	Communication to unsuccessful applicants	31st November 2025
7	Start of assignment	Mid December 2025

9. Award Conditions:

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

- Provide a proof of legal registration as a consultancy firm or an individual contractor.
- Sign a declaration confirming no Conflict of Interest.
- Be legally permitted to perform work in the country where the contract will be performed.
- Commit to and sign the FIND Code of Conduct and Ethics.
- Sign the Due Diligence Self declaration form.

10. CONTRACTUAL TERMS, DURATION AND CONDITIONS:

- The contract will be awarded to the successful consultant following completion of the evaluation and selection process.
- The agreement shall become legally binding only upon signature by both parties and the issuance of a formal contract agreement by FIND.
- The consultant must execute the services in accordance with the scope of work outlined in this RFP.
- The consultant is responsible for ensuring high-quality performance, timely deliverables, and compliance with agreed methodologies.
- **Location:** The consultancy will be conducted remotely.
- **Duration:** The assignment is expected to require approximately **30 working days (non-consecutive)**, up until 31 March 2026.
- **Contract period:** The consultant is expected to begin work starting **mid-December 2025** and complete all deliverables within the agreed timeframe.
- **Payments** will be linked to deliverables and made upon approval of completed milestones.
- FIND reserves the right to withhold payment if the consultant fails to meet agreed-upon performance standards.
- **Extension:** In the event additional time is required to complete the agreed scope, the consultant may request an extension. Any extension must be formally approved by FIND in writing.
- **Renewal:** FIND reserves the right to renew or extend the contract for additional phases of work if further engagement is necessary. Renewals will be based on the consultant's performance, availability of funding, and evolving organisational needs.
- **Confidentiality and Data Protection:** All information received, created, or shared during the consultancy will remain confidential and must not be disclosed to third parties without FIND's prior written consent. The consultant must comply with applicable data protection laws and ensure the security of sensitive information.
- **Intellectual Property:** Any documents, reports, frameworks, tools, or methodologies developed under this contract will become the property of FIND. The consultant grants FIND unrestricted usage rights to all deliverables.

11. CONFIDENTIALITY

FIND considers any proposal received under the RFP as confidential. If required, FIND can sign a Confidentiality Disclosure Agreement (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.

12. HOW TO APPLY:

Please email the proposals in English, in pdf format to: procurement@finddx.org
It is recommended that the entire Proposal be consolidated into as few attachments as possible.
All files must be free of viruses and not corrupted.
The proposer should receive an email acknowledging receipt of the proposal.
Applications will be accepted and responded to expediently until November 5th, 2025.

In case you have any questions, kindly contact procurement@finddx.org.