**EOI questionnaire (IVD)**

**NOTE TO THE APPLICANT: Please answer each question below as clearly and concisely as possible. Incomplete applications may jeopardize your status as an applicant. Please do not provide attachments unless specifically asked, and if asked to provide an attachment please be sure that it consists of only the relevant information.**

**COMPANY DETAILS**

Please provide: (1) the name and location of your company; (2) a company website; (3) a valid email address as your preferred point of contact.

**ORGANIZATIONAL PROFILE AND MANUFACTURING**

1. Therapeutic Area Expertise:
   1. In Vitro Diagnostics (IVD) Expertise: Please describe your experience in the manufacturing of IVDs.
      1. Are your assays based on ELISA, PCR, lateral flow, or other technology? [Please specify]
   2. Please describe your experience in the manufacturing of other therapeutic goods, for example: Biological Materials for IVDs, Medical Devices, Medicines, other (mention only the therapeutic categories).
   3. Are you a startup company, institution, SME or large business?
   4. Number of production and quality system staff.
   5. Scope of current manufacturing activities (e.g. packaging and assembly, reagent manufacture, strips manufacture, full manufacture, other (please specify))
2. Product regulatory approvals:
   1. Please provide details of any IVDs you manufacture:
      1. that are prequalified by WHO and/or
      2. have been granted a regulatory approval by a National or International Regulatory Authority (please specify) or a CE Certification by a designated EU Notified Body.
   2. Please provide details of any biological starting material (for IVDs) you manufacture, and the details of any regulatory approvals obtained.
   3. Please provide details of any medical devices (other than IVDs) you manufacture, and the details of any regulatory approvals obtained
   4. Please provide details of any medicines manufactured and any regulatory approvals obtained.
3. Please complete the information requested below for your current and planned manufacturing facilities for IVD tests, and attach all relevant documents and certificates for each site:
   1. Existing site
      1. Name of facility
      2. Location (Country, City, Area)
      3. Type of facility (IVD and/or Biological starting material):
         1. type of IVD (e.g. ELISA, PCR, lateral flow, specify other) and
         2. type of biological material (if manufactured)
      4. Estimated annual manufacturing capacity (IVDs). What’s your planned commercialization date?
      5. Current facility inspections with approval dates (please specify the IVDs covered by the scope of inspections):
         1. WHO inspection(s)
         2. European Notified Body, or MDSAP (Medical Devices Single Audit Program) accredited certification body (please specify the scope of MDSAP or CE) audit
         3. National Regulatory Authority
         4. International Accreditation Forum (IAF) Accredited Certification Bodies [please specify]

vi. First commercial production date (mm/yy)

* 1. New site (if applicable)
     1. Name of facility
     2. Location (Country, City, Area)
     3. Planned annual manufacturing capacity for IVDs
     4. Expected timelines (please provide all that apply below):
        1. Facility Completion
        2. First WHO inspection or an audit by MDSAP, EU Notified Body or IAF accredited Certification Body [please specify]
        3. First WHO prequalification or First Facility Certification by a Regulatory Authority (please specify) or an Accredited Certification Body (please specify)
  2. First expected commercial production date (mm/yy)

1. Manufacturer’s current QMS certification status:
   1. Are you certified ISO 13485:2016? (If so, please specify the scope of certification and the certifying body/authority)
   2. Are you certified ISO 9001:2015? (If so, please specify the certifying body/authority)?
   3. Other certifications, e.g. GMP (please specify the regulatory authority)?
2. If you are an established manufacturer in IVDs, please indicate (for all IVDs):
   1. Quantity of IVDs sold for use in LMICs in the last year
   2. Number of kits/tests of IVDs sold for use in LMICs in the last year
3. Innovation: Do you have any examples of innovative and cost-effective processes that you have developed? If yes, please indicate:
   1. IVD type (technology e.g. ELISA, PCR, lateral flow. ..) and Specific IVD, or biological starting material for the manufacture of specific IVD(s).
   2. What types of cost reductions were you able to achieve (indicative)?
   3. Did you develop and register any intellectual property? Please provide examples.

**FINANCIALS**

1. Please provide your three-year financial history (please include at least, Consolidated Balance Sheet, Income Statement, Cash Flow Statement, Manufacturing expenditure, and R&D expenditure).
2. What percent share of your net revenue for all products is from developing countries?
3. What percent share of your net revenue is from IVDs?
4. Please indicate the specific financial investment you plan to make for the development and/or manufacturing of XXX (IVD). Please indicate if you do not envisage any new investment.

**PRODUCT STRATEGY AND TIMELINES**

1. Will you use this licence to manufacture, sell and distribute IVDs or both IVDs and biological starting materials?
2. What is your organization’s approach to sourcing biological starting materials for the IVDs covered by this license (own biological starting materials, outsourced biological starting materials)?
3. If you will also be developing additional IVDs under this license, please indicate your:
   1. Current status of development
   2. Estimated timelines for development
   3. Proposed dossier submission date (mm/yy) to WHO or another Regulatory Authority (please specify), after signing of the MPP license.
   4. Key milestones such as design locked date, validation batches, stability data analysis, external laboratory evaluation and dossier submission.
4. Provide a forecast for three years from the date of launch of the IVD, including timelines based on the ramp-up of capacity and the quantity of IVD you plan to manufacture annually, including the number of individual tests.
5. Explain your plans for manufacturing, distribution, and marketing in the short- and mid-term for the IVD being considered. Describe how it fits with the strategy of your company in the field of COVID-19 treatment. How will a license granted to you improve access to COVID-19 medications in low- and middle-income countries?

**GEOGRAPHICAL PRESENCE**

1. Please list the low-and-middle-income countries (LMICs) where you have registered IVDs with National Regulatory Authorities (NRAs).
2. Please list LMICs where you actively sell IVDs, if applicable
3. Which public health procurement agencies are you currently working with? Please list the product categories sold to such agencies
4. Please list LMICs where you propose to file and distribute the IVDs using this license, including an average estimated filing timeline from your submission date

**REGULATORY**

1. Do you have responsibility for all key manufacturing and regulatory activities, including those activities outsourced?
2. Do you have your own facility(ies) or shared facilities i.e., premises, laboratories, equipment, staff.
3. Does your company currently have a process for post market surveillance and vigilance reporting?
4. In the last two years, were there any Field Safety Corrective Actions, recalls of your products, and has your company received any warning letters or any inspection designated as OAI (Official Action indicated) by USFDA, or a similar action by other Regulatory Authority or other Accredited Certification Body?
5. Does your company currently use a Unique Device Identification system (UDI)?  If no, please explain your plans to begin employing UDI