

## TERMS OF REFERENCE

### **Consultancy for experts to support landscape assessment for clinical trials and bio-analytical (including BA/BE trials) capabilities/opportunities in Africa.**

#### **TERMS OF REFERENCE**

These Terms of Reference (TOR) are an overall framework for the services to be provided under this consultancy by the Contractor selected from this Request for Proposal (RFP 2024.10).

#### **DESIRED TIMEFRAME**

Anticipated start date: End-April 2024

Completion date: End-July 2024

#### **1. BACKGROUND**

##### **General information**

Unitaid is a hosted partnership of the World Health Organization (WHO) and is an international organisation that accelerates the introduction of health products in Low- and Middle-Income Countries (LMICs) to prevent, diagnose and treat HIV/AIDS, tuberculosis, and malaria more quickly, affordably, and effectively. Our work, as reflected in Unitaid Strategy 2023-2027 ([available here](#)), also covers maternal, newborn and child health and pandemic response.

Over the past 15 years, Unitaid has led the way in identifying promising health innovations, demonstrating their utility, effectiveness, and impact in low-resource settings, and laying the foundations for governments and partners to make them available at scale by removing access barriers that hinder their scaled-up use. Unitaid plays this vital role in the market-shaping and introduction of numerous innovative medicines and health products, working through an extensive network of partners, including governments, NGOs and civil society, groups, research, and academic institutions. Unitaid is a financial and technical partner of the WHO prequalification program, and, beyond being the founder, a financial and technical partner of the Medicines Patent Pool (MPP). With a new ambitious 2023 - 2027 strategy, Unitaid aims to continue driving equitable access to innovative health products as a core function. In addition, the new Unitaid strategy

facilitates relevant workstreams to ensure that the value goes beyond introducing innovative products to creating systemic conditions for sustainable equitable access and partnerships.

The COVID-19 pandemic saw severe inequities in access to lifesaving health tools, including therapeutics. Many of the root causes of these inequities remain and must be addressed in advance of future pandemics. Bearing the lessons learnt from the COVID-19 pandemic, Unitaid, through the work in Pandemic Prevention, Preparedness and Response (PPPR, [Pandemic Prevention, Preparedness and Response](#)) and the strategic initiative in Regional Manufacturing for Equitable Access (RMEA), aims to ensure that countries are better prepared for pandemics by strengthening health systems' capabilities for new product development and manufacturing to ensure equitable access, increase the speed, affordability and accessibility of new tools.

Unitaid's Regional Manufacturing for Equitable Access (RMEA) strategic initiative aims to address the challenge of equitable access to affordable, quality-assured health products in low- and middle-income countries, mainly focusing on Africa. Despite the continent's significant disease burden, over 95% of active pharmaceutical ingredients and 70% of consumed pharmaceuticals are imported, leaving countries vulnerable to supply chain disruptions and unavailability of essential health products. The COVID-19 pandemic highlighted the risks of dependence on imports. The initiative focuses on strengthening regional manufacturing, starting with Africa, which highly relies on imported health products.

Likewise, there is consensus that the lack of efficient clinical evaluations during the COVID-19 pandemic for the few therapeutic existing candidates was a major obstacle to the response, as reflected in the World Health Assembly 2022 resolution (WHA 75.8, Seventy-fifth World Health Assembly, Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination, May 2022, available [here](#)). Likewise, African partners have strongly called for a greater focus to increase the efficiency of the African clinical trial ecosystem to respond to the pandemic and non-pandemic priorities (African Union, Africa CDC, AUDA-NEPAD. Optimizing Efficiency and Impact in the African Clinical Trials Ecosystem, May 2023).

A robust landscape for health products' development and research, including clinical trials for the evaluation of promising candidates as well as bio-analytical/ bioequivalence capabilities to bridge the gap between R&D and market entry, is crucial for pandemic preparedness. The availability of

adequate knowledge (and experience), systems, and infrastructure enables rapid evaluation and deployment of medical interventions during the crisis periods and monitoring of disease dynamics during inter-crisis periods. To effectively support both regional manufacturing and pandemic preparedness, it is imperative to identify and assess the existing infrastructure, strengths, weaknesses, and opportunities within R&D networks and institutions, clinical research organisations (CROs), bioanalytical laboratories, and contract development and manufacturing organisations (CDMOs).

Unitaid's RMEA and PPPR initiatives require a landscape of capabilities across these enabler services on the continent of Africa to design pathfinder interventions.

## **2. WORK TO BE PERFORMED**

Unitaid seeks a consultancy/specialized firm to conduct a comprehensive landscape assessment of clinical trials and bio-analytical capabilities/opportunities in Africa, specifically focusing on supporting regional manufacturing and pandemic preparedness initiatives. The assessment should aim to:

- Identify existing clinical trial capacity (including recently initiated and planned initiatives) across different regions of Africa, differentiating from Phase I to Phase III as possible and covering ambulatory and in-patient studies.
- Evaluate the capabilities, infrastructure, and compliance with Good Clinical Practices (GCP) standards of identified entities.
- Analyze the strengths, weaknesses, opportunities, and threats (SWOT analysis) within the landscape of biologics research institutions, clinical trials and bio-analytical capabilities in Africa.
- Assess the readiness of these entities to support GCP-compliant, Bioavailability/Bioequivalence (BA/BE) trials.
- Assess the potential of these entities to deliver cost-competitive, GCP-compliant Bioavailability/Bioequivalence (BA/BE) trials.
- Provide recommendations for enhancing the capabilities and capacities of identified entities to offer cost-competitive, GCP-compliant services to support regional manufacturing and pandemic preparedness efforts.

The consultant will provide the following deliverables:

- a) An inception report detailing the methodology, work plan, and timeline for the assessment.
- b) Draft and final reports presenting the landscape assessment's findings, conclusions, and recommendations.
- c) Any additional materials, such as presentations or data sets, generated during the consultancy.

### **Deliverables**

Deliverable #1: Inception Report

Deliverable #2: Draft report

Deliverable # 3: Final report (Word document and PowerPoint Slides) including presentation

### **3. PLACE OF WORK AND MANAGEMENT**

The scope and extent of partner engagement will be discussed and calibrated during the inception phase.

#### **Place of work**

The Contractor will work remotely and in close communication with Unitaid. The Contractor is also expected to operate in a manner that minimises their carbon footprint during this exercise.

#### **Management and communication**

The Contractor will work closely with Unitaid's RMEA and PPPR teams during the project.

### **4. QUALIFICATION AND SKILLS**

Unitaid hereby seeks services of external consultancy/specialized firm with the following technical qualifications and demonstrated experience (both in firm and the proposed team):

## Essential

1. Extensive experience conducting landscape assessments or market analyses in the healthcare or pharmaceutical sector, preferably in Africa.
2. Extensive experience and knowledge of clinical and biologics research, bioanalytical services, and regulatory requirements for conducting clinical trials, particularly in Africa.
3. Extensive experience in and knowledge of health product manufacturing processes and systems across geographies (in particular in LMICs).
4. Extensive experience in and knowledge of health systems and stakeholder management across geographies, especially in LMICs
5. Extensive experience in writing technical reports for public dissemination, with a proven capacity to translate complex technical content into a simple narrative and critical messages.

## Desirable:

1. Strong network within the global pharmaceutical and diagnostics manufacturing sectors
2. Demonstrated experience working with stakeholders from government, industry, academia, and international organisations.

## 5. DELIVERABLES

It is expected this assignment will run for between 30 to 40 days over three months, with deliverables to be submitted on the following indicative dates (to be confirmed during the inception phase):

Phase	Steps	Target dates
Inception	Kick-off meeting	End April 2024
Execution	Deliverable #1 (Inception Report)	15 May 2024
	Deliverable #2 (Draft Report)	14 June 2024
Closing	Deliverable #3 (Final Report) and Exit meeting	31 July 2024

## 6. BUDGET

All bidders are expected to submit their proposed budget, broken down across the three (3) deliverables requested under this TOR.

## PAYMENT TERMS AND SCHEDULE

For *professional fees*, payments will be made following satisfactory completion of the ToR deliverables and submission of corresponding invoices detailing the actual level of effort incurred. For *travel costs (if requested separately by Unitaid during contract implementation)*, payment will be made in accordance with WHO policies and rates and upon submission of invoices indicating actual travel costs with proof of payment. The Contractor is responsible for organising all travel logistics, including hotel booking and local transportation, in the most economical manner.

Basis for Payment	Payment Percentage
1. Upon satisfactory completion of Deliverable #1 and acceptance by Unitaid (RMEA & PPPR) teams	10% of Professional Fee
2. Upon satisfactory completion of Deliverable #2 and acceptance by Unitaid (RMEA & PPPR) teams	40% of Professional Fee
3. Upon satisfactory completion of Deliverable #3 (including presentation) and acceptance by Unitaid (RMEA & PPPR) teams	50% of Professional Fee