EXPERTISE FRANCE
GROUPE AFD

Funded by the European Union

TERMS OF REFERENCE

General information

Assignment name	Consultancy services - Individual expertise for Clinical Trials Project Support
Beneficiary	Rwanda Biomedical Centre and five clinical trials sites
Host Institution	Rwanda Biomedical Centre (RBC)
Total estimated number of days	Maximum 100 days over a one-year period, with approximatively 2 days/week
Expected start date	by 11th January 2027.
CTU sites (duty locations)	UGHE, King Faisal Hospital, Rwanda Military Teaching and Referral Hospital at Kanombe, CHUK, CHUB
Overall contract duration	20 Months up to August 2028

1. Context and justification of the needs

Expertise France (EF) is a public inter-ministerial agency for international technical cooperation. EF provides project design, technical assistance and institutional capacity building worldwide, operating across diverse fields such as health, safety and security reform, education and skills development, crisis recovery and stabilization, human rights, governance, climate change etc. EF has extensive experience in managing complex, multi-stakeholder international programs, including strong expertise in administrative and financial management. Expertise France implements the MAV+ project with funding from the European Union, in close cooperation with national stakeholders and other European implementing partners.

The MAV+ Project is supporting the establishment and operationalization of clinical trials units (CTU), in order to strengthen Rwanda's capacity to conduct high-quality clinical research and clinical trials in accordance with national and international standards. To assess the readiness of selected clinical trial sites, the International Vaccine Institute (IVI) conducted a Gap Analysis at the following clinical trial sites:

- Centre Hospitalier Universitaire de Butare (CHUB)
- Rwanda Military Teaching and Referral Hospital at Kanombe(RMTH)
- Centre Hospitalier Universitaire de Kigali (CHUK)
- King Faisal Hospital (KFH)
- University of Global Health (UGHE), Kuvumbura Clinical Trial Site

The assessments identified critical gaps in infrastructure, human resources, governance, quality systems, and operational processes required for successful conduct of clinical trials.

To support implementation of the recommendations from these assessments, coordinate the clinical trials initiative in its operational aspects, generate and disseminate information among the multiple stakeholders of the project, prepare briefing notes, reports, and documents for the senior management approval, and provide operational coordination, the MAV+ project managed by Expertise France seeks to recruit a clinical trials project Consultant, to support the Rwanda Biomedical Centre (RBC), in order to ensure that by August 2028, all five clinical trials sites have implemented the recommendations of the IVI gap assessment and are operational.,

2. Objectives and desired results

The clinical trials project consultant will provide operational coordination to support the implementation of activities arising from the IVI Gap Analysis, the ongoing initiatives, and the workplan to be elaborated and approved by the technical working group (TWG). The clinical trials project consultant will also advise the senior leadership of the project on clinical trials matters.

The clinical trials project consultant shall:

- Ensure that recommendations from the IVI Gap Analysis and QMS Assessment reports are implemented
- As the permanent secretary of the technical working group (TWG) on clinical trials, that meets every month, he will make sure that the TWG receives all the requested information to take decisions and is able to amend and implement the work plan
- Support in the Organisation and Coordination of training activities required for CTU readiness among different training service providers and donors,
- Make sure that the activities of the consulting firms in charge of infrastructure readiness and operational preparedness for clinical trial implementation (premises, equipment, software, SOP documents, business plans) are in line with the work plan and contributing in a timely manner, with the highest quality possible, to the objective of sites readiness.
- Facilitate collaboration among RBC, participating CTU, IVI, MAV+ partners, and other stakeholders, particularly the TWG members

It is expected that at the end of the consultancy, all major actions forecasted in the IVI Gap analysis as well as in the work plan are implemented, and that the technical working group is empowered to follow-up on the programme.

3. Description of the assignement

Activities

Technical oversight and implementation of gap analysis report recommendations

The clinical trials project consultant shall:

- Review IVI Gap Analysis report

- Amend the existing work plan for all recommendations, per site, based on the existing drafts, the progress accomplished so far, and submit it to the TWG for approval.
- Support each site to develop detailed action plans, timelines, responsibilities, and monitoring indicators.
- Monitor implementation progress and provide weekly updates to RBC and Expertise France MAV+ leadership.
- Coordinate follow-up visits and technical support to participating sites.
- Participate in the supervision of specific consultancies, jointly with RBC and Expertise France.
- Develop monitoring tools to track implementation progress.
- Maintain a consolidated tracker of recommendations and actions across all sites.
- Prepare quarterly progress reports.
- Document achievements, challenges, risks, and mitigation measures.
- Support preparation of reports required by RBC, MAV+, and partners, including the donor.

Work as the secretary of the technical working group (TWG) on clinical trials

The clinical trials Project consultant will serve as secretary to the TWG by:

- Preparing meeting agendas
- Scheduling meetings
- Recording minutes
- Tracking action points
- Providing regular updates on implementation progress and challenges
- Prepare meeting agendas, reports, and action trackers.
- Facilitate communication and information sharing among stakeholders.
- Monitor follow-up of agreed actions and recommendations.

The clinical trials project consultant will also support RBC in the coordination of the clinical trials activities, and as such, will organize and coordinate meetings between RBC and key national and international stakeholders.

Support the implementation of the project

The clinical trials project consultant shall:

- Coordinate implementation of capacity-building activities identified in the assessment reports.
- Liaise with trainers, facilitators, and participating institutions to ensure smooth coordination of training programs.
- Support the development of clinical trial site governance structures
- Support the development of coordination and reporting mechanisms between sites and RBC.
- Liaise with procurement, and administrative teams within Expertise France and partner institutions to facilitate timely procurement, contracting, and approvals.

4. Anticipated Deliverables

The clinical trials project consultant shall deliver:

- Consolidated and quarterly updated implementation plan, based on IVI Gap Analysis and QMS Assessment reports, and the TWG workplan.
- Site-specific and quarterly updated action plans for CHUB, RMTH, CHUK, KFH, and UGHE.
- Training and capacity-building consolidated plans.
- Training coordination reports and attendance records.
- TWG meeting reports and action trackers.

Coordination

The clinical trials project consultant will:

- Be working with the Rwanda Biomedical Centre (RBC) and report to the MAV+ Project Lead at Expertise France and RBC leadership, with RBC approving the deliverables, and the MAV+ project lead giving a second approval and authorizing disbursements.
- Work closely with site leads, hospital management teams, and the TWG
- Liaise regularly with technical partners supporting CTU development.

5. Place, duration and terms of performance

Place:

In Kigali at RBC headquarters, with possible travels to the clinical trials site

Duration

Contract period: From January 2027 to August 2028

6. Required expertise and profile

Education

Master's degree in clinical research, Public Health, Medicine, Biomedical Sciences, Epidemiology, Health Systems Management, or equivalent field.

Experience

- Minimum of 7 years of experience in clinical trial management, or research capacity strengthening, management of projects related to clinical trials.
- Experience supporting partner institutions in an international co-operation framework Experience in training coordination and stakeholder engagement, with at least 2 similar assignments successfully completed.
- Familiarity with clinical research institutions in Rwanda is highly desirable.
- Fluency in English is required; working knowledge of French is a strong asset.

7. Performance Indicators

Deliverables	Verification sources
Consolidated and updated implementation plan based on IVI Gap Analysis and QMS Assessment reports.	Implementation plan available
Site-specific and updated action plans for CHUB, RMTH, CHUK, KFH, and UGHE.	Actions plans available
Training and capacity-building plan.	Training Plans available
Training coordination reports and attendance records.	Documents/reports available
Quarterly progress reports.	Reports available
Stakeholder meeting reports and action trackers	Documents available

8. Evaluation Criteria

The offers will be analysed, evaluated and awarded based on the following criteria:

Criterion	Weighting	Max Score
SELECTION STAGE FOR THE SHORTLISTING		
Minimum of 7 years of experience in clinical trial management, or research capacity strengthening, management of projects related to clinical trials.	YES/NO	
Experience supporting partner institutions in an international co-operation frame-work Experience in training coordination and stakeholder engagement, with at least 2 similar assignments successfully completed	YES/NO	
Familiarity with clinical research institutions in Rwanda is highly desirable.	YES/NO	
Proficiency in French and English	YES/NO	
AWARD STAGE / INTERVIEW		
Understanding the ToR, Relevance and Quality of the proposed methodological note	40%	40
Relevance of the Work plan	30%	30
Financial offer	30%	30
TOTAL	100%	100

9. Practical information

Confidentiality

The clinical trials project consultant shall maintain strict confidentiality regarding all project, institutional, and research-related information and shall comply with all applicable ethical, regulatory, and professional requirements governing clinical research in Rwanda.

General Conditions

The clinical trials project consultant shall comply with Expertise France's Code of Conduct and its Policy on the Prevention of Sexual Exploitation, Abuse and Harassment (PSEAH).

Content of the Offer

Candidates are invited to submit a complete application including:

Technical Offer

- Detailed CV highlighting relevant qualifications and experiences.
- Methodological Note (max 3 pages) presenting an understanding of the assignment and the proposed implementation approach.
- References for similar assignments (at least 2), including copies of contact details or certificates of good completion or any other relevant proof.

Financial Offer

- Expert daily rate excluding VAT (fees) (payments will be made quarterly, upon presentation of the quarterly progress report and corresponding timesheets, duly signed by the supervisor at RBC and validated by the Project Manager.