

Terms of reference (ToR) for the procurement of services below the EU threshold

CONFIDENTIAL

Preclinical GLP Toxicology Network	Project number/ cost centre: 21.2258.8-004.00
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0. List of abbreviations

BMZ	German Federal Ministry for Economic Cooperation and Development
DoH	Department of Health
DSTI	Department of Science, Technology and Innovation
EU	European Union
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
GLP	Good Laboratory Practices
MAV+	Manufacturing and Access to Vaccines
PCDDP	Preclinical Drug Development Platform
ToR	Terms of Reference

1. Context

SAVax is a bilateral technical cooperation programme between the Governments of Germany and South Africa. It is co-steered at the national level by the Department of Health (DoH), the Department of Science and Innovation (DSI), and the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ), acting on behalf of the German Federal Ministry for Economic Cooperation and Development (BMZ) and the European Union (EU). Since June 2024, the programme has also been co-financed by the EU through the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) for Sub-Saharan Africa.

The programme is structured around two key components:

1. Support for vaccine distribution and pandemic preparedness, and
2. Support for local vaccine production, focused on four strategic pillars:
 - Skills development
 - Innovation
 - Market shaping
 - Regulatory strengthening

Context and Rationale for the Preclinical Good Laboratory Practice (GLP) Toxicology Network

The Preclinical Good Laboratory Practice (GLP) Toxicology Network initiative presents a strategic opportunity to address key gaps in South Africa's and the broader continent's pharmaceutical and biotechnology sectors. Conducting preclinical toxicology studies in compliance with GLP standards is critical for assessing the safety of new vaccines and drugs before they proceed to clinical trials. These studies generate high-quality, reproducible data essential for regulatory approval and alignment with international benchmarks. Despite this, South Africa and much of Africa continue to face major obstacles in this area. The region remains largely dependent on international Contract Research Organizations (CROs) for full-service GLP toxicology studies, an over-reliance that drives up costs, prolongs timelines, and reduces local control over research activities.

To address this challenge, the Preclinical Drug Development Platform (PCDDP) at the Faculty of Health Sciences, North-West University, have developed the concept of a Preclinical GLP Toxicology Network, which is a collaborative, locally anchored network for preclinical toxicology research. The Network aims to function as a fully integrated ecosystem that meets global pharmaceutical standards and regulatory expectations, positioning it as a critical component in the regional pharmaceutical value chain. This tender will focus on engaging key stakeholders to jointly develop the legal frameworks, build a strong business case, and arrive at a well-informed "go/no-go" decision.

The objective of this tender is twofold: 1. To assess the Preclinical GLP Toxicology Network through a detailed business case analysis. 2. To develop an appropriate legal framework under which the Network would operate.

2. Tasks to be performed by the contractor

Key responsibilities of the contractor include developing a business case to demonstrate the Network's economic viability, as well as drafting a legal framework to govern collaboration among stakeholders.

The contractor will be responsible for the following 2 (two) Work Packages:

Work Package (WP) 1: Development of a Business Case Model

2.1.1 Tasks:

Provide strategic, technical, and facilitative expertise to support the development of a financially viable, operationally sustainable, and partner-aligned Preclinical GLP Toxicity Network. By performing a

detailed market analysis to identify the demand and supply dynamics for preclinical GLP toxicology services in South Africa and the wider region. Assess the current gaps and challenges in the toxicology testing landscape, including cost implications, timelines, and control issues

1. Stakeholder Mapping

- Engage with key actors through:
 - Interviews
 - Surveys
- Workshops and focus groups
 - The contractor will plan this workshop and the catering
 - Compiling the participants' list and inviting them
 - Sourcing out venues and possible location venues are Potchefstroom and Cape Town (Will be informed by the participants' list)
- This step helps validate assumptions, refine needs, and ensure buy-in.

2. Market and Demand Analysis

- Assess the current and projected demand for GLP toxicology services:
 - Who are the potential clients?
 - What is the size of the market (local, regional)?
 - Trends in biotech, pharma, and regulatory needs
- This step should also consider competing providers and pricing models

3. Technical and Operational Feasibility

- Identify:
 - Infrastructure and technology needs
 - Required certifications (e.g., GLP accreditation)
 - Human resources and skills availability, including specific skills related to GLP compliance
 - Equipment and laboratory capabilities as required for the provision of preclinical GLP toxicology services
 - Supply chain/logistics needs

4. Financial and Economic Analysis

- Develop cost estimates and revenue projections:
 - Capital expenditure (CAPEX)
 - Operating expenditure (OPEX)
 - Expected income streams (services, grants, partnerships)
- Conduct Cost-Benefit Analysis or Return on Investment (ROI) analysis
- Include sensitivity analysis (different scenarios: optimistic, pessimistic, most likely)

5. Risk Assessment

- Identify and assess key risks:
 - Regulatory and compliance risks
 - Financial and market risks
 - Operational risks
 - Political or partnership-related risks
- Propose mitigation strategies to manage the key risks identified

6. Implementation Plan (High-Level)

- Outline key steps for rollout:
 - Implementation roadmap
 - Phases and timelines
 - Resource requirements
 - Operational plan
 - Key milestones and indicators for success

7. Develop and Present the Business Case Report

- Compile all the findings into a comprehensive, decision-ready document that includes:
 - Executive summary
 - Methodology
 - Analysis and findings
 - Recommendation
 - Appendices (data sources, stakeholder inputs, etc.)

2.1.2 WP1 Deliverables:

1. Business model proposal including:
 - Market and ecosystem analysis
 - Financial model
 - Sustainability plan
 - Strategic implementation of roadmap and operational plan
 - Business case document (Draft & Final)
2. Planning and execution of two workshops

Key Milestones

Milestones / Process Steps / Partial Services	Estimated Deadline	Place	Person Responsible
1. Adapt the milestones according to the contractor	Week 1–4	Online	Contractor (Stakeholder Engagement Lead), supported by GIZ
2. Stakeholder Consultation	Month 1–6	Online interviews / hybrid workshops	Contractor (Stakeholder Engagement Lead), supported by GIZ
3. Market and Demand Analysis	Month 6–7	Virtual / Industry and academic consultations	Contractor (Market Analyst)
4. Technical and Operational Feasibility	Month 8–9	Network site visits / Expert interviews	Contractor (Technical Lead)
5. Financial and Economic Analysis	Month 10–11	Desktop + stakeholder data sources	Contractor (Finance Specialist)
6. Risk Assessment	Month 12	Internal workshop / remote	Contractor (Risk & Compliance Lead)
7. Implementation Plan (High-Level)	Month 15	Virtual	Contractor (Project Lead), reviewed by GIZ
8. Develop and Present the Business Case Report	Month 16–18	Final report submission to GIZ	Contractor (Project Lead) with full team contributions

Work Package 2: Drafting of a Legal Framework for the GLP Toxicology Network

2.1.3 Tasks:

Draft the legal framework necessary to establish and operate the Preclinical GLP Toxicology Network. Outline the governance structure for the Network, including the roles and responsibilities of different stakeholders. Ensure the legal framework supports collaboration among diverse stakeholders, including academia, regulatory bodies, and industry. The data collected from WP1 on Stakeholder Mapping will be used in some of the processes in this WP.

1. Review Legal and Regulatory Context

- This ensures the proposed structure is legally permissible and aligns with regulatory frameworks by conducting a legal scan of:
 - South African laws on partnerships, research collaboration, and public-private cooperation
 - Sector-specific legislation (e.g., National Health Act, Animal Research Ethics, SAHPRA Act)
 - Contracting rules for public universities and government departments
 - International standards (e.g., OECD GLP, ICH, data protection laws)

2. Develop a Draft Partnership Agreement

The contractor should develop a Memorandum of Understanding (MoU) or draft Partnership Agreement that outlines:

- Governance structure (steering committee, advisory boards)
- Legal status of the Network
- Roles, responsibilities, and resource commitments of each partner
- Ownership and use of infrastructure, equipment, and data
- Decision-making processes
- Dispute resolution mechanisms
- Exit and dissolution clauses

3. Ensure Compliance with Institutional Requirements

- Check each partner's internal requirements (e.g., university senate approval, board sign-off)
- Align with procurement, research ethics, and financial management policies
- Ensure compatibility with donor requirements (e.g., GIZ, EU, BMZ)

4. Facilitate Legal Review and Negotiation

- This is a critical step to ensure that all parties are legally protected and aligned
- Therefore, engage legal counsel (internal or external) from each partner to:
 - Review draft agreements
 - Identify legal risks or conflicts
 - Refine governance and operational models

5. Finalize and Approve the Legal Framework

- Incorporate feedback from legal and institutional stakeholders
- Obtain necessary sign-offs from:
 - Institutional leadership (VCs, CEOs, DGs)
 - Legal and compliance units
 - Donor or government authorities (if needed)
- Finalize governing documents (MoU or Terms of reference)
- Ensure legal alignment with business case

6. Prepare Implementation and Governance Instruments

- Draft additional documents, such as:
 - Terms of Reference (ToRs) for the Steering Committee

- Standard Operating Procedures (SOPs)
- IP and data-sharing agreements
- Reporting and accountability mechanisms

7. Document and Report on the Legal Framework

- Deliver a comprehensive legal framework report, including:
 - Legal analysis
 - Partnership model
 - Institutional responsibilities
 - Draft legal instruments
 - Implementation recommendations

2.1.4 WP2 Deliverables:

1. Collaborative framework guidelines.
2. Legal Framework Options Analysis
3. Final Partnership Agreement or MoU
4. Proposed governance/ownership structure
5. Legal framework report with annexes

Key Milestones

Milestones / Process Steps / Partial Services	Deadline	Place	Person Responsible
1. Review Legal and Regulatory Context	Months 1–5	Desktop research / Legal databases	Contractor Legal Expert
2. Develop a Draft Partnership Agreement	Months 5–7	Contractor's offices / Virtual meetings	Contractor Legal Expert with input from GIZ
3. Ensure Compliance with Institutional Requirements	Months 8–9	Institution-specific sites / Online	Contractor in consultation with partner legal teams
4. Facilitate Legal Review and Negotiation	Months 10–12	Virtual meetings / Hybrid	Contractor, with GIZ coordinating
5. Finalize and Approve the Legal Framework	Months 13–14	GIZ / Stakeholder sign-off meetings	Contractor finalizes, GIZ ensures sign-offs
6. Prepare Implementation and Governance Instruments	Months 15–16	Contractor and stakeholder sites	Contractor drafts, reviewed by stakeholders
7. Document and Report the Legal Framework	Months 17–18	Submitted to GIZ	Contractor compiles and submits final report

Period of assignment: from 03.11.2025 until 30.04.2027.

The assignment is expected to commence on 03.11.2025 and conclude by 30.04.2027, with each report/workshop to be delivered within a specified time frame agreed upon with the SAVax team. The

contractor will be required to submit the final report within two weeks after the conclusion of the last workshop. Interim payments to be provided at key milestones will be determined in consultation with SAVax team.

3. Concept

In the tender, the tenderer is required to show *how* the objectives defined in Chapter 2 (Tasks to be performed) are to be achieved, if applicable under consideration of further method-related requirements (technical-methodological concept). In addition, the tenderer must describe the project management system for service provision.

Note: The numbers in parentheses correspond to the lines of the technical assessment grid.

3.1 Technical-methodological concept

Strategy (1.1): The tenderer is required to consider the tasks to be performed with reference to the objectives of the services put out to tender (see Chapter 1 Context) (1.1.1). Following this, the tenderer presents and justifies the explicit strategy with which it intends to provide the services for which it is responsible (see Chapter 2 Tasks to be performed) (1.1.2).

The tenderer is required to present the actors relevant for the services for which it is responsible and describe the **cooperation (1.2.1)** with them. The tenderer is responsible for elaborating a strategy for cooperation and then cooperating with the relevant actors (1.2.2).

The tenderer is required to present and explain its approach to **steering** the measures with the project partners (1.3.1) and its contribution to the **results-based monitoring system** (1.3.2).

The tenderer is required to describe the key **processes** for the services for which it is responsible and create an **operational plan** or schedule (1.4.1) that describes how the services according to Chapter 2 (Tasks to be performed by the contractor) are to be provided. In particular, the tenderer is required to describe the necessary work steps and, if applicable, take account of the milestones and **contributions** of other actors (partner contributions) in accordance with Chapter 2 (Tasks to be performed) (1.4.2).

The tenderer is required to describe its contribution to knowledge management for the partner (1.5.1) and GIZ and to promote scaling-up effects (1.5.2) under **learning and innovation**.

3.2 Project management of the contractor (1.6)

The contractor is required to explain its approach for coordination with the GIZ project. In particular, the project management requirements specified in Chapter 2 (Tasks to be performed by the contractor) must be explained in detail (1.6.1).

The contractor is required to draw up a personnel assignment plan with explanatory notes that lists all the experts proposed in the tender; the plan includes information on assignment dates (duration and expert days) and locations of the individual members of the team complete with the allocation of work steps as set out in the schedule (1.6.2). The contractors backstopping strategy (including CVs of the senior consultant and the key expert 1) (1.6.3).

The contractor is expected to organize two workshops: one for stakeholder mapping and another for validating data from Work Package 1 (WP1) and Work Package 2 (WP2).

1. Kick-Off Meeting

Held between GIZ, the contractor, and Network representatives to align on:

- Objectives and scope
- Roles and responsibilities

- Timeline and deliverables
- Points of contact and communication channels
- 2. Regular Project Steering Meetings
Monthly or bi-monthly meetings organized by the contractor with:
 - Contractor lead(s)
 - GIZ technical team
 - Select Network representatives
 - Purpose: To monitor progress, resolve challenges and to align on decisions or changes
- 3. Stakeholder Consultations and Validation Workshops
These will be led by the contractor but co-facilitated by GIZ to ensure:
 - Inclusive engagement of all relevant institutions
 - Transparent communication
 - Shared ownership of outputs
- 4. Reporting and Quality Control
 - Contractor submits progress reports every 6 months, draft deliverables, and a final report to GIZ
 - GIZ provides structured feedback
 - GIZ may also appoint technical reviewers or external experts to review outputs (especially the legal framework)

Backstopping

The tenderer is required to describe its backstopping concept. The following services are part of the standard backstopping package, which (like ancillary personnel costs) must be factored into the fee schedules of the staff listed in the tender in accordance with Section 3.3.1 of the GIZ AVB:

- Service-delivery control
- Managing adaptations to changing conditions
- Ensuring the flow of information between the contractor and GIZ
- Assuming personnel responsibility for the contractor's experts
- Process-oriented steering for implementation of the commission
- Securing the administrative conclusion of the project

4. Personnel concept

The tenderer is required to provide personnel who are suited to filling the positions described, on the basis of their CVs (see Chapter 7), the range of tasks involved and the required skills and qualifications.

The activities in these Terms of Reference (TORs) allow for up to 1 Senior Consultant and one consultant. The senior consultant will be responsible for the overall management and oversight of the contract, including technical, financial, and logistical aspects of the activities and deliverables described above. The below-specified qualifications and experience represent the requirements to meet the maximum number of points in the technical assessment.

Senior Consultant

Tasks of the team leader

- Overall responsibility for the advisory packages of the contractor (quality and deadlines)
- Coordinating and ensuring communication with GIZ, partners and others involved in the project
- Regular reporting in accordance with deadlines
- Conduct Market Analysis – Perform a detailed market analysis to identify the demand and supply dynamics for preclinical GLP toxicology services in South Africa and the wider region. Assess the current gaps and challenges in the toxicology testing landscape, including cost implications, timelines, and control issues.
- Build a Business Model – Propose a sustainable business model that ensures the long-term viability and competitiveness of the Network.

- Organize two workshops: one for stakeholder mapping and another for validating data from Work Package 1 (WP1) and Work Package 2 (WP2).

Qualifications of the team leader

- Education/training (2.1.1): university degree (Master's) in (Business Administration, Finance, Strategy, Economics and any related fields)
- Language (2.1.2): C2 -level language proficiency in English language
- General professional experience (2.1.3): All professionals with 10 years of professional experience in the business sector
- Specific professional experience (2.1.4): At least 5 years of experience in conducting or managing market analyses, feasibility studies, or business case development in the biomanufacturing sector
- Leadership/management experience (2.1.5): Minimum 5 years of management/leadership experience as a project team leader or senior manager in a company, consultancy, or public institution.
- Regional experience (2.1.6): At least 10 years of experience in projects in South Africa.
- Development Cooperation (DC) experience (2.2.7): Minimum 3 years of experience in DC projects, ideally with bilateral or multilateral development partners
- Other (2.2.8): Strong facilitation and stakeholder engagement skills, especially for organizing workshops and participatory processes.

Key expert 1

Tasks of key expert 1

- Draft Legal Framework – Draft the legal framework necessary to establish and operate the Preclinical GLP Toxicology Network, ensuring compliance with international standards and regulatory requirements.
- Outline Governance Structure – Outline the governance structure for the Network, including roles and responsibilities of different stakeholders.
- Ensure Collaborative Framework – Ensure the legal framework supports collaboration among diverse stakeholders, including academia, regulatory bodies, and industry.

Qualifications of key expert 1

- Education/training (2.2.1): Master's or higher in Law (LLB).
- Language (2.2.2): C2 -level language proficiency C2 in English
- General professional experience (2.2.3): At least 10 years of professional legal experience, including advising on and drafting legal or regulatory frameworks.
- Specific professional experience (2.2.4): Minimum 5 years of experience in drafting legal documents such as MoUs, contracts, legal frameworks, or governance agreements for multi-stakeholder projects. Experience with legal drafting in development cooperation settings, including public-private partnerships or donor-funded initiatives. Familiarity with regulatory and institutional frameworks in the relevant sector (e.g. health, education, environment).
- Leadership/management experience (2.2.5): N/A
- Regional experience (2.2.6): Experience working in Southern Africa or Sub-Saharan Africa is required.
- Development Cooperation (DC) experience (2.2.7): Minimum 3 years of experience working on development cooperation projects, preferably with international donors, NGOs, or UN agencies.
- Other (2.2.8): Strong analytical, communication, and negotiation skills. Proven ability to work in multicultural and multi-disciplinary environments. Familiarity with gender-responsive or human rights-based legal approaches is an asset.

Soft skills of team members

In addition to their specialist qualifications, the following qualifications are required of team members:

- Team skills
- Initiative
- Communication skills
- Socio-cultural skills
- Efficient, partner- and client-focused working methods
- Interdisciplinary thinking

5. Costing requirements

Assignment of personnel and travel expenses

Per diem allowances are reimbursed as a lump sum up to the maximum amounts permissible under tax law for each country as set out in the country table in the circular from the German Federal Ministry of Finance on travel expense remuneration (downloadable from the [German Federal Ministry of Finance – tax treatment of travel expenses and allowances for international business travel as of 1 January 2024/2025 \(GERMAN ONLY\)](#)).

Accommodation allowances are reimbursed as detailed in the specification of inputs below. With special justification, additional Accommodation costs up to a reasonable amount can be reimbursed against evidence. All business travel must be agreed in advance by the officer responsible for the project.

Sustainability aspects for travel

GIZ has undertaken an obligation to reduce greenhouse gas emissions (CO₂ emissions) caused by travel. When preparing your tender, please incorporate options for reducing emissions, such as selecting the lowest emission booking class (economy) and using means of transport, airlines and flight routes with a higher CO₂ efficiency. For short distances, travel by train (second class) or e-mobility should be the preferred option.

CO₂ emissions caused by air travel must be offset. GIZ specifies a budget for this, through which the carbon offsets can be settled against evidence. There are many different providers in the market for emissions certificates, and they have different climate impact ambitions. The [Development and Climate Alliance \(German only\)](#) has published a [list of standards \(German only\)](#). GIZ recommends using the standards specified there.

Specification of inputs

Fee days	Number of experts	Number of days per expert	Total	Comments
Designation of TL	1	45	45	
Designation of key expert	1	25	25	
Travel expenses	Quantity	Number per expert	Total	Comments

Per-diem allowance in country of assignment	16	2	32	
Overnight allowance in country of assignment	15	2	30	
Transport	Quantity	Number per expert	Total	Comments
International flights				Travel to the place of service delivery
Domestic flights	10	2	20	Flights within the country of assignment during service delivery
CO₂ compensation for air travel				A fixed budget of EUR is earmarked for settling carbon offsets against evidence.
Travel expenses (train, car) • Shuttles	8	2	16	Travel within the country of assignment, transfer to/from airport etc.
Other travel expenses	8	2	16	What other travel costs, please name them
				s: .
Other costs	Number	Price	Total	Comments
Flexible remuneration				A budget of EUR is foreseen for flexible remuneration. Please incorporate

				this budget into the price schedule. Use of the flexible remuneration item requires prior written approval from GIZ.
Workshops	2		200, 000 ZAR	The budget includes the following costs: the venue, catering, and equipment to run the workshop.
Other costs				The budget contains the following costs .

Workshops, events, and trainings

GIZ and/or other actors are expected to make the following available:

- Names and contacts of the secretaries/leads of the GLP toxicology Network
- Additional names and contacts of key stakeholders
- Additional key questions for the workshop evaluation and feedback, which will be included in the course monitoring reports

6. Requirements on the format of the tender

The structure of the tender must correspond to the structure of the ToR. In particular, the detailed structure of the concept (Chapter 3) should be organised in accordance with the positively weighted criteria in the assessment grid (not with zero). The tender must be legible (font size 11 or larger) and clearly formulated. It must be drawn up in English.

The complete tender must not exceed 12 pages (excluding CVs). If one of the maximum page lengths is exceeded, the content appearing after the cut-off point will not be included in the assessment. External content (e.g. links to websites) will also not be considered.

The CVs of the personnel proposed in accordance with Chapter 4 of the ToRs must be submitted using the format specified in the terms and conditions for application. The CVs shall not exceed 4 pages each. They must clearly show the position and job the proposed person held in the reference project and for how long. The CVs must be submitted in English.

Please calculate your financial tender based exactly on the parameters specified in Chapter 5 Quantitative requirements. The contractor is not contractually entitled to use up the days, trips, workshops or budgets in full. The number of days, trips and workshops and the budgets will be contractually agreed as maximum limits. The specifications for pricing are defined in the price schedule.

7. Outsourced processing of personal data

The contractor will ensure compliance with all processing of personal data to ensure compliance with the General Data Protection Regulation (GDPR), and Protection of Personal Information Act (POPIA). Data processing and management protocols will be drafted and agreed with the GIZ project team prior to collection of any data from data subjects related to the execution of this contract.

The data protection and information security provisions set out in the most recent GIZ AVB (section 1.10 Data Protection) apply.