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1. PURPOSE

The purposes of this procedure are to describe the Terms of Reference for the appointment of contracts to External Auditors to:

a) design and carry out the assignments specified below under International Auditing Standards and the scope and procedures of this engagement.

Audits have the purpose of establishing whether:

- The accounts give a true and fair view;
- The control systems put in place function properly;
- The underlying transactions are legal and regular

b) to perform an opinion on the operation of the control system of PRIMA.

This opinion will accompany the annual report sent by PRIMA to the European Commission according to Article 19 of the Delegation Agreement (DA).

- the control systems put in place function properly;
- the underlying transactions are legal and regular and
- the audit work puts in doubt the assertions made in the management declaration

2. SCOPE

This procedure applies to the following tasks:

2.1. AUDIT OF PRIMA-IS FINANCIAL STATEMENTS

The purpose is to produce 2023, 2024, and 2025 financial statements under IPSAS and submit them for audit/certification.

The Audit review of PRIMA-IS Financial Statements aims to ensure that the financial management and control of budget operations comply with relevant legislation, budget descriptions, International Public Sector Accounting Standards (IPSAS), and the principles of sound financial management, transparency, efficiency, effectiveness, and economy. The Auditor will provide a report expressing an opinion on the examined financial statement.

2.2 AUDIT ON INTERNAL CONTROL SYSTEMS

To ensure that the procedures approved by the Foundation are being carried out correctly. The Auditor will provide a report which will express an opinion on the selected tested on each chapter of the current document and state the factual findings for each.

3. ABBREVIATIONS/ACRONYMS

- DIS  Dedicated Implementation Structure
- EC   European Commission
- DA   Delegation Agreement
4. TERMS OF REFERENCE.

4.1. DESCRIPTION OF REQUESTED SERVICES

The requested services for 2023, 2024 and 2025 will be the following:

4.1.1. AUDIT OF PRIMA-IS FINANCIAL STATEMENTS

The auditors will be asked to conduct an audit in accordance with International Standards on Auditing issued by the International and Assurance Standards Board on PRIMA-IS financial statements. Those standards require that the auditors plan and perform the Audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement. The audits shall be conducted to obtain evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditors' judgment, including assessing the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the Auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements to design audit procedures that are appropriate in the circumstances, but not to express an opinion on the effectiveness of the entity's internal control. Audits also include evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management and evaluating the overall presentation of the consolidated financial statements. In particular, the following shall be audited:

- Cash management: review bank reconciliations, count on-hand cash, confirm restrictions on bank balances, and issue bank confirmations.
- Accounts receivable: confirm account balances.
- Fixed Asset Management: observe assets, review purchase and disposal authorizations, review lease documents, examine appraisal reports, and recalculate depreciation, and amortization.
- Accounts payable. Confirm accounts, and test year-end cut-off.
- Accrued expenses. Examine subsequent payments, compare balances to prior years, recomputed accruals.
- Revenue: examine documents supporting the transfer of funds by the European Commission to PRIMA-IS.
- Expenses: examine documents supporting a selection of expenses, review subsequent transactions, and confirm unusual items with suppliers.

4.1.2. INTERNAL CONTROL SYSTEMS

The detailed table to be checked for the internal control systems is Annex 1.

4.1.2.1 Substantial changes in the control environment

The Auditor must confirm that the following information has been communicated to the European Commission (the "Commission"):

- Substantial changes to the dedicated implementation structure (DIS) systems, rules, or procedures that relate to the management of the entrusted EU funds
• A significant change in the DIS legal, financial, technical, organizational, or ownership situation

4.1.2.2 Risk assessment
Obtain the DIS risk register and confirm that there is a risk response for each risk identified. In case of critical risks, confirm that the Commission has been informed.

4.1.2.3 Whistleblowing and Fraud Follow-up
Obtain the internal DIS reporting on whistleblowing and fraud cases and confirm that if an investigation is mentioned in the reporting, a follow-up by the DIS is indicated in the reporting.

4.1.3 GRANTS
4.1.3.1 Awarding grants (Article 7 of the DA)
Obtain a list of all Calls for the grant awarded during the year and confirm for 50% of calls (selected randomly) with a minimum of 2 calls and 5 proposals by call that:

• the call was mentioned in the work plan and has been published
• admissibility and eligibility checklist as completed for all applications under the related call(s);
• the independent review took place with 3 independent reviewers;
• if it is a joint call with third countries or third parties, confirm that the evaluation and selection procedure involves a balanced group of independent experts appointed by each party;
• the members of the evaluation committee sign the evaluation report with the final ranking list;
• the BoT made the formal decision to award the grants;
• Indicate issues arising from the above verification and those reported by:
  o the evaluation report
  o the observer report, if applicable

4.1.3.2 Request for redress
Indicate the number of requests for redress received by PRIMA. Give the number of appeals and the number of cases lost by the DIS.

4.1.4 RULES AND PROCEDURES FOR APPOINTING EXPERTS
Confirm for 10% of experts involved in the selection and monitoring processes with a minimum of 10 experts (selected randomly) that they have signed a declaration of absence of conflict of interests.

Indicate if the rules applied by the DIS for selecting experts comply with the H2020 Rules for Participation and Decision 2017/1324.

4.1.5 PROCUREMENT
4.1.5.1 Obtain the details/breakdown of contracting costs
Obtain the detail/breakdown of contracting costs, which are registered under other actions and administrative expenses and select a random sample of cost items (full coverage is required if there are fewer than 10 items; the selection should have a minimum of 10 items, or 10% of the total, whichever number is highest).
• If it concerns pre-commercial procurements or procurement of innovative solutions the Auditors verify that the provisions of the rules for participation are followed (DA Article 8).
• suppose the Beneficiary did not fall under the above-mentioned category for the items included in the sample. In that case, the Auditor verifies that the DIS followed its rules and procedures on procurements and indicates any non-compliance, specifically those related to the thresholds for open procedures.
• For the items included in the sample, verify that:
  o when it concerns other actions, it was mentioned in the work plan
  o there were signed agreements between the Beneficiary and the contractor;
  o there was evidence that the contractor provided the services/equipment.

4.1.5.2 Unsuccessful tenderers
Indicate the number of complaints of unsuccessful tenders received by PRIMA. Give the number of appeals and the number of cases lost by the DIS

4.1.6 ADMINISTRATIVE EXPENDITURE
4.1.6.1 Personnel directly assigned to the implementation of the program
Allocation of staff costs are based on actual hours and actual salary according to the ex-ante assessment- For 10% of the persons paid under the PRIMA program with a minimum of 5 persons selected randomly, verify:
• a contract is signed, and the payroll paid in December is compliant with the contract and promotions
• the person is assigned to the implementation of PRIMA
• timesheets are signed and reviewed by the line manager
• reconcile the details of costs calculated and allocated to PRIMA with:
  o the end-of-year calculation of hours by a project approved by the DFA
  o the end of year calculation of salaries paid

4.1.6.2 Other direct costs
For a random sample of 10% for each of the following categories of other direct costs assigned to the implementation of the PRIMA program, verify that internal PRIMA rules are followed and check compliance with:
• Missions
• Service contracts
• Consumables and supplies
• Depreciation of equipment
• Costs fees for Audit of annual statutory accounts

4.1.7 PUBLICATION OF INFORMATION ON RECIPIENTS AND EXPERTS
The information on recipients of EU Funds (for grants and contracts) and experts is published annually on the DIS website in compliance with DA Article 16.
4.1.8 MANAGEMENT DECLARATION
Declare that the audit work performed does not put in doubt the assertions made in the management declaration (DA Article 19 (d) (iv) opinion independent body).

4.1.9 IMPLEMENTATION OF THE RECOMMENDATIONS OF THE EX-ANTE ASSESSMENT
Document in an annexe to this questionnaire the review of the implementation of the recommendations of the ex-ante assessment (provided in the annexe to the DA). The review will be presented by recommendation, mentioning the work performed and the conclusion(s) on the implementation.

4.1.10 EARLY DETECTION AND EXCLUSION SYSTEM
Auditors check that Articles 15.1 and 15.3 have been complied with by the DIS.

4.2. REQUIREMENTS.

4.2.1. GENERAL PRINCIPLES.
PRIMA-IS requires an audit firm to be:

- An independent professional audit firm (private sector) which is a member of an established national Accounting or Auditing Body (IFAC) must perform under the applicable national standards on auditing, and these standards comply with International Standards on Auditing ('ISAs') issued by the International Auditing and Assurance Standards Board (IAASB).
  The audit company must sign the Code of Conduct of PRIMA-IS, which establishes the fundamental ethical principles of PRIMA-IS. Also, the Auditor shall perform the Audit according to the Code of Ethics, which sets the basic ethical principles for auditors, compliant with the IFAC code of ethics for professional accountants, issued by IFAC's International Ethics Standards Board of Accountants (IESBA). The audit firm shall provide evidence of the adoption of such a Code of Ethics is written. The audit company must guarantee the maximum independence of the Auditor to processes and activities object of the assignment.

- A national audit institution or Supreme Court of Auditors are INTOSAI (International Organization of Supreme Audit Institution) members. In this case, the Audit shall be performed under the applicable national standards on auditing, which shall comply with INTOSAI Standards.
  The auditors must sign the Code of Conduct of PRIMA-IS, which establishes the fundamental ethical principles of PRIMA-IS. Also, the Auditor shall perform the Audit according to the Code of Ethics, which sets the basic ethical principles for auditors, compliant with the INTOSAI code of ethics (ISSAI 30) or equivalent. Auditors shall provide evidence of the adoption of such a Code of Ethics is written. The audit company must guarantee the maximum independence of the Auditor concerning the processes and activities object of the assignment.

Also, the signatory of the Audit Firm shall declare under their responsibility that the audit firm:

a) Is not bankrupt or is being wound up, where the court is administering the affairs of the applicant, nor has entered into any arrangement with creditors, nor has suspended business operations or is any analogous situation arising from a similar procedure under national laws and regulations
b) is not the subject of proceedings for a declaration of bankruptcy, for an order for a compulsory winding up or administration by the court or of an arrangement with creditors or any other similar proceedings under national laws and regulations

c) has not been convicted of any offence under the legal provisions of the country of any offence concerning the applicant’s professional misconduct

d) has not been guilty of grave professional misconduct

e) has fulfilled the obligation to pay any taxes or social security under the law of the country of residence.

All information shall be treated confidentially.

4.2.2. PERSONNEL.

4.2.2.1. EXPERTS

This Terms of Reference contains expert profiles, and the tenderer shall submit CVs and Statement of Exclusivity and Availability for the experts.

All experts must be independent and free from conflicts of interest in the responsibilities accorded to them.

The Auditor shall employ adequate staff with appropriate professional qualifications and suitable experience with IFAC standards, particularly International Standards on Auditing and with experience in auditing the accounts of entities comparable in size and complexity to PRIMA-IS. Besides, the audit team as a whole should have:

Experience with audits of projects funded by national and international donors and institutions. The leader of the fieldwork team, i.e. either the audit manager or the senior Auditor, should have experience with audits of EU-funded actions;

It requires fluency in English for all the team.

All experts who have a crucial role in implementing the contract are called experts. The profiles of the experts for this contract are as follows:

Expert 1: Audit Partner

An audit partner must be a highly qualified expert with a relevant university or professional qualification, assuming or assuming senior and managerial responsibilities in the public audit practice. They should be a member of a national accounting or auditing body or institution. They must have at least 12 years of professional experience as a professional Auditor or accountant in the public audit practice.

An audit partner, or another person in a position similar to that of a partner, is the person of the audit firm responsible for the engagement and its performance and shall sign the report issued on behalf of the firm. They have the appropriate authority from a professional, legal, or regulatory body and are authorized to certify accounts by the laws of the country where the audit firm is registered.

The Auditor Partner is ultimately responsible for the engagement and an engagement team.
Expert 2: Senior Auditor

A senior auditor must be a qualified expert with a relevant university or professional qualification and at least three years of professional experience in public audit practice.

Other experts, support staff & backstopping.

CVs for experts other than the experts should not be submitted in the tender. The Auditor shall select and hire other experts according to the needs. The selection procedures used by the Auditor to choose these other experts shall be transparent. They shall be based on pre-defined criteria, including professional qualifications, language skills, and work experience.

Cost for backstopping and support staff, as needed, are considered to be included in the financial offer of the tenderer.

4.2.2.2. CURRICULA VITAE

The Auditor will provide PRIMA-IS with the CVs of the partner or other person in the audit firm responsible for the engagement and for signing the report together with the audit managers, supervisors, and staff proposed as part of the engagement team. CVs will include appropriate details on the type of audits and other engagements (particularly agreed-upon procedures) carried out by the staff, indicating capability and capacity to undertake the engagement and details on relevant specific experience.

PRIMA-IS will examine the CVs before it signs an order document for the engagement and will reject them if they are not considered suitable for the engagement requirements.

4.2.3. LOGISTICS AND TIMING

4.2.3.1. LOCATION

The expenditure verification will be performed at PRIMA-IS headquarters. PRIMA-IS will grant access to its headquarters for the auditing periods during the following working hours: from 9 AM to 6 PM.

4.2.3.2. COMMENCEMENT DATE & PERIOD OF IMPLEMENTATION OF TASKS

Both parts shall agree the commencement date after the signature of the contract and the period of implementation shall be twelve months from the commencement date.

4.2.4. REPORTS

Audit Opinion

Audit opinions can be unqualified, qualified, adverse, or a disclaimer of opinion and should be formulated under the format of the Independent Auditor’s Report for a Financial Audit. This format is included in the model report for a Financial Audit in Annex 1. The model report also provides guidance for the use of opinions.

The Auditors will submit reports in English and Spanish and, for each language, one original, a copy in paper, and an electronic version using MS Word, MS Excel, or PDF formats. The reports to be prepared for each assignment are:
• **Draft report** [in the format given in the corresponding Annex]. It is recommended that the Auditor submits a draft report to PRIMA-IS before issuing the final report to validate the findings (i.e., to sort out potential misunderstandings, additional information/documents to be provided, etc). This report shall be submitted no later than 5 days after the end of fieldwork.

• **A final report** with the same specifications as the draft final report, incorporating any comments received from the concerned parties on the draft report. The final report shall be provided by the latest three days after the receipt of the comments on the draft final report. The final report must be provided along with the corresponding invoice.

Reports shall cover at least:

- the results of the audits performed, in terms of number of audits, audit coverage in terms of amount audited in comparison with the amounts paid out to beneficiaries (for Audit on beneficiaries), conclusions and costs eventually disallowed;

- the nature, amount, and recurrence of the findings, and the costs categories affected and in particular whether any irregularity or fraud has been discovered;

- any consequences from errors/irregularities identified (if applicable);

- any fraud or irregularity that was highlighted during the audits.

The report referred to above must be submitted to the contact person that shall be identified in the contract. The contact person is also responsible for approving the reports.

### 4.3 ECONOMICAL OFFER

The economic offer must be detailed per each year and include the price for all the services described in point 4.1 (Description of the services required) separately:

2. Price for Audit on the PRIMA internal control systems.

### 4.4 PRESENTATION OF PROPOSALS

The documentation will be submitted via email to the address: pau.guell@prima-med.org.

The body of the email must indicate the following:

• Title of the contract: Contract for the **Financial Audit and internal control systems reports for 2023-2025**

• Company details: Address, telephone, email, and contact person for communications and relations that generally derive from this procedure.

The maximum presentation term is 3rd November at 13h CET.

Proposals must be typed or in other mechanical or computer printing types and written in English. The authorized representative of the company must sign all sheets of the proposal. All documentation must be submitted in digital format (PDF format). Technical offers submitted must have a limited length: they may not exceed 10 DIN-A4 pages, using the Arial 11 font and single-line spacing. Where applicable, PRIMA reserves the right to request additional clarifications or information regarding the technical offer submitted.
4.5 PROPOSAL ASSESSMENT AND EVALUATION

At the end of the period for the receipt of proposals, the Evaluation Committee constituted by PRIMA will proceed with an internal and non-public act to examine and assess the proposals.

If any of the tenders submitted does not comply with these Terms and Conditions, and the defect detected is not correctable, it will be excluded from the contracting procedure. If the defects are rectifiable, a time limit will be set for them to submit the appropriate amendment. Among the proposals submitted, the Evaluation Committee will conduct an evaluation of the technical offer taking into consideration the technical description of the service, according to the following evaluation criteria:

1- Definition and planning of the service, both strategy and execution • Team Work • Service organisation • Coordination of tasks • Follow-up reports and meetings • Results of the service
2- Economic proposal
3- Experience in auditing projects funded by the European Commission under the framework programs FP7, H2020, and Horizon Europe. Experience in audits of public subsidies at a national and international level will also be valued.

The announcement of the company selected for the execution of the service will be communicated via email directly and published on PRIMA's website.

ANNEX 1: Internal Control Systems

ANNEX 2: Code of Conduct