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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 annual accounts of PRIMA.

This opinion will accompany the annual report that PRIMA sends to the European Commission under 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 2026, 2027, and 2028 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 exanimated 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 assurance to all points in Annex 1, confirming the selected tests in each chapter of the current document and stating 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 2026, 2027 and 2028 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 Auditing and Assurance Standards Board, of 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 an assessment of the risks of material misstatement in 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, and recompute 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:
    - the evaluation report
    - 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 interest.

Indicate if the rules applied by the DIS for selecting experts comply with the HE 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 for procurement and identifies any non-compliance, specifically those related to the thresholds for open procedures.
- For the items included in the sample, verify that:
    - When it concerns other actions, it was mentioned in the work plan
    - there were signed agreements between the Beneficiary and the contractor;
    - 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 is 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:
    - the end-of-year calculation of hours by a project approved by the DFA
    - 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

Information on recipients of EU Funds (for grants and contracts) and on 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 annex to this questionnaire the review of the implementation of the recommendations of the ex-ante assessment (provided in the annex to the DA). The review will be presented with a recommendation, detailing the work performed and the conclusion(s) regarding 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 PRIMA-IS's Code of Conduct, which establishes PRIMA-IS's fundamental ethical principles. Also, the Auditor shall perform the Audit in accordance with the Code of Ethics, which sets out the basic ethical principles for auditors and is aligned 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 that it has adopted the Code of Ethics. The audit company must guarantee the Auditor's maximum independence in the processes and activities subject to the assignment.
- A national audit institution or Supreme Court of Auditors is an INTOSAI (International Organisation of Supreme Audit Institutions) member. In this case, the Audit shall be performed in accordance with the applicable national auditing standards and shall comply with the INTOSAI Standards.
  The auditors must sign PRIMA-IS's Code of Conduct, which establishes PRIMA-IS's fundamental ethical principles. Also, the Auditor shall perform the Audit in accordance with the Code of Ethics, which sets out the basic ethical principles for auditors, and be compliant with the INTOSAI code of ethics (ISSAI 30) or an equivalent. Auditors shall provide evidence that the Code of Ethics has been adopted. The audit company must guarantee the Auditor's maximum independence with respect to the processes and activities that are the subject 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

These Terms of Reference contain expert profiles, and the tenderer shall submit CVs and a Statement of Exclusivity and Availability for the experts.

All experts must be independent and free from conflicts of interest when performing their responsibilities.

The Auditor shall employ adequate staff with appropriate professional qualifications and suitable experience with IFAC standards, particularly the International Standards on Auditing, and with experience 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 English fluency for the entire 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 and assume senior and managerial responsibilities in the public audit practice. They should be members of a national accounting or auditing body or institution. They must have at least 12 years of professional experience as an Auditor or accountant in 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 authorised 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 the 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 as needed. 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.

The cost of backstopping and support staff, as needed, is considered included in the tenderer's financial offer.

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 types of audits and other engagements (particularly agreed-upon procedures) carried out by the staff, indicating capability and capacity to undertake the engagement, and details of relevant specific experience.

PRIMA-IS will review the CVs before signing the engagement order document 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 during the audit periods from 9 AM to 6 PM.

4.2.3.2. COMMENCEMENT DATE & PERIOD OF IMPLEMENTATION OF TASKS

Both parties shall agree on the commencement date upon signing the contract, and the implementation period shall be 3 years from that 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, with one original in each language, a paper copy, and an electronic version in MS Word, MS Excel, or PDF format. 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 submit a draft report to PRIMA-IS before issuing the final report to validate

the findings (e.g., to address potential misunderstandings, identify any 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 within 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 the number of audits, audit coverage in terms of the 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 who shall be identified in the contract. The contact person is also responsible for approving the reports.

4.3 ECONOMIC OFFER

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

1- Price for Audit for PRIMA Annual Financial Accounts.
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 2026-2028**
• Company details: Address, telephone, email, and contact person for communications and relations that generally derive from this procedure.

The maximum presentation term is 24th November at 13h CET.

Proposals must be typed or printed by other mechanical or computer methods and written in English. The authorised 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 be limited to 10 DIN-A4 pages, using Arial 11 font and single-line spacing. Where applicable, PRIMA reserves the right to request additional clarification or information regarding the submitted technical offer.

4.5 PROPOSAL ASSESSMENT AND EVALUATION

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

If any of the tenders submitted do 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 submitting 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: 30%
2- Economic proposal: 30%
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: 40%

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

ANNEX 1: Internal Control Systems

ANNEX 2: Code of Conduct