INFO SESSION

Service contract to design, develop, deliver and maintain HERA's Advanced Technology for Health INtelligence and Action IT System (ATHINA)

HADEA/2023/OP/0005

Introduction

Agnès Mathieu-Mendes
Head of Unit A2, EU4Health and SMP Food
HaDEA

Meeting settings

Please note that:

- Your microphone and camera have been turned off for the duration of this webinar;

- The chat and participants' list are disabled;

- In case of technical issues, you can still contact the organisers (HaDEA Webex C – tech support) via the Webex chat.

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Contacts

- Any request for additional information about this call for tenders must be submitted in writing via Ted eTendering in the "Questions & answers" tab of the call

- Deadline to submit your questions: 16/06/2022, 23:59 (CEST)

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Agenda

14:30	**Welcome** Angelo Marino, Head of Department A , Health and Food - HaDEA
14:35	**Policy context and political priorities** *Political relevance of ATHINA* Laurent Muschel, Deputy Head of HERA
14:45	**What is ATHINA** *Main highlights of the call, objectives, budget available* Jaime LOPEZ LOOSVELT, IT Portfolio Officer - DG HERA Maria LOUREIRO, Intelligence Analyst - DG HERA Athanasios LAPATINAS, Intelligence Analyst - DG HERA
15:15	**How to participate in the ATHINA call for tender** *Overview of technical and administrative steps to submit requests to participate* Stepan Svoboda, Head of Sector A2.3 - HaDEA
15:25	**Closing remarks** Agnès Mathieu-Mendes, Head of Unit A2 - HaDEA

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Welcome

Angelo Marino
Head of Department A, Health and Food Safety
European Health and Digital Executive Agency (HaDEA)

What is ATHINA

Jaime Lopez Loosvelt, IT Portfolio Officer
Maria Loureiro, Intelligence Analyst
Athanasios Lapatinas, Intelligence Analyst

HERA 02- Intelligence Gathering, Analysis and Innovation

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ATHINA will support HERA activities

HERA's intelligence gathering and threat assessment activities must:

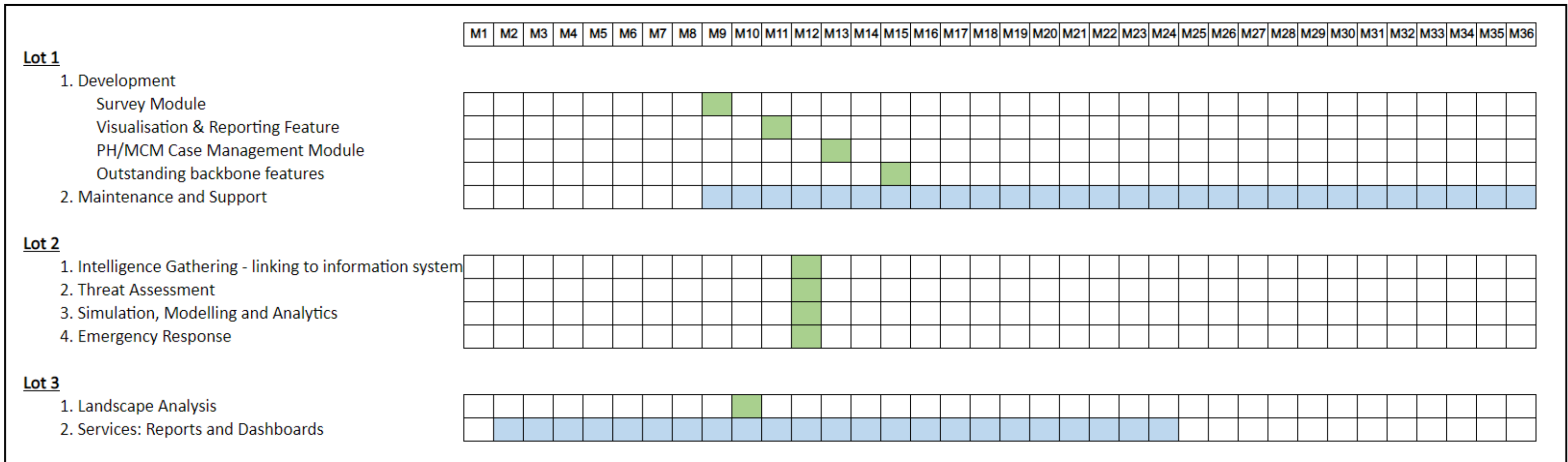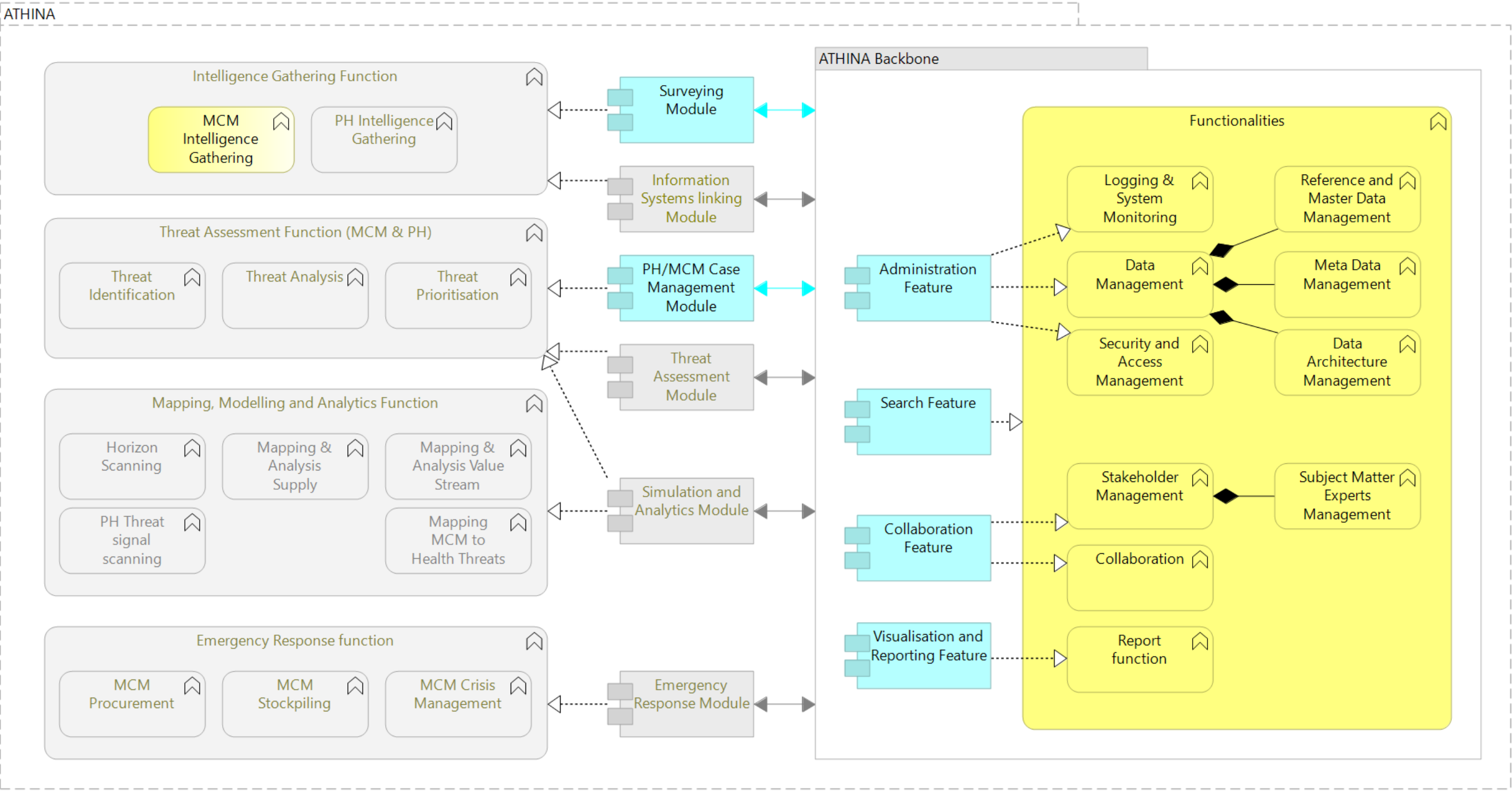| Pick up signals on health threats requiring medical countermeasures (MCM) response and threats related to the supply of MCM in preparedness times	Provide an early/anticipatory assessment of the health threat identified, and response options for decision/policymaking concerning MCM	Track MCM supply chains, addressing shortages and vulnerabilities

Therefore, HERA has launched a call for tenders in order to develop an IT system (ATHINA) to support its daily activities and generate actionable insights for decision-making

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Project timeline

This call is divided into three lots:

	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33	M34	M35	M36
Lot 1																																				
1. Development																																				
Survey Module									■																											
Visualisation & Reporting Feature											■																									
PH/MCM Case Management Module													■																							
Outstanding backbone features															■																					
2. Maintenance and Support									▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨
Lot 2																																				
1. Intelligence Gathering - linking to information system												■																								
2. Threat Assessment												■																								
3. Simulation, Modelling and Analytics												■																								
4. Emergency Response												■																								
Lot 3																																				
1. Landscape Analysis										■																										
2. Services: Reports and Dashboards		▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨												

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ATHINA Modules

Lot Number 1

Development and maintenance of ATHINA state-of-the-art backbone, survey module and Public Health (PH) and Medical Countermeasures (MCM) case management

Lot 01 – Context and Objectives

- Development and maintenance of ATHINA state-of-the-art backbone, survey module and Public Health (PH) and Medical Countermeasures (MCM) case management

- Design, development, delivery and maintenance of an IT system to support HERA daily activities

Task	Description
Task 01	Initiation and planning - refinement of requirements and design of the Surveying Module, PH/MCM Case Management Module and of the "Backbone" of ATHINA
Task 02	Execution – development, testing and acceptance of the Surveying Module, the PH/MCM case management module and of the "Backbone" of ATHINA
Task 03	Closure
Task 04	Maintenance and support

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Lot 01 – Activities

Task 1

Task 01 represents the **Initiation and Planning** stage for the project. It includes the **refinement of requirements** and **design** of the Surveying Module, PH/MCM Case Management Module and of the "Backbone" of ATHINA

Activities

- A01: Initiation of the ATHINA Project and configuration of environments (e.g. testing, production, stress tests, training)
- A02: Requirements refinement (including security and data protection aspects) and design analysis
- A03: Assessment of hosting/housing needs and drafting of technical requirements and specifications

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Lot 01 – Activities

Task 2

Task 02 represents the **execution** stage of the project. Its main activities are the **development, testing and acceptance** of the Surveying Module, the PH/MCM case management module and of the "Backbone" of ATHINA

Activities
- A04: Finalization of hosting and housing proposal
- A05: IT Solution Development
- A06: Testing activities and Code Reviews
- A07: Deployment of any modules or components into the production environment (according to Deployment Plan)
- A08: Drafting and submission of the Training Plan (see expected Volume and Timetable of Trainings in Annex 17)

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Lot 01 – Activities

Task 3

Task 03 is the **closing** of activities for this lot.

Activities

- A09: Execution of the training activities (drafting training material, conducting training sessions, drafting training evaluation forms)
- A10: Execution of the project Handover
- A11: Drafting sustainability plan, including risks and mitigation actions for the future of ATHINA
- A12: Drafting Final Progress Report

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Lot 01 – Activities

Task 4

Task 04 represent the **maintenance and support activities** for the modules developed and implemented in the context of this lot.

Activities

- A13: Registration, analysis and tracking of all incidents and defects raised by any user.
- A14: Providing support to the user and meeting to present status of the incidents and proposed resolution plan
- A15: In the resolution process of incidents leading to defects, impact assessment, development, drafting and execution of corresponding test cases, including regression, security and performance tests if applicable, followed by the implementation of change requests in accordance with the decisions taken in the Change Management Board.
- A16: Maintenance of the ATHINA backbone and modules from the moment of the deployment of the first modules of ATHINA in the production environment until the end of the contract

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Lot 01 – Cost information

- This tender requests a proposal for a cloud solution.

- The cloud costs details are expected over 36 months.

It must be noted that the **system's cloud services costs will be procured as part of Cloud II**, a contract already established between the cloud provider and the European Commission and should not be budgeted in the Financial Offer.

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Lot Number 2

Functional analysis of ATHINA modules on information systems linking, threat assessment, simulation and analytics and emergency response

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Lot 02 – Context and Objectives

Lot 2 aims at further analysing the provided business requirements, translating them into functional and potentially non-functional requirements for the **remaining modules.**

- The future <u>information systems linking module</u> that will interconnect to other systems to support HERA's intelligence gathering function.

- A module allowing for <u>simulation and analytics</u> to manage threats and related MCM to see and interact with a threat case.

- A <u>threat assessment module</u> to support threat identification and prioritisation by retrieving information on criteria such as the burden on health, likelihood of entering and spreading in the EU and at global level, availability and accessibility of efficient MCM, level of preparedness.

- An <u>emergency response module</u> that will support HERA in the sharing of information and reporting on actions to reduce/mitigate health threats during a crisis phase.

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Lot 02 – Tasks

The following tasks shall be carried out by the contractor:

Task	Description
01	Initiating and planning
02	Analysis of the information systems linking module
03	Analysis of the threat assessment module
04	Analysis of the simulation and analytics module
05	Analysis of the emergency response module
06	Closing

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Lot 02 – Tasks (in detail)

Task 1

The scope of this task is to **plan and manage the inception of the projec**t and it shall cover all the activities of the Initiating phase in the PM2 Agile Methodology.
The Contractor will **setup the project team**, allocating the **key roles** and define a **comprehensive plan for the iterations and releases**.

Task 2

With this task, the contractor will **analyse the requirements for ATHINA to gather intelligence by exchanging data** (inbound and outbound) on MCM and PH from relevant databases (e.g., ECDC and EMA's), reusing existing systems (e.g., EIOS) and use other sources (e.g., OSINT).

Task 3

With this task, the contractor will **analyse the requirements for a threat assessment module** that will allow ATHINA to use PH and MCM intelligence to update a list of high-impact health threats requiring MCM preparedness, support rapid evaluation of health threats to identify the relevant MCM response and support MCM prioritisation.

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Lot 02 – Tasks (in detail)

Task 4

The contractor shall analyse functional needs for **further development of an ATHINA module for simulation and analytics**. This module will be **identifying and forecasting potential risks** to the supply chain networks of MCM, assessing the potential impact of these risks, and identifying strategies for their mitigation and management.

Task 5

The contractor shall analyse functional needs for further development of an ATHINA module for **emergency response**. This module will enable HERA to assist the **crisis/consequence management community** in planning, deploying, and monitoring response actions in case of a PH emergency

Task 6

This task implements the activities in the last phase of the PM2 Agile Methodology and **focuses on all final deliverables and documentation**. The artefacts specified in the PM2 Agile Methodology shall be provided.

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Lot Number 3

Analytics as managed services

Lot 03 – Context and Objectives

- ATHINA will be complemented by data analytics as managed services <u>both on MCM and PH intelligence</u>, provided on a subscription and/or pay-per-use basis (excluding databases and services already available to the Commission), to ensure access to relevant information and services (for HERA to use in addressing its needs and scope) before the full development of the IT system.

- The contractor shall provide <u>access to market analytics</u> for pharmaceutical ingredients and chemicals sectors, as well as market insights to enhance HERA's understanding of the market, including information about the market size, segments key players, and trends. The market analytics service provided by the contractor shall also cover commercial and regulatory data on Active Pharmaceutical Ingredient (API), raw materials, components and intermediates.

Lot 03 – Context and Objectives

- The contractor shall also provide access to data analytics from service providers that will allow HERA to understand the flow of pharmaceutical products from manufacturer through wholesaler to outlet location. If necessary, the contractor can subcontract analytics and/or data services from different providers.

- The contractor will also explore additional analytics services providers for health emergency preparedness and response that could potentially be contracted for supporting the PH and MCM supply chain intelligence activities of HERA including forecasting.

Lot 03 – Context and Objectives

- Once agreed by HERA on the data analytics providers (in the inception phase), the contractor shall provide/subcontract access to MCM supply (from raw materials to final MCMs – including MCM developments) and PH intelligence in the form of:

    - Dashboards and/or platforms.

    - MCM intelligence ➡️ Regular detailed reports: the regularity of the reports will depend on the updates of the provided services/data, as well as on the ad-hoc needs/requests of HERA.

    - PH intelligence ➡️ Daily updates on the health signals/alerts picked up in the previous 24 hours from open sources (social media, news sources etc).

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Lot 03 – Tasks

Task 1

Initiation and Planning: The scope of this task is to plan and manage the inception of the project and it shall cover all the activities of the Initiating phase in the PM2 Agile Methodology. The Contractor will setup the project team, allocating the key roles and define a comprehensive plan for the iterations and releases.

Task 2

Analytics as Managed services: The scope of this task is to quickly acquire data and analytics as managed service on a pay-per-use and/or subscription basis from various services providers, for HERA to use the data and analytics services offered.

Task 3

Closing: This task implements the activities in the last phase of the PM2 Agile Methodology and focuses on all final deliverables and documentation. The artefacts specified in the PM2 Agile Methodology shall be provided.

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Questions?

Please submit your questions via **TED eTendering**

Overview

This call for tenders is divided into 3 lots:

Lot number	Lot title	Budget (€)
1	Development and maintenance of ATHINA state-of-the-art backbone, survey module and Public Health (PH) and Medical Countermeasures (MCM) case management	16 000 000
2	Functional analysis of ATHINA modules on information systems linking, threat assessment, simulation and analytics and emergency response	3 000 000
3	Analytics as managed services	4 900 000

Tenders may be submitted for any of the three lots or for all three lots.

The contracting authority has chosen to award the contracts resulting from this call for tenders through an open procedure pursuant to Article 164(1) (a) of the Financial Regulation.

Who may submit a tender?

Tender Specification, paragraph 2.2 'Entities subject to restrictive measures and rules on access to procurement: who may submit a tender?'

General rules

- Participation in this call for tenders is open on equal terms to <u>all natural and legal persons</u> coming within the scope of the Treaties, as well as to international organisations.

- It is also open to all natural and legal persons established in a third country provided that it has a special agreement with the European Union in the field of public procurement on the conditions laid down in that agreement.

Specific situations are addressed in the same paragraph.

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Who may **not** submit a tender?

- Tenderers must ensure that no involved entities nor any subcontractors, including those which do not need to be identified in the tender are subject to EU restrictive measures adopted under Article 29 of the Treaty on the European Union (TEU) or Article 215 of the Treaty on the Functioning of the EU (TFEU)23, consisting of a prohibition to make available or transfer funds or economic resources or to provide financing or financial assistance to them directly or indirectly, or of an asset freeze. The prohibition applies throughout the whole performance of the contract.

- Following the Council Implementing Decision (EU) 2022/2506, as of 16th December 2022, no legal commitments can be signed with Hungarian public interest trusts established under Hungarian Act IX of 2021 or any entity they maintain. This applies to all contractual level commitments, including subcontractors.

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Registration in the Participant Register and Submission of the Tenders

- Any economic operator willing to participate in this call for tenders must be registered in the <u>Participant Register</u> - an online register of organisations and natural persons (participants) participating in calls for tenders or proposals of the European Commission and other EU institutions/bodies.

- Tenders are to be submitted via the <u>eSubmission application</u> according to the instructions laid down in the Invitation letter and the eSubmission Quick Guide available at the link: <u>https://wikis.ec.europa.eu/display/FTPortal/Open+procedures_EN</u> (*see section 4.1*)

Tender Specifications: Evaluation and Award

The evaluation of the tenders that comply with the submission conditions will consist of the following elements:

- Check if the tenderer is not subject to restrictive measures and has access to procurement (*see Section 2.2*);

- Verification of administrative compliance (if the tender is drawn up in one of the official EU languages and the required documents signed by duly authorised representative(s) of the tenderer);

- Verification of non-exclusion of tenderers on the basis of the exclusion criteria (*see Section 3.1*);

- Selection of tenderers on the basis of selection criteria (*see Section 3.2*);

- Verification of compliance with the minimum requirements specified in the procurement documents (see Section 3.3);

- Evaluation of tenders on the basis of the award criteria (see Section 3.4).

Exclusion Criteria (Section 3.1)

- The objective of the exclusion criteria is to assess whether the tenderer is in any of the exclusion situations listed in Article 136(1) of the Financial Regulation. Tenderers found to be in an exclusion situation will be rejected.

- As evidence of non-exclusion, each tenderer needs to submit with its tender a Declaration on Honour in the model available in Annex 2.

- Please see Section 3.1 'Exclusion criteria'

The documents mentioned in the Declaration on Honour as supporting evidence on non-exclusion must be provided with the tender

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Selection Criteria (Section 3.2)

- The purpose of the selection criteria is to determine whether a tenderer has the capacity necessary to implement the contract.

- <u>Selection criteria are verified on a pass/fail basis.</u>

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SELECTION CRITERIA (*Section 3.2*)

3.2.1 Legal and regulatory capacity

- Tenderers can be natural or legal persons.

- Tenderers are not obliged to take a specific legal form in order to submit their tenders.

- Tenderers do **not** need to prove specific legal and regulatory capacity to perform the contract.

3.2.2 Economic and financial capacity

- Please refer to Criterion F1 for each Lot.

- All details are included in section *3.2.2 Economic and financial capacity*

Economic and financial capacity (Section 3.2.2)

Important:

The minimum level of economic and financial capacity for tenderers submitting tenders for two or more lots should be the average yearly turnover of the last two financial years equal to the aggregate of the respective lots. I.e. if applying for Lot 1 and 2, average yearly turnover of the last two financial years must be EUR 6 500 000 (Lot 1 EUR 5 000 000 and Lot 2 EUR 1 500 000).

<u>All of the above-specified evidence of economic and financial capacity must be provided with the tender.</u>

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Technical and professional capacity (Section 3.2.3)

LOT 1, LOT 2 and LOT 3

Criterion T1

A list of projects meeting the minimum level of capacity is requested.

Criterion T2

The tenderer must demonstrate the ability to provide a Core Team with the specified expertise for each Lot.

All details are included in section 3.2.3 Technical and professional capacity of the Tender Specifications.

All of the above-specified evidence of technical and professional capacity must be provided with the tender.

3.4 Award criteria

- The objective of the award criteria is to evaluate the tenders with a view to choosing the most economically advantageous tender.

- Tenders will be evaluated on the basis of the following award criteria and their weighting:

Price: 30%

The price considered for evaluation will be the total price of the tender, covering all the requirements set out in the tender specifications.

3.4 Award criteria

Quality: 70%

- **Award criterion 1**: Methodology

- **Award criterion 2**: Appropriateness of the organisation of the work and resources

- **Award criterion 3**: Quality of the measures implemented for a continuous high performance, including quality control and, data protection strategy and cybersecurity

Please refer to Section 3.4 for all the details.

Content of the tender: documents to submit

Technical tender

- The technical tender for any lot must provide all the information needed to assess the compliance with Section 1.4 of these specifications and the award criteria

- When submitting the technical tender it is **highly recommended** that the tenderer:
  - limits the technical tender to a **maximum of 50 pages**, excluding evidence provided for the assessment of exclusion and selection criteria, such as CVs, past projects or profit and loss accounts, cover page and annexes, etc.;
  - and uses Times New Roman font with a minimum font size of 11, A4 page size and all margins (top, bottom, left, right) at least 15 mm (excluding any footers or headers).

Content of the tender: documents to submit

Financial tender

- The Financial Model in Annex 6 shall be used.

- One Financial Form for each Lot.

- Any modification of the template of the financial tender may lead to rejection of the tender.

Tenderers willing to submit tenders for more than one lot need to upload a separate technical and financial tender for each of the lots in which they are interested.

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Contact during the procedure

- Any request for additional information and request of clarification must be made in writing only through the TED eTendering website in the "Questions & answers" tab:

- Any other additional information will be published on the TED eTendering website

Upload of latest Annexes

25/05/2023: A new package of documents was uploaded.

02/06/2023: New draft contract:

Main changes:

- Compliance check following the adoption of the new Belgian Civil Code.

- Additional provisions in order to allow the upcoming onboarding to eProcurement.

- New model Annex has been published on "Group members' shares in total contract value for VAT purpose" for joint tenders.

Timeline

- **25 April 2023:** Publication of the call for tenders

- **16 June 2023**, 23:59 (CEST): Deadline to submit your questions via Ted eTendering

- **23 June 2023**, 16:00 (CEST): Deadline for submission of tenders

- **27 June 2023**, 10:00 (CEST): Opening of tenders

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Useful Links
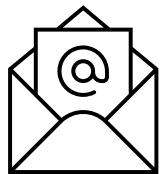
TED e-tendering to ATHINA call for tenders

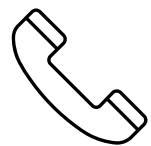**Funding & Tender Opportunities Portal**

Participant Register

Detailed instructions on how to submit a tender

Technical help

Contact the tender platform support team, from 08:00 to 20:00 CEST:

ec-funding-tender-service-desk@ec.europa.eu

+32 (0) 229 71063

The support team operates in **English only.**

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Closing remarks

Agnès Mathieu-Mendes
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