Call for tenders HADEA/2023/OP/0036

Speed up the development of and access to innovative medical countermeasures

Open Procedure

TENDER SPECIFICATIONS

Annual Work Programme 2023

CP-p-23-15 Support to speed up the development of, access to and/or uptake of innovative technologies and critical medicines (HERA)

Model version of 14-06-2023

TABLE OF CONTENTS

1 SCOPE AND DESCRIPTION OF THE PROCUREMENT

1.1 Contracting authority: who is the buyer?

This call for tenders is launched and managed by the European Health and Digital Executive Agency, (henceforth "HaDEA"), referred to as *contracting authority* for the purposes of this call for tenders.

HaDEA, acting under the powers delegated by the European Commission (henceforth "the Commission"), is launching the present invitation to tender for the conclusion of service contracts (henceforth "the contracts").

HaDEA was established on 16 February 2021. HaDEA implements parts of the following Union programmes:

a. EU4Health Programme
b. Single Market Programme: Food safety
c. Horizon Europe, Pillar II, cluster 1: Health
d. Connecting Europe Facility: Digital
e. Digital Europe Programme
f. Horizon Europe, Pillar II, cluster 4: Digital, industry and space

The Agency is entrusted by the Commission with programme implementation tasks and works closely with the Directorate-General for Communications Networks, Content and Technology; Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs; Directorate-General for Research and Innovation; Directorate-General for Defence Industry and Space; Directorate-General for Health and Food Safety and Directorate-General for Health Emergency Preparedness and Response.

1.2 Subject: what is this call for tenders about?

The subject of this call for tenders is to conclude service contracts for purchasing clinical and concurrent non-clinical development[1] services in view of developing innovative medical countermeasures (MCMs) and speed up availability and access to them. By medical countermeasures we refer to medicines and medical supplies that can be used to diagnose, prevent or treat diseases that could become a serious cross-border threat to health[2].

[1] For the purpose of this tender "concurrent non-clinical development" refers to all activities which are not clinical services but are relevant in the context of the clinical development of the candidate. This explicitly excludes pre-clinical development of the candidate.

[2] "Medical countermeasures' are defined under Article 3 of the Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R2371&qid=1693388351191.

The scope of the call for tenders focuses on the speed up of the development of promising vaccines, medicinal products and diagnostics, that are indicated to diagnose/detect, prevent, protect from, or treat conditions associated to serious cross-border health threats and to the acquisition of the priority right to purchase to ensure access to the investigational medicinal products (IMPs) and products. The products can be at different stages of the product development lifecycle. Any supply contracts devoted to purchasing the medical countermeasures, possibly developed as a result of the implementation of the contracts to following the call, are not in the scope of the present procedure.

1.3 Lots: is this call for tenders divided into lots?

This call for tenders is divided into 4 lots (see details in table below), according to the different medical countermeasures (MCM) targeted under this action.

Lot number	Lot title	Maximum value of the contract (million EUR)
1	Vaccines to combat antimicrobial resistance (AMR)	22
2	Broad spectrum antivirals against respiratory diseases	18
3	Broad spectrum antivirals to treat viral-haemorrhagic fevers	18
4	Point of care metagenomic sequencing for universal pathogen detection	24
	Maximum total amount of all purchases	**82**

The contracting authority envisages to conclude four (4) direct contracts, one for each of the lots. Tenders may be submitted for one or several lots. Economic operators submitting tenders for more than one lot must submit a tender for each lot. Each lot will be assessed independently of any other lot.

If economic operators submit tenders for more than one lot but their validity is declared as being conditional to the award of any of the lots, all submitted tenders will be rejected.

In case tenderers apply as a group of economic operators (*de jure* or *de facto*), members of this group cannot participate as a sole tenderer or a member of another group for the same lot.

1.4 Description: what do we want to buy through this call for tenders?

This call for tenders aims at purchasing services to speed up the development of and support the access to medical countermeasures which address HERA's priority threats, as defined in July 2022[3]. The list of the top three health threats is: 1) agents with pandemic potential, 2) chemical, biological, radiological and nuclear threats and 3) threats resulting from antimicrobial resistance. To accelerate development and support access to MCMs, the requested services include the provision of clinical and concurrent non-clinical development services and the priority right to purchase the promising products (Investigational Medicinal Product - IMP for

[3] List of top-3 health threats to prepare against (europa.eu)

lots 1, 2 and 3 and product for lot 4), that shall allow bringing innovative products to the market and ensure EU/EEA access to them. A detailed description of the priviledged access is outlined in section 1.4.2.

Clinical services refer to activities to be carried out after the successful completion of the Phase I clinical trial and needed for the conduct of the clinical trials in Phase II and III, e.g., assessment of clinical findings, hence all activities for the module 5 of clinical trial in the marketing authorisation application. Concurrent non-clinical development services also refer to activities needed for the manufacturing of the Investigational Medicinal Product (IMP), hence all activities for the module of quality in the marketing authorisation.

The purchases that are the subject of this call for tenders, including any minimum requirements, are described in detail below (sections 1.4.1, 1.4.2 and 1.4.3).

1.4.1 Background and objectives

The European Health Emergency Preparedness and Response Authority (HERA) as announced in the Commission Communication "Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union" of 16 September 2021[4], has been set up to "strengthen Europe's ability to prevent, detect, and rapidly respond to cross-border health emergencies, by ensuring the development, manufacturing, procurement, and equitable distribution of key medical countermeasures".

Promoting research on key and emerging pathogens and other health threats as well as incentivising advanced research, innovation and development of relevant technologies and countermeasures – including diagnostics, therapeutics, and vaccines – is an important aspect of HERA's work during the preparedness Phase. In synergy with Horizon Europe, HERA has earmarked funding to support innovation, access, and uptake of medical countermeasures under the EU4Health Programme, in order to ensure innovative MCMs availability and accessibility at Union level.

This call for tenders implements the action "CP-p-23-15 Support to speed up the development of, access to and/or uptake of innovative technologies and critical medicines (HERA)" laid down in the EU4Health 2023 work programme. This action will contribute towards general objective (c) and specific objective (c) of the EU4Health Regulation[5].

1.4.2 Detailed characteristics of the purchase

For this call for tenders, "medical countermeasures" including vaccines, therapeutics, broad spectrum antivirals and innovative diagnostics that are under development, e.g. clinical trials, investigations and/or performance evaluations being either on-going or close to be initiated, are targeted. The innovative MCMs to be developed shall address specific health threats further described in the tender specifications.

[4] COM (2021) 576 final

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0522

The services to be purchased by the contracting authority (HaDEA) related to the clinical and concurrent non-clinical development activities under the different lots are illustrated in Figure 1 and Figure 2 below:

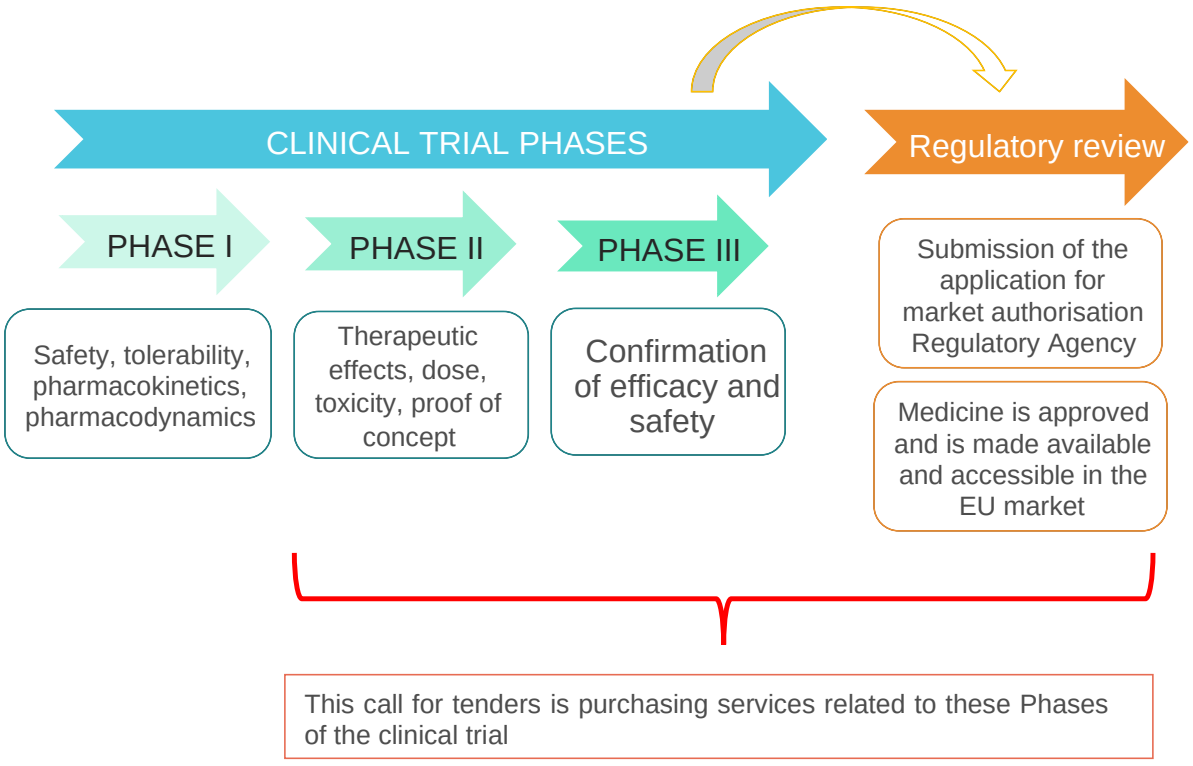

Figure 1 – Scope of this call for tenders for Lots 1, 2 and 3.

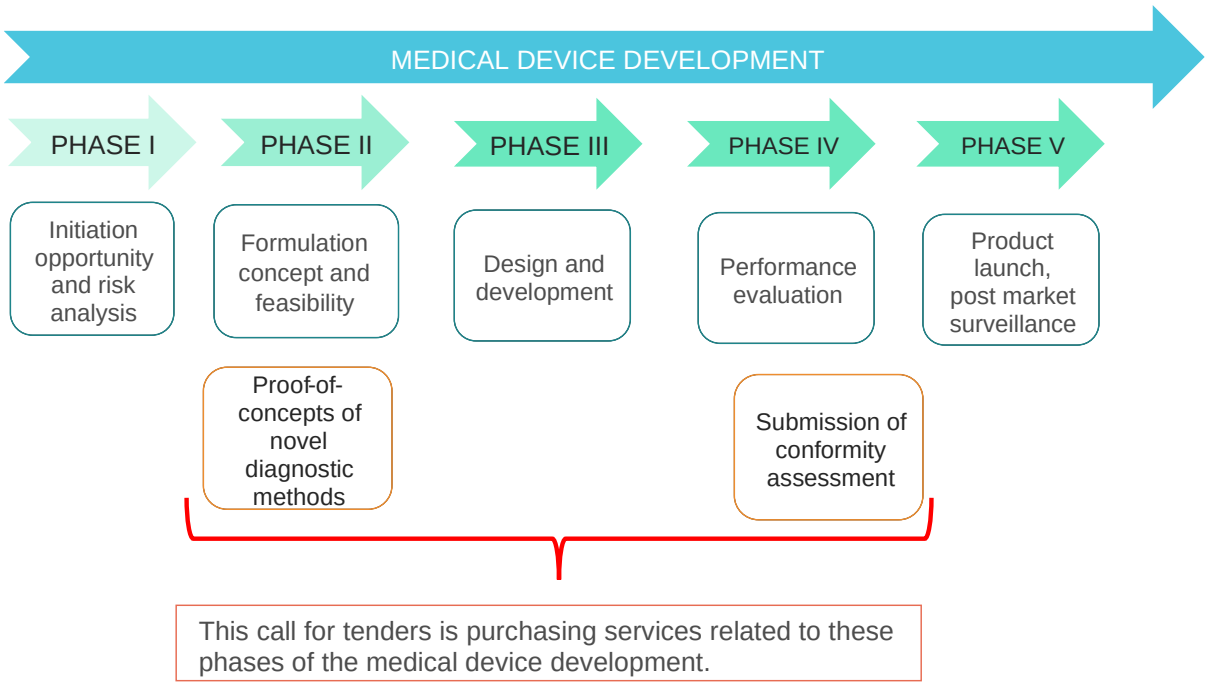

Figure 2 – Scope of this call for tenders for Lot 4.

This procurement procedure aims at enabling the EU/EEA to have privileged access to promising and innovative products for:

- preparedness purposes

  or

- response to crisis situations,

regardless of whether the product is still in the investigational Phase or has been placed on the market.

The priviledged access envisaged in this call for tenders refers to (1) the priority right to purchase and (2) the obligation to ensure exclusive reservation production upon notification. These are explained in detail below.

(1) Right to purchase

It relates to the priority right to purchase by the contracting authority and/or the European Commission the products (in the form of investigational medicinal products (Lot 1, 2 and 3), or medical devices (Lot 4)) being developed by the contractors awarded under each of the lots. To this end, the contracting authority and/or the European Commission shall have the right to activate the right to purchase, whenever deemed necessary to address needs arising during e.g. a crisis situation to facilitate compassionate use.

The contractor shall include in the technical tender a unit price for a minimum of 2 000 IMPs (for Lot 1, 2 and 3 respectively) or 200 products (Lot 4). These minimum volumes will allow to acquire the IMP/performance products produced during the clinical/performance development. The specificities of this particular call (e.g. financial capacity criteria, the scale of the clinical activities and the volume of the priority rights) have been designed to facilitate the submission of tenders by Small and Medium Enterprises (SMEs).

The contracting authority and/or European Commission are not obliged to purchase the above-mentioned products and/or quantities. The contracting authority and/or European Commission can exercise their priority right to purchase at any time during a three (3) year time period after the end of the contract. Where the contracting authority and/or the European Commission exercise their right to purchase, the ensuing separate contract will be based on a price not higher than the price per unit offered in the technical tender submitted under the present procedure, unless, the contracting authority and/or the European Commission agrees to a different unit price, following due justification by the contractor. Where the contracting authority and the European Commission exercise their right to purchase, the IMPs and/or final products ordered shall be received according to the timelines proposed in the technical offer and further elaborated in the potential supply contract. The contracting authority and/or European Commission shall be able to donate the doses at their discretion.

The contracting authority and/or the European Commission may exercise its right to purchase for lower quantities than the minimum amount indicated in technical offer. In that case, the right to purchase shall not cease for the outstanding quantities. To be noted that the intention to purchase the products may be triggered by a health threat emergency (crisis situations) and/or due to global market dynamics of medical countermeasures (preparedness purposes).

(2) Obligation to ensure production upon notification

Irrespective of the effective exercise of the priority right to purchase, the contractors shall be obliged to ensure sufficient production capacity for the volume of IMPs and products indicated in their technical tenders in order to facilitate access during a timeframe of three (3) years after the end of the contract. The obligation to ensure this production capacity is subject to the notification to the contractor by the contracting authority and/or the European Commission. Notification shall be sent in written form not later than two (2) months after submission of the final report. At the end of the three (3) years after the end of the contract, the awarded contractors are entitled to release the production capacity and any of the stock products, without any liability or obligation to the contracting authority or the European Commission.

The technical tender shall include a description of the remaining technical details relating to the priority right's exercise, mentioning the unit price per dose/unit, plans/existing structure for manufacturing stockpiling (if already available the manufacturing authorisation), supply and distribution of the products to the EU/EEA.

Under each lot, further detail is provided regarding the types of activities foreseen for the acceleration of development of specific MCMs.

1.4.2.1 Minimum requirements

The following shall be considered as constituting the tenders' minimum requirements of the offer.

The tenderers shall include in their offers a detailed explanation of how their products address market gaps in the field of MCMs and why these specific products are relevant for preparedness and response to cross-border health threats. The products to be supported shall demonstrate the EU added value[6] and the rationale for the need of public funding. Under this light, tenderers shall explain how they will ensure EU/EEA market readiness and access to the product once its development is completed and is close to be commercialised.

In their offers, tenderers shall identify the stages of their MCM product development lifecycle, and specially detail on the phases of the development activities that could benefit from EU support through the contract, with an adequate justification. In this respect, offers shall present an implementation plan of the development of the product accompanied by a Gantt chart outlining the activities, the milestones, and deliverables to be achieved during the timeframe of the contract.

In summary, the submitted offers shall include, in detail, the following key elements:

ALL LOTS

a. EU added value and the rational for the need of public funding;

[6] **European added value** means the value resulting from an EU intervention which is additional to the value that would have otherwise been achieved by Member State action alone or an action by a group of Member States.

b. Implementation plan which must specify the current stage of development of the product and the expected steps to advance further on the innovation throughout the duration of the contract. The implementation plan must take into consideration the end goal for each of the lots, and it has to be accompanied by a Gantt chart outlining the clinical and non clinical activities for lots 1 – 3 and the development activities for lot 4 to be performed and the milestones to be attained taking into consideration the schedule of progress reports and final report requested; a detailed timeline respecting section 1.4.2 and 1.4.3 timetables shall be provided in the tender;

c. Breakthrough innovation description, including when relevant:

- public health benefits (e.g., expected impact on mortality and morbidity rates in the EU/EEA and in the world),
- lack of alternatives for the same indication/intended use or improved health outcomes when compared with existing alternatives, information showing that the product has a better efficacy and safety profile, or the device speeds up the obtention of results or is more sensitive,
- development time and cost,
- ease of use.

d. Level of development, including:

- key milestones,
- existing reviews and authorisations by authorities (if relevant).
    - A preliminary roadmap/actionable plan for placing the product on the EU/EEA market – to be revised and updated in accordance with the implementation of the tasks.

e. A description of the technical details relating to the priority right's exercise, mentioning the unit price per dose/unit, plans/existing structure for manufacturing stockpiling (if already available the manufacturing authorisation), supply and distribution of the products to the EU/EEA;

f. The composition of the project team, with clear roles and tasks' distribution of each member commensurate to the resources and tasks to be performed as part of this call for tenders. In case of joint tender, the role and tasks of each member and of the Group leader who will act as the contracting authority's contact point for the contract's administrative or financial aspects and operational management must be clearly indicated.

LOTS 1, 2 AND 3

g. The explanation of the clinical trials/development and concurrent non-clinical development activities/performance studies foreseen, the timelines for the submission of the clinical trial protocol to regulatory authorities or performance studies, the choice of location(s) and infrastructure where the services will be performed, the choice for study protocol (e.g. sample size of patients to be recruited, as well as clinical trial workflow and capabilities foreseen in the submission of the clinical trial application for Phase II), as well as, in a more general manner, activities that will be developed concomitantly for the specific product candidate, but not under this contract, and how they are interrelated;

h. Product description and indication/intended use;

   a. For lot 1: the product shall target at least one of the twelve bacterial families classified as "priority pathogens" in the 2017 WHO Bacterial Priority Pathogens List[7]. The tender may also target *Mycobacterium tuberculosis.*

   b. For lot 2: the product shall target broad-spectrum antivirals targeting respiratory RNA viral families, such as *Paramyxo-, Orthomyxo and Coronaviridae.*

   c. For lot 3: the product shall target viral families known for causing viral haemorrhagic fever (VHF), such as *Arena-, Bunya-, Flavi-, Filoviridae*.

i. Level of development, including:

   - The clinical trial authorisation and, when possible, proof that vaccine candidates have successfully completed at least Phase I clinical studies,
   - For Lots 2 and 3, if the active substance is already authorised, the market authorisation in the EU.

j. Indicate the risk of drug resistance (for Lot 2 and 3), by explaining how it was/it will be addressed during early development of the product and overall scientific considerations that support the broad use of the product;

k. A detailed data management plan of the clinical trials (including trial master file template, case report form design, among other), as well as a robust methodology for technological measurement, and a statistical analysis plan, allied with the EU regulatory requirements;

l. A product risk assessment and mitigation measures plan.

LOT 4

m. The explanation of the device development and detailed information on the attributes mentioned in table 1 under section 1.4.2.4;

n. Product description and indication/intended use;

   a. For lot 4: the product is a metagenomic next-generation sequencing (mNGS)-based device that can detect any respiratory viral pathogen, including novel and emerging, from human respiratory samples;

o. A clear regulatory strategy, outlining a regulatory path to market that ensures compliance with all legal requirements and a performance evaluation plan;

p. A project risk management and performance evaluation plan as required by the IVDR;

q. A detailed plan underpinning the submission of an application seeking EU certification, meaning relevant EU conformity assessment procedure in accordance with the In Vitro Diagnostic Medical Device Regulation - IVDR (EU) 2017/746, that will allow for the placing of the device on the EU market.

[7] WHO publishes list of bacteria for which new antibiotics are urgently needed

1.4.2.2 Lot 1 – Vaccines to combat antimicrobial resistance (AMR)

Background

The increase of antimicrobial resistance (AMR) has become a pressing global health concern as it limits the availability of effective antibiotics in treating life threating infections. In recognition of its seriousness, AMR has been listed as a top priority health threat by the Commission[8]. On 13 June 2023, the Council adopted the Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach[9]. The Recommendation emphasises the need to reduce the unnecessary use of antibiotics and to increase investment in research and innovation to develop new antimicrobial agents, diagnostic tools, and alternative treatment strategies.

Objectives of Lot 1

In line with these efforts, Lot 1 of this call aims to speed up the development of vaccine candidates targeting bacterial infections as an alternative treatment strategy to address the rising incidence of AMR. Such vaccines offer a potential solution by preventing infections and consequently reducing the use of antibiotics[10].

The identified vaccine candidates shall be designed to target bacteria belonging to at least one of the twelve bacterial families classified as "priority pathogens" in the 2017 WHO Bacterial Priority Pathogens List[11]. These families encompass *Acinetobacter baumannii, Pseudomonas aeruginosa, Enterobacteriaceae, Enterococcus faecium, Staphylococcus aureus, Helicobacter pylori, Campylobacter spp., Salmonellae, Neisseria gonorrhoeae, Streptococcus pneumoniae, Haemophilus influenzae, Shigella spp.*. The tender may also target *Mycobacterium tuberculosis*[12].

Vaccine candidates must have shown promising biological activity based on immunogenicity data of Phase I and safety data from Phase I clinical trials. Lot 1 aims at supporting the advancement of vaccine candidates that have successfully completed at least Phase I clinical studies (see figure 1 above).

This call for tenders foresees the support:

- for further (and more precise) characterisation of immunogenicity, and safety of the vaccine candidate (within Phase II clinical trials), as well as clinical trials and concurrent non-clinical development of Phase III vaccine trials;

[8] List of top-3 health threats to prepare against (europa.eu)
[9] Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach (europa.eu)
[10] The role of vaccines in combatting antimicrobial resistance | Nature Reviews Microbiology
[11] WHO publishes list of bacteria for which new antibiotics are urgently needed
[12] WHO stresses urgent need for R&D for drug-resistant TB alongside newly-prioritized antibiotic-resistant pathogens

- the assessment of the candidate's efficacy and further assessment of safety (within Phase II clinical trials), as well as any development that helps identify the most promising preparation, dose, and schedule to be tested in Phase III clinical trials.

When relevant and duly justified (e.g., lack of commercial interest or another type of market failure that leads to crowding out investments and partnerships), tenders may only cover the assessment of a primary efficacy endpoint of Phase III trials, specifying the measure of the disease-related outcome of public health interest, such as mortality or disease morbidity, that supports the vaccine candidate indication for use.

The offer shall contain the approval (or provide evidence to be in the process of obtaining approval) to run a clinical trial for Phase II. Clinical trials should be ideally planned in one or several EU/EEA Member States. Justification should be provided where the Phase II clinical trials are conducted entirely outside the EEA. When possible, tenderers shall aim to conduct clinical trials in multiple countries, including the EU Member States/EEA countries and to include groups of people across different populations (age group, severity of the disease to be treated, gender). In this context, the offer should detail the methodology for recruitment and possible challenges, to obtain more robust study results.

More so, offers shall propose a detailed data management plan of the clinical trials (including trial master file template, case report form design, among other), as well as a robust methodology for technological measurement, and a statistical analysis plan, allied with the EU regulatory requirements. If applicable, the offer should provide information regarding the sponsor[13] of the clinical trial.

The offer shall contain an implementation plan of the development of the vaccine candidate, which must specify the current stage of development of the product and the foreseen steps to advance further on the support to the innovation throughout the duration of the contract. The implementation plan must clearly identify the end goal and it must be accompanied by a Gantt chart outlining the clinical and non clinical activities to be performed and the milestones to be attained taking into consideration the schedule of progress reports and final report requested below. The reasoning behind the timeframe shall be justified regarding the expected end-goal to be accomplished. This shall include the completion and publication, or at least communication of, the clinical trial Phase paid by the contract, or other clearly defined research results.

Additionally, the offer shall outline a preliminary roadmap for placing the product on the market and a plan fostering regular information update between the tenderer and the contracting authority. The contracting authority acknowledges that the clinical development might not be successful or regulatory approval may not be obtained and subsequently an authorised vaccine or IMP may not be available. Therefore, the offer shall also contain a risk assessment and mitigation measures plan to be updated should any changes occur throughout the implementation of the tasks.

[13] According to REGULATION (EU) No 536/2014 'Sponsor' means an individual, company, institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial.

The duration of the contract under Lot 1 will be 48 months – with submission of progress reports at M6, M12, M24, M36, and of a final report at M48.

Regular meetings with the contracting authority and DG HERA will take place every three months to monitor the implementation of the tasks and address potential challenges (these will be in general online or face to face in specific cases).

Detailed characteristic of the purchase

The following tasks shall be carried out by the contractor of Lot 1.

Task	Description
1	Initiation and risk management
2	Clinical and concurrent non-clinical development of the product(s)
3	Phasing-out

Task 1: Initiation and risk management

This task refers to the initiation and risk management of the project highlighting activities to be delivered during the entire period of the contract. This task foresees the presentation of a planning of the services to be performed including any update of the implementation plan.

Activities

- A1.1: Initiation, planning of the activities.

Deliverables:

- D1.1: Inception Report (M2)

The structure of the Inception Report is presented under section 1.4.3.

Task 2: Clinical and concurrent non-clinical development of the product(s)

This task includes all the activities necessary for the contractor to advance as much as possible with the clinical and concurrent non-clinical development of the product.

Activities relevant for **clinical development** within the scope of Lot 1 should include, but are not limited to:

- Project and data management tasks, as well as reporting and monitoring;
- Safety management and quality control tasks;
- Conduct feasibility evaluation and/or pre-study site visits/screening visits;
- Patients' recruitment, both within the EU/EEA, and outside the EU/EEA in duly justified cases. The contractor will not communicate any personal data to the contracting authority; anonymity will be fully respected;

- Securing the R&D supply chain of the clinical trial and administering the study protocol;
- Collection of samples/clinical assessment and measurement of biochemical or other indicators;
- Conducting on-site trial tasks, such as study visit attendance, protocol adherence and study logs;
- Development of documentation of adverse events, tracking of participant disposition, review board submissions and approvals;
- Monitoring and evaluation of recruiting sites, including preparation for inspections and audits;
- Statistical analysis;
- Submission package preparation for conducting the clinical trial phase II, documents, forms, and translations into English of the key documents;
- Authorisation of the clinical trials in relevant jurisdictions, including the EU and EEA, for Phase II.

Activities relevant for the **concurrent non-clinical development** within the scope of Lot 1 should support the clinical development of the vaccine candidate and include, but are not limited to, the following non-exhaustive list of possible activities:

- Good Laboratory Practice (GLP) experiments for the evaluation of chronic toxicity, reproductive and developmental toxicity, carcinogenicity and genotoxicity, carried out during the clinical phase of development;
- Quality documentation and required analytical procedures to produce such documentation in the context of manufacturing process (e.g., development, validation and evaluation); control of raw materials and starting materials; characterisation (e.g., integrity, impurities and homogeneity); control of the active substance; reference standards and materials; container and closure systems; and stability;
- Demonstrations related to formulation development, such as compatibility of materials used; requirements for products requiring additional preparation (e.g., reconstitution process is sufficiently robust and will not cause a negative impact on quality/safety/clinical properties); development of batch formula, control of excipients, control of the IMP, adventitious agents' safety evaluation;
- Addressing formulation optimisation, change or change in manufacturing, including necessary adaptations during clinical development, as well as development of activities related to the preparation, dose, and schedule to be tested in Phase III clinical trials;
- Further assessment of clinical findings.

In the tender, the tenderer shall specify, in detail, the content of the proposed activities and why they are necessary for the successful clinical development. The tender shall also specify, in a more general manner, activities that will be developed concomitantly for the specific vaccine candidate, but not under this contract, and how they are interrelated.

Even if the contract ends before the submission for marketing authorisation (i.e., submission of the Common Technical Document (CTD) to the relevant authority), all the activities under this task shall be performed in a manner that ensures compliance with marketing authorisation requirements and all the applicable legal framework, including the applications for clinical trials approvals submitted prior to submission of the tender.

The tender shall include all available data, at the time of tender submission, related to the product development lifecycle in the EU/EEA or in third countries.

Activities

- A2.1: Clinical and concurrent non-clinical development of product(s)

Deliverables

- D2.1: Progress report 1 (M6)
- D2.2: Progress report 2 (M12)
- D2.3: Progress report 3 (M24)
- D2.4: Progress report 4 (M36)

The structure of the **Progress reports** is described under section 1.4.3. It shall be accompanied by the following documents, as applicable, in line with the roadmap approved during the inception phase (see Activity A1.1):

- Copy of the clinical trial authorisation for the Phase II (if not already provided with the tender),
- Copy of EU Clinical Trial register, where applicable, for the Phase II,
- Written scientific advice from EMA or relevant national authority regarding the development of the product, or information about other engagement with regulatory authorities,
- Evidence that patient enrolment has started.

Report on patient enrolment results (end of recruitment). Each subsequent progress report shall contain the additional number of patients enrolled and results of the trials. Contractors are encouraged to get the clinical trial authorisation for the Phase II, at the latest, by the time of the Progress Report 2 (M12).

Task 3: Phasing-out

This task refers to the activities in the last period of the project and the submission of the draft and of the final report accompanied by all final deliverables and relevant documentation.

A draft final report shall be submitted no later than 46 months after the signature of the contract to provide sufficient time to evaluate and send back comments to be implemented in the final version.

The Final Report will describe all the work carried out and the results obtained. It will be accompanied by all final deliverables and relevant documentation.

A detailed description of the structure of the reports (inception, progress and final) is provided under section 1.4.3.

Publication and communication

The final report shall contain an executive summary for publication by the contracting authority highlighting the deliverables of the contract, a summary of the clinical trials results and concurrent non-clinical development activities. More details on the rules for publication are outlined under section *Requirements for publication on Internet.*

Activity

- A3.1: Drafting the Final Report

Deliverables

- D3.1: Draft Final Report (M46)
- D3.2: Final Report (M48) – including publication or communication of the clinical trial Phase or research results

1.4.2.3 Lot 2 and Lot 3 – Broad Spectrum antivirals

Background

Viral infections represent the biggest pandemic threat, and consistently pose a substantial economic and public health burden due to their ability to cross species barriers and cause unpredictable outbreaks of viral diseases in humans. The current strategy for the management of emerging and re-emerging viral diseases is heavily reliant on vaccines and antiviral treatment; however, because the development of novel antivirals is long, laborious, and often unprofitable, the current strategy for management of viral outbreaks is heavily reliant on the development of vaccines over antiviral treatments.

Nevertheless, while vaccines are an effective public health measure to stop community spread of a well-characterised virus, it is difficult to predictively develop vaccines against viral diseases that may emerge in the future. Therefore, the development of broad-spectrum antivirals (BSA), and BSA-containing drug combinations (BCC) can be a crucial key tool for pandemic preparedness when targeting HERA's defined viral families of concern as they target many viruses of the same family (pan-family inhibitors), or viruses belonging to different viral families (cross-family inhibitors). An important direction in the development of BSAs is to expand their antiviral activity, i.e., to find new targets. Given that the usual medicinal product discovery requires years to progress from target validation, to initial lead series identification and optimisation to select a candidate medicine for clinical trials, having invested in medicines discovery efforts during preparedness times aiming to build a robust pipeline of antiviral lead series and medicines candidates is essential to have more options available for clinical deployment when a new outbreak linked to agents with pandemic potential emerges.

Objectives of Lot 2 and 3

Lot 2 will support the development of broad-spectrum antivirals targeting respiratory RNA viral families, such as *Paramyxo-, Orthomyxo and Coronaviridae.*

Lot 3 will support the development of broad-spectrum antivirals targeting viral families known for causing viral haemorrhagic fever (VHF), such as *Arena-, Bunya-, Flavi-, Filoviridae*.

The antivirals subject of this call shall aim to (1) directly block viral targets and function (direct-acting antivirals), (2) have an anticipated efficacy against multiple species or genera in at least one, but preferably several viral families, (3) be preferably new chemical entities which include small molecules and small biotherapeutics like nucleic acids or peptides that are directly acting against viral targets and functions, i.e. not through the modulation of the host responses, (4) and preferably have safety profiles and suitable routes of administration (e.g. oral or intranasal) for broad use in the outpatient setting to treat early stages of infection by reducing viral burden.

Broad spectrum antivirals candidates supported under the scope of these two lots under this call for tenders have finalised pre-clinical data (proof of principle), which means that the medicine design can meet the pharmaco-therapy challenge established, as well as first-in-man studies characterising pharmacokinetics, potential effective concentration and/or dose ranges.

Additionally, tenderers will have to provide in their offers:

- the data of the Phase I clinical trial, which includes evidence of safety and tolerability, including margins, in healthy adult volunteers, including aggregated data on haematological and biochemical parameters; and data regarding suspected adverse reactions, local and system adverse effects, and serious adverse effects;
- a known and acceptable safety and toxicology profile as evidenced by Phase I results, or having obtained market authorisation for another therapeutic indication, with the potential to undergo indication expansion, with the potential to complement existing therapies to improve patient outcomes or serve as effective monotherapy for single or multiple viral families of concern. Accordingly, this call for tenders, under these two lots, aims to assess the candidate's effectiveness and further assessment of safety (within Phase II clinical trials), as well as concurrent non-clinical trials that help identify the most promising preparation, dose, and schedule to be tested in Phase III clinical trials. It is encouraged that the antiviral candidate is presented and discussed at the joint assessment advisory mechanism (JAAM)[14] that was established in the context of the COVID-19 pandemic, to explore the suitability of using EU-funded clinical trial networks for trial implementation.

When relevant and duly justified (e.g., lack of commercial interest or another type of market failure that leads to crowding out investments and partnerships), tenders may only cover the assessment of a primary efficacy endpoint of Phase III trials, specifying the measure of the disease-related outcome of public health interest, such as high mortality or disease morbidity, that supports the antiviral candidate indication for use.

The tender should fully detail, with scientific accuracy, the choice for clinical trial design, the choice of location(s) and infrastructure where the services will be performed, the choice for study protocol and sample size, as well as clinical trial workflow and capabilities. The use of existing EU-funded clinical trial networks[15] is encouraged for this purpose. The offer shall contain the approval (or provide evidence to be in the process of obtaining approval) to run a clinical trial for Phase II in at least one country. Clinical trials should be ideally planned in one

[14] https://covid19trials.eu/en/jaam

[15] https://covid19trials.eu/en/about

or several EU/EEA Member States. Justification should be provided where the Phase II clinical trials are conducted entirely outside the EEA.

The clinical trial should include groups of people from different populations (age group, severity of the disease to be treated, gender). In this context, the offer should detail the methodology for recruitment of patients and possible challenges, to obtain more robust study results. More so, offers shall propose a detailed data management plan (including trial master file template, case report form design, among other), as well as a robust methodology for technological measurement, and a statistical analysis plan, allied with the EU regulatory requirements. If applicable, the offer shall provide information regarding the sponsor of the clinical trial.

In the context of the above description, a candidate can also be considered as a combination of more than one active substance, even if both or more active substances are authorised medicines (same conditions as repurposing authorised medicines described in the paragraph below), as long as the combination is innovative.

These two lots permit also to support broad-spectrum antivirals authorised in the EU, in line with the description provided above, aiming to obtain a new indication, or combination of those. For this purpose, the contracting authority targets offers of candidate broad-spectrum antivirals that fulfil the following criteria: 1) feature a well-established antiviral; 2) authorised in the EU, while being out of data exclusivity and market protection periods and out of basic patent/supplementary protection certificate (SPC); 3) target an indication in a condition distinct from the current authorised indication(s); 4) and target an indication for which there is a market failure, which should be justified (i.e. due to lack of commercial interest). In this context, the requirements and areas covered under these two lots apply, but additionally, offers may feature bridging studies relevant in the context of clinical development (from Phase II to Phase III clinical trials).

Tenderers are invited to use Real World Data (RWD) to support the clinical development, given the market availability of the candidate intended for repurposing.

A very important aspect of broad-spectrum antivirals development is risk of drug resistance. Therefore, offers shall address this risk, how it was/it will be addressed during early development and overall scientific considerations that support the broad use of the candidate.

Additionally, the contract authority will monitor the clinical and regulatory developments of the supported candidate, for which the offer shall outline a roadmap to market access and a plan fostering regular information update between the relevant entities. The offer shall also contain a risk assessment and mitigation measures plan.

The duration of the implementation of the tasks of Lot 2 and 3 is 48 months – with submission of progress reports at M6, M12, M24, M36, and of a final report at M48. Regular meetings with the contracting authority and DG HERA will take place every three months to monitor the implementation of the tasks and address potential challenges (these will be in general online or face to face in specific cases).

Detailed characteristic of the purchase

The following tasks shall be carried out by the contractor and are to be considered for each of the two lots (Lot 2 and Lot 3).

Task	Description
1	Initiation and risk management
2	Clinical and concurrent non-clinical development of the product(s)
3	Phasing-out

Task 1: Initiation and risk management

This task refers to the initiation and risk management of the project highlighting activities to be delivered during the entire period of the contract. This task foresees the presentation of a planning of the services to be performed including any update of the implementation plan.

Activities

- A1.1: Initiation and planning of the activities

Deliverables

- D1.1: Inception Report (M2),

The structure of the Inception Report is presented under section 1.4.3.

Task 2: Clinical and non-clinical development of the product(s)

This task includes all the activities necessary for the contractor to implement the proposed services and advance as much as possible the clinical and concurrent non-clinical development of the product. In the offer, the tenderer shall specify, in detail, the content of the proposed actions and why they are necessary for the successful clinical and concurrent non-clinical development. The offer shall also specify, in a more general manner, activities that will be developed concomitantly, but not covered under this contract, and how they are connected.

Activities relevant for the **clinical development** within the scope of Lot 2 and 3 should support the clinical development of the antiviral and include, but are not limited to, the following non-exhaustive list of possible activities: :

- Determination of study objectives and the design of the study
- Preparation of clinical trial protocol (determination of inclusion and exclusion criteria for recruitment of participants)
- Project and data management tasks, as well as reporting and monitoring
- Safety management and quality control tasks
- Conducting feasibility evaluation and/or pre-study site visits/screening visits
- Patients' recruitment, both within the EU/EEA, and outside the EU/EEA in duly justified cases
- Securing the R&D supply chain of the clinical trial and administering the study protocol
- Collection of samples/clinical assessment and measurement of biochemical or other indicators

- Conducting on-site trial tasks, such as study visit attendance, protocol adherence and study logs
- Development of documentation of adverse events, tracking of participant disposition, review board submissions and approvals
- Monitoring and evaluation of recruiting sites, including preparation for inspections and audits;
- Statistical analysis;
- Submission package preparation for conducting the clinical trial phase II, documents, forms, and translations into English of the key documents;
- Data handling and record keeping

Activities relevant for the **concurrent non-clinical development** within the scope of Lots 2 and 3 should support the linical development of the candidate and should include the following non-exhaustive list of activities:

- Good Laboratory Practice (GLP) experiments for the evaluation of chronic toxicity, reproductive and developmental toxicity, carcinogenicity and genotoxicity, carried out during the clinical phase of development;
- quality documentation and required analytical procedures to produce such documentation: regarding manufacturing process (e.g., development, validation and evaluation); control of raw materials and starting materials; characterisation (e.g., integrity, impurities and homogeneity); control of the active substance; reference standards and materials; container and closure systems; and stability;
- demonstrations related to formulation development, such as compatibility of materials used; requirements for products requiring additional preparation (e.g., reconstitution process is sufficiently robust and will not cause a negative impact on quality/safety/clinical properties); development of batch formula, control of excipients, control of the investigational medicinal products, adventitious agents' safety evaluation;
- additional formulation optimisation, change, or quality tests, with activities relevant for Phase II of clinical development (e.g. addressing formulation change or change in manufacturing);
- further assessment of clinical findings;
- adaptations necessary to the formulation during clinical development, related to the preparation, dose, and schedule to be tested in Phase III clinical trials.

In the offer, the tenderer shall specify, in detail, the content of the proposed activities and why they are necessary for the successful clinical development. The tender should also specify, in a more general manner, activities that will be developed concomitantly for the specific antiviral, but not covered under this contract, and how they are connected.

During the course of this task, the contractor shall regularly update the contracting authority and HERA on the state of the clinical development, progress and results of the purchased services, by organising regular meetings with the contracting authority each three months and preparing a power point presentation and the agenda of the meeting to be shared at least five days before the meeting. The starting point for this task will be considered at the signature of the contract. Development activities should be partially or fully developed in the EU/EAA States, if the recruitment allows it.

The offer shall specify clearly which clinical and concurrent non-clinical development activities will be delivered in each progress report at M6, M12, M24, M36 and M48. During the

implementation of the contract, interim and final payments may be advanced or postponed depending of the completion of all activities foreseen in the progress and final reports.

Even if the contract ends before the submission for marketing authorisation (i.e., submission of the Common Technical Document (CTD) to the relevant authority), all the activities under this task shall be performed in a manner that ensures compliance with marketing authorisation requirements and all the applicable legal framework.

Activities

- A2.1: Clinical and concurrent non-clinical development of product(s)

Deliverables

- D2.1: Progress report 1 (M6)
- D2.2: Progress report 2 (M12)
- D2.3: Progress report 3 (M24)
- D2.4: Progress report 4 (M36)

The structure of the **Progress reports** is described under section 1.4.3. In detail, the progress reports must contain at least the following:

- A description of the tasks carried out, progress and results of the purchased services;
- Market authorisation application-like documents related to the activities performed;
- Any deviation from the initial implementation plan shall be indicated and explained. A description of the difficulties encountered;
- Source data/files and all other relevant documents as annexes;
- An overview of the performance indicators collected for the tasks performed during the respective reporting period.

Task 3: Phasing-out

This task refers to the activities in the last period of the project and the submission of the draft and of the final report accompanied by all final deliverables and relevant documentation.

A draft final report shall be submitted no later than 46 months after the signature of the contract to provide sufficient time to evaluate and send back comments to be implemented in the final version.

The Final Report (one for Lot 2 and one for Lot 3) will describe all the work carried out and the results obtained. It will be accompanied by all final deliverables and relevant documentation.

A detailed description of the structure of the reports (inception, progress and final) is provided under section 1.4.3.

Publication and communication

The final report shall contain an executive summary for publication by the contracting authority highlighting the deliverables of the contract, a summary of the clinical trials results and concurrent non-clinical development activities. More details on the rules for publication are outlined under section *Requirements for publication on Internet.*

Activity

- A3.1: Project closure and drafting Final Report

Deliverables

- D3.1 Draft final report (M46)
- D3.2 Final Report (M48) – including submission of the market authorisation application, publication and communication material.

1.4.2.4 Lot 4 – Point of care metagenomic sequencing for universal pathogen detection

Background

The COVID-19 pandemic has shown that early detection of in particular novel pathogens causing severe infections is of greatest importance to minimise the consequences of pandemics or even stop one in its tracks. SARS-CoV-2 circulated in humans up to two months before it was identified as a novel virus by sequencing a clinical sample in late December 2019[16]. Routine-use pathogen-agnostic diagnostic medical devices could drastically reduce the time between the index case and identification of a novel pathogen, making the difference between a contained local outbreak and a global pandemic.

Such agnostic diagnostics will also significantly accelerate the public health response in the early stages of an outbreak, allowing testing for the novel pathogen from the start of the pandemic. This will bridge the time until targeted diagnostic tests like the PCR and antigen tests widely used in the Covid-19 pandemic are developed, verified and validated for regulatory approval.

Objective

This call therefore supports the development of a metagenomic next-generation sequencing (mNGS)-based test that can detect any respiratory viral pathogen, including novel and emerging, from human respiratory samples. Metagenomic sequencing offers a comprehensive view of all microbes within a sample without targeting specific pathogens, with next-generation approaches matching the sensitivity and specificity of PCR-testing.

16 https://www.science.org/doi/full/10.1126/science.abf8003

mNGS workflows at the point-of-care have already demonstrated their value for pathogen detection and determining antimicrobial resistance[17]. However, they have failed to gain significant traction at the point of care and are still mostly used in specialised laboratories. The main barriers to widespread clinical use are high cost and slow time-to-result, but especially the complex workflows requiring skilled professionals for both test preparation and result interpretation.

Beyond its value for the early identification of disease outbreaks, such solutions will provide clinical utility for the treatment of ongoing infectious diseases and AMR. A significant share of viral and bacterial disease cases remains unattributed in relation to the causing pathogen, therefore hampering their treatment. As such, devices that enable cost-efficient pathogen-agnostic testing at the point-of-care and provide results directly interpretable to clinicians will allow to the latest to administer more precise and pathogen-specific treatment options. Additionally, widespread mNGS technology could broaden the capability to identify and track viral variants as they arise.

While there is substantial investment in the sequencing space, it is not directed towards infectious disease diagnostics but mostly towards more profitable use cases such as oncology or human whole genome sequencing. This lot targets MGS-based solutions optimised for infectious disease diagnostics and early outbreak detection. Together with the US Biomedical Advanced Research and Development Authority (BARDA), a Target Product Profile for a point-of-care mNGS device has been developed. Based on this, this lot supports the development and submission of application seeking EU certification of a device that fulfills the attributes set out in Table 1.

Table 1: Product Attributes	
Intended use	• Early identification of infections caused by pathogens of concern • For use in clinical settings when early detection of infection pathogens cannot be obtained in time through standard diagnostic approaches • For future pandemic preparedness where a conventional diagnostic test is not (yet) available for a novel pathogen
Description of System (Device Architecture)	A complete sample-to-answer solution; including sample processing, enrichment of target sequences and ideally removal of interfering nucleic acids (the generation of host genomic information is not an intended output of the device), library generation, sequencing, bioinformatics analysis, and reporting of results in a clinically relevant format
Result Output	Visual output easily readable by clinicians based on the bioinformatics analysis of mNGS data that **qualitatively** and **ideally quantitatively** (e.g., viral load) reports the viral pathogen(s) most likely to correlate with a patient's history and other diagnostic information.

17 https://pubmed.ncbi.nlm.nih.gov/28169558/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10004755/

Time to Results	Ideally less than 6 hours
Cost	Both device and especially per-sample cost equivalent to or less than existing molecular test panels (e.g., multiplex PCR devices)
Target Population Being Tested	Patients with acute symptoms of viral infection, e.g., the common cold or influenza-like illness
Target Use Setting	Point of care settings (hospitals, ICUs, clinical labs)
Clinical Performance Characteristics	Positive predictive value (PPV) > 90% (ideally > 98%) and negative predictive value (NPV) > 99%, sensitivity=> 95%, specificity > 95% (ideally >99%), and limit of detection < 1000 (ideally < 10) genome equivalents/mL
Pathogen Targets	All pathogenic respiratory viruses including emerging/novel viruses at a minimum. An ideal device would target all existing and emerging/novel pathogens including bacteria, viruses, fungi, and parasites.
Specimen Type	Respiratory samples, (nasopharyngeal, nasal, bronchoalveolar lavage (BAL), saliva, and other upper or lower respiratory samples). Ideally the device should be usable on any human sample type

Tenderers are expected to prove they have experience in research and development in the field of diagnostics. They should demonstrate previous experience in scientific product life cycle and procedure management (ideally in the phases of the proposed services), and scientific evidence management, or access to scientific and regulatory expertise to support them through the required activities. Tenders need to include a clear regulatory strategy, outlining a regulatory path to market that ensures compliance with all legal requirements and a performance evaluation plan.

The offer shall include an implementation plan as well as a project risk management and performance evaluation plan as required by the IVDR. Those will be updated during the initiation and planning stage of the contract. The tenderers shall detail the plan underpinning the submission of an application seeking EU certification, meaning relevant EU conformity assessment procedure in accordance with the In Vitro Diagnostic Medical Device Regulation - IVDR (EU) 2017/746[18], that will allow for the placing of the device on the EU market, including a roadmap to market with envisaged timeline of the different steps. The implementation plan has to clearly identify the end goal and it has to be accompanied by a Gantt chart outlining the activities to be performed and the milestones to be attained taking into consideration the schedule of progress reports and final report. The reasoning behind the timeframe shall be

[18] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU - https://eur-lex.europa.eu/eli/reg/2017/746/oj

justified in regard to the expected end-goal to be accomplished. The offer shall also contain a risk assessment and mitigation measures plan.

The duration of the execution of the tasks of Lot 4 is 48 months. The contracting authority will monitor the relevant developments of the supported product, for which the offer shall outline regular information update with the contracting authority and HERA, through the submission of progress reports at M6, M12, M24, and M36 and of a final report at M48, and through regular meetings with the contracting authority and DG HERA occurring at least every three months.

The offer shall specify clearly which development activities will be delivered in each progress report at M6, M12, M24, M36 and M48.

Once the stage related to the EU conformity assessment preparation starts, the contractor shall provide regular updates to the contracting authority on the preparation and submission of an application for EU conformity assessment (and on its outcome if applicable) , and in parallel, of the status of device certification in third countries in case it is also pursued.

Detailed characteristic of the purchase

The following tasks shall be carried out by the contractor.

Task	Description
1	Initiation and planning
2	Product development activities (performance studies and conformity assessment)
3	Phasing-out

Task 1: Initiation and planning

This task refers to the initiation and risk management of the project highlighting activities to be delivered during the entire period of the contract. This task foresees the presentation of a planning of the services to be performed including any update of the implementation plan.

Activities

- A1.1: Initiation and planning of the activities
- A1.2: Project risk management plan as required by the IVDR
- A1.3: Performance evaluation plan as required by the IVDR

Deliverables

- D1.1: Inception Report (M2)

The structure of the Inception Report is presented under section 1.4.3.

Task 2: Product development activities (performance studies and conformity assessment)

This task includes all the activities necessary for the contractor to implement and advance as much as possible in **the development of a device** fulfilling the criteria outlined in Table 1. This

will involve developing a fully integrated sample preparation cartridge and integrating it with a sequencing device usable at the point of care. All the activities under this task shall be performed in line with the risk management and performance evaluation plan and in compliance with all applicable legal requirements.

This task also includes all the activities necessary for the contractor to implement and advance and conclude **the performance evaluation phase**. The contractor must demonstrate the analytical performance, the scientific validity and clinical performance of the product. This will include a validation of the device against the attributes outlined in Table 1, including sensitivity and specificity of the device e.g., using samples from biobanks.

This task includes also the activities related to establishing a **'Technical Documentation'** which shall form the basis for an application to a relevant notified body to be involved into the relevant EU conformity assessment procedure and issuing relevant certificates for the proposed diagnostic device.

In their offer, the tenderer shall explain how they will proceed with the different steps leading to the submission of an application to allow for the placing on the market of the in-vitro-diagnostic device including a roadmap to market including timeline of the different steps. The application for conformity assessment shall be submitted at the latest two months before the completion of the project.

Activity

- A2.1: Product development activities
- A2.2: Performance evaluation including performance studies of the product
- A2.3 Preparation of the conformity assessment procedure

Deliverables

- D2.1: Progress report 1 (M6)
- D2.2: Progress report 2 (M12)
- D2.3: Progress report 3 (M24)
- D2.4: Progress report 4 (M36)

The structure of the Progress reports is described under section 1.4.3. These reports shall include the list of tests performed and outcomes compared against the requirements set out in Table 1. The reports will also contain updates, when applicable, on the state of play of the preparation of the relevant Conformity Assessment procedure including identification and any communication with relevant Notified Bodies.

The progress reports must contain, when applicable, at least the following:

- A description of the tasks carried out, progress and achieved results against the requirements outlined in Table 1.
- Parts of the 'Technical Documentation' related to the activities performed, under this contract, which will include at relevant stages:
    - Performance evaluation
    - Proof of authorisation of performance studies

    - Application submitted to the relevant notified body
    - Other milestones in the conformity assessment procedure
- Any deviation from the initial work plan shall be indicated and explained. A description of the difficulties encountered.
- An overview of the performance indicators collected for the tasks performed during the respective reporting period.

All the activities under this task shall be performed in accordance with the safety and performance requirements as well as conformity assessment requirements currently in force in the EU.

The offer shall include all the relevant performance studies authorisations and scientific and ethical review, prior to submission of the offer, or applications for approval. The tender shall include all available data related to the above-mentioned development stages in the EU or in third countries.

Task 3: Phasing-out

This task refers to the activities in the last period of the project and the submission of the draft and of the final report accompanied by all final deliverables and relevant documentation.

A draft final report shall be submitted no later than 46 months after the signature of the contract to provide sufficient time to evaluate and send back comments to be implemented in the final version.

The Final Report will describe all the work carried out and the results obtained. It will also contain a summary of the main results obtained as follows:

- The detailed description of the tasks implemented to the development of a point-of-care metagenomic sequencing device for universal pathogen detection in relation to the characteristics outlined in Table 1 under Lot 4.
- Challenges faced during implementation and how they have been addressed.
- The description of clear regulatory path to market including the submission of the application for conformity assessment to ensure compliance with the legal requirements.
- If applicable, the results stemming from conformity assessment of the device, which will demonstrate compliance with the IVD Regulation.
- Copy of the EU conformity assessment certificate, if applicable.

Submission of the application to the notified body for the conformity assessment

At the end of the contract, the developers are expected to submit an application to a Notified Body (and provide evidence of such submission) for conformity assessment seeking full compliance with IVDR and obtention of authorisation for placing the device in the EU/EEA market.

Publication and communication

The final report shall contain an executive summary for publication by the contracting authority highlighting the deliverables of the contract, and a summary of the activities. More details on the rules for publication are outlined under section *Requirements for publication on Internet.*

Activities

- A3.1: Project closure and drafting Final Report

Deliverables

- D3.1: Draft Final Report (M46)
- D3.2: Final Report (M48) – including copy of the submission of the application to the notified body and any updates on the conformity assessment and publication and communication material.

A detailed description of the structure of the reports (inception, progress and final) is provided under section 1.4.3.

1.4.2.5 Timeframe overview applicable to all lots

The contracts will enter into force after both parties have signed it. The period of execution of the implementation of the tasks is maximum **48 months**.

Month	Activity/Deliverable/Meeting
M1	• Inception meeting
M2	• Submission of Inception Report (D1.1)
M5-M6	• Interim progress meeting • Submission of draft version of 1st Progress Report (D2.1)
M6	• Final version of D2.1
M11-12	• Interim progress meeting • Submission of draft version of 2nd Progress Report (D2.2)
M12	• Final version of D2.2
M23-24	• Interim progress meeting • Submission of draft version of 3rd Progress Report (D2.3)
M24	• Final version of D2.3
M35-36	• Interim progress meeting • Submission of draft version of 4th Progress Report (D2.3)
M36	• Final version of D2.4
M46	• Submission of Draft Final Report (D3.1)
M48	• Final progress meeting • Final report (D3.2)

Each interim progress report and the final report shall have tangibles deliverables as defined in the initial offer.

Confidentiality:

For the purpose of these contracts any facts, information, knowledge, documents or other matters which may have been communicated to or obtained by the respective contractors in the context of the contracts ("confidential information") shall be deemed confidential per se even after the completion of the tasks. More concretely, but not exhaustively, the following items shall constitute the confidential information: results of development activities, clinical performance, clinical trials results/performance study, description of the product. The contractor and the contracting authority have to put in place all necessary measures ensuring that the confidential information is not unduly and prematurely disclosed to harm or hamper the performance of the contract, commercialised or transferred, without a written approval of the other party. The written approval will not be withdrawn for unjustified reasons, e.g. in case of a need to apply for patent protection or similar related to the results of the innovation under this call for tenders.

The tenderer shall clearly identify in the tender and the contractor in the deliverables/reports, the parts of the documents and the items that contain business secrets and thus are subject to be protected as "confidential information" based on the above definition.

Data protection

Data must be processed only within the EU, the EEA and any other country relevant for the performance of the contract. Servers must be kept in the EU.

The contractors should ensure the compliance with the General Data Protection Regulation (GDPR)[19] rules for the conduct of the clinical trials or other studies where applicable. The contracting authority should never receive personal data from those clinical trials or studies. Full anonymisation shall be ensured in the conduct of the trials/studies. Given that the patients for the clinical trials/studies will be recruited from within the EU (with the possibility to extend such recruitment to outside the EU only in duly justified cases), their personal data shall be processed only within the EU and servers must be kept in the EU. The personal data of patients recruited outside the EU may be processed outside the EU, following the approval of the duly justified cases.

Use of specific technical security measures for processing special categories of data shall apply (e.g. anonymisation, use of pseudonymisation, encryption, secured servers located in the EU and further measures). The transfer of personal data outside EU shall only be possible if indispensable for the performance of the services under this call for tenders. Tenderers are requested to provide in the technical offer:

- The mapping of all actors involved in the processing of personal data (including subcontractors – identified in the offer or not);
- Proposed measures for ensuring that the service delivery will be compliant with the data protection rules, information on anonymisation, principles and obligations, including a description of the proposed technical security measures for personal data processing.

Please refer to Criterion 4 in the award criteria, see section 3.4.

Intellectual property rights

Compliance with copyright law and other intellectual property legislation is of utmost importance for the contracting authority. When providing the services, the contractors have to ensure compliance with the applicable copyright and other intellectual property legislation.

It is in the responsibility of the contractor to ensure that all IPR agreements are adhered to, related to the delivery of these services.

The contractors shall hold the contracting authority harmless and shall provide compensation in the event of any action, claim or proceeding brought against the contracting authority by a third party as a result of damage caused by the contractor(s) in performance of the contract(s), especially due to the fact that the contractor(s) would not hold the rights and authorisations required under the contract(s) to be concluded. In the event of any action brought by a third

[19] https://gdpr.eu/what-is-gdpr/

party against the contracting authority in connection with performance of the contract(s), the contractor(s) shall assist the contracting authority.

The contracting authority will not own the Intellectual Property Rights (IPR) generated by the development activities, notably of the data generated on the innovative medical countermeasures developed in the context of these contracts and this aspect should be reflected in the offered price. Please also refer to the related clauses of the published draft contract.

1.4.3 Deliverables linked to payments

The payment schedule will be implemented according to the level of accomplishment of the milestones outlined in the implementation plan of the development of the product(s), submitted by the contractor within the maximum of 48 months of the contract and as previously announced in the tender.

Against this background and together with the progress reports/final reports mentioned above, the contractor may claim the payment of an invoice:

- Up to 10% of total amount for an interim payment at M6;
- Up to 20% of total amount for an interim payment at M12;
- Up to 20% of total amount for an interim payment at M24;
- Up to 20% of total amount for an interim payment at M36;
- Balance (30%) for the final payment at M48.

Each payment has to be approved by the contracting authority against the submission of the progress reports and supporting documents and deliverables. It has to commensurate the deliverables submitted and the tangible advancement of tasks described in the deliverables.

Month	Deliverables linked to payments
M6	Final version D2.1 linked with invoice for the 1st interim payment (10%)
M12	Final version D2.2 linked with invoice for the 2nd interim payment (20%)
M24	Final version D2.3 linked with invoice for the 3rd interim payment (20%)
M36	Final version D2.4 linked with invoice for the 4th interim payment (20%)
M48	Final version D3.2 Final report linked with invoice for payment of the balance (30%)

Reports

Each report (except the final version of the Final Report) shall have an introductory page providing an overview and orientation of the report.

a) All reports must be drafted in English and submitted according to the timetable included under section 1.4.2. Electronic files must be provided in Microsoft ® Word format and in Adobe ® Acrobat pdf format.

b) All reports are for sole delivery to the contracting authority and any publications of the reports can only occur if specifically agreed in advance by the contracting authority.

- **Inception report**

The report will describe a detailed plan of the activities related to the scope of each lot, including the state of play of the activities and updated methodologies, the updated implementation plan with clear timeline (Gantt chart) for the development of the product(s) a revised roadmap for placing the product on the EU market and the description of next steps.

The report will outline how the methodology proposed in the tender is going to be implemented in detail, after e.g. having further examined the sources of information , further technical/clinical developments, the input received on the evaluation of the technical offer and/or input received during the inception meeting, etc.. It shall not exceed 50 pages, annexes excluded. It shall also cover the organisation of the work of the whole contract, particularly addressing the discussion points raised at the inception meeting with the contracting authority, after the contract's signature.

- **Progress Reports**

The progress report is an instrument to closely follow the implementation of the activities through meetings between the contractor and the contracting authority. In case of need, the risk assessment and mitigation measures can be presented through as many iterations as necessary, according to changes in risk, newly identified risks, or concretisation of risks followed by application of mitigation measures.

This report will provide a description of the tasks implemented until the moment of its submission. It shall not exceed 50 pages, annexes excluded, and it shall include:

  - any updates on risk assessment and mitigation measures; a description of the tasks carried out (e.g. recruitment of patients, progression in relation to the application for market authorisation). Any deviation from the initial work plan shall be indicated and explained. A description of the difficulties encountered shall also be provided;
  - an overview of the performance indicators collected for the tasks performed during the respective reporting period.

- **Final report**

The Final Report will describe all the work carried out during the implementation of the contract and the results obtained. It shall contain a summary of the main results obtained and be accompanied by all final deliverables and relevant documentation. The Final Report shall not exceed 80 pages, annexes excluded, and it shall include elements such as:

For all Lots

- An executive summary (max. one page) for publication by the contracting authority highlighting the deliverables of the contract and a summary of the activities
- The detailed description of the tasks performed and the level of accomplishment with the initial plan.
- Clear information and interpretation of quantitative data related to the implementation of tasks;
- The performance indicators framework showing the results of the tasks implemented.
- Challenges faced during implementation and how they have been addressed.

- The description of clear regulatory path to market in order to ensure compliance with the applicable legal requirements.
- The updated roadmap to market access in the EU/EEA
- Summary of the results and the outline of possible next steps.
- The technical details for the European Commission and the contracting authority to exercise the priority right to purchase.
- Any update on full compliance with the GDPR (EU DPR).

For Lot 1, 2 and 3

- Clinical trial design and implementation, a description of the location(s) and infrastructure where the services have been performed, the potential use of EU-funded trial networks and coordination mechanisms, the description of the study protocol and sample size, as well as clinical trial workflow and capabilities; the results stemmed from the methodology for recruitment, challenges encountered and how they were tackled through the risk assessment and mitigation measures plan;
- Updated version of the documentation that will be incorporated in the Common Technical Document (CTD) or equivalent;
- How the data management plan (including trial master file template, case report form design, among other) was conducted, as well as the methodology for technological measurement, and the statistical analysis plan, in alignment with the EU regulatory requirements;

For Lot 4

- The results stemming from conformity assessment of the device, which will demonstrate compliance with the IVD Regulation;
- Copy of the EU market authorisation certificate or the proof of submission of the application dossier for a conformity assessment to the relevant notified body for the granting of CE certification for the proposed diagnostic device.

Requirements for publication on Internet

The Executive Agency is committed to making online information as accessible as possible to the largest possible number of users including those with visual, hearing, cognitive or physical disabilities, and those not having the latest technologies. The Commission supports the Web Content Accessibility Guidelines 2.1 of the W3C as provided at:

https://commission.europa.eu/resources-partners/europa-web-guide/design-content-and-development/accessibility/what-accessibility_en

For full details on the Commission policy on accessibility for information providers, see:

https://commission.europa.eu/resources-partners/europa-web-guide_en

For the publishable version of the Final report, the contractor must respect these requirements for accessible pdf documents as provided.

Structure

All reports should have numbered paragraphs and pages and a clear identification, containing:

- the contract number (not the call number),
- the acronym,
- the version (draft, revision or final) and
- the date.

The reports and the deliverables shall be in English, unless otherwise indicated in these tender specifications.

Procedure for reporting

All reports shall be submitted in accordance with the timeline indicated in Section 1.4.2. All reports shall be sent 15 days ahead of the interim progress meetings to the contracting authority. The draft final version of the final report shall be submitted to the contracting authority no later than 46 months after the signature of the contract to provide sufficient time to evaluate and send back comments to be implemented in the final version. The contracting authority is entitled to ask for clarifications on the elements and parameters of the report and the contractor shall provide such clarifications in writing before the final deliverables are submitted for approval.

The contracting authority shall have 30 days from receipt to approve or reject the deliverables, and the contractor shall have 30 days in which to submit additional information, corrections or new deliverables.

Meetings

The meetings between the contractor and the contracting authority and European Commission - DG HERA, will be held at the premises of HaDEA or DG HERA in Brussels or, alternatively, via videoconference. These include the inception, interim progress and final meetings, linked with the respective deliverables described in Section 1.4.2.

For each of the lots, progress meetings will be organised every three months (to be held via videoconference) and on ad-hoc basis at the request of HaDEA or DG HERA, on a schedule agreed among the participants. For these meetings, the contractor will prepare a power point presentation on the state of play of the activities, will draft the minutes of the meeting and adapt the calendar and action plan (if needed) for the activities foreseen under the contract. The draft minutes and supporting documentation shall be sent for comments and validation of the contracting authority before setting the final version, which should be sent to the contracting authority for formal approval not later than 5 days after the meeting.

- **Inception meeting**

The start of the service will be formalised by an inception meeting with the contracting authority and HERA which shall take place in the contracting authority/European Commission premises in Brussels or online within 2 weeks following the signature of the contract. The purpose of the inception meeting is to discuss and fine-tune the methodology, including aspects highlighted

during the evaluation of tenders, as well as to discuss all aspects concerning the execution of the service.

Regular meetings/videoconferences are foreseen in Brussels and/or online and will be agreed with the contractor during the inception meeting. In the meetings, the contractor shall be represented by the main project leader/manager and at least two of the key staff. Fortnightly calls/online meetings can take place throughout the implementation of the tasks if agreed between the contractor and the contracting authority during the inception meeting.

1.4.4 Performance indicators for the contract

The contractor must provide the deliverables and performance indicators indicated below. Contractors shall submit data on the following specific action-level indicators in their regular reporting activities:

Lots 1, 2 and 3

1. Number of medical countermeasures doses to which access is secured in the EU/EEA as laid down under the priority right to purchase;
2. Number of patients enrolled in the clinical trial;
3. Number of milestones in the development concluded and closeness to market.

Lot 4

1. Number of samples processed in the performance studies;
2. Number of medical countermeasures doses/units to which access is secured in the EU/EEA as laid down under the priority right to purchase.

The tenderers are required to include in their tender additional specific action-level indicators, which will be agreed with the contracting authority at the inception phase.

When deemed necessary to complement the above indicators, the contracting authority will require, and agree with the contractor, to collect data for a maximum of three additional specific action-level indicators.

An overview of the data on performance indicators shall be included, where applicable, in each progress report and in the final report.

1.5 Place of performance: where will the contract be performed?

The services will be performed at the following locations:

- the contractor's premises
- in relevant EU Member States, EEA and third countries

1.6 Nature of the contract: how will the contract be implemented?

The procedure will result in the conclusion of the following contract types per lot:

Lot	Contract type

Lot 1	a direct service contract
Lot 2	a direct service contract
Lot 3	a direct service contract
Lot 4	a direct service contract

In direct contracts all the terms governing the provision of the services, supplies or works are defined at the outset. Once signed, they can be implemented directly without any further contract procedures.

Tenderers need to take full account of the full set of procurement documents, including the provisions of the draft contract as the latter will define and govern the contractual relationships to be established between the contracting authority and the successful tenderers. Special attention is to be paid to the provisions specifying the rights and obligations of the contractor, in particular those on payments, performance of the contract, confidentiality, and checks and audits.

☝ Please be aware that if a tenderer to whom the contract is awarded (any of the group members in case of a joint tender) has established debt(s) owed to the Union, the European Atomic Energy Community or an executive agency when the latter implements the Union budget, such debt(s) may be offset, in line with Articles 101(1) and 102 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union (Financial Regulation)[20] and the conditions set out in the draft contract, against any payment due under the contract. The contracting authority will verify the existence of overdue debts of the successful tenderers (any of the group members in case of a joint tender), and, if any such debt is found, will inform the tenderer (the group leader in case of a joint tender who will then have the obligation to inform all other group members before signing the contract) that the debt(s) may be offset against any payment under due the contract.

1.7 Volume and value of the contract: how much do we plan to buy?

The maximum total amount of all purchases under this call for tenders is indicated under Section II.1.5 of the contract notice and in Section 1.3 of these specifications.

1.8 Duration of the contract: how long do we plan to use the contract?

The contracts resulting from this call for tenders will be concluded for the duration specified per lot below. The details of the initial contract duration and possible renewals are set out in the draft contract for the respective lot.

Lot number	Lot duration
Lot 1	48 months

[20] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193 of 30.07.2018, p.1).

Lot 2	48 months
Lot 3	48 months
Lot 4	48 months

1.9 Electronic exchange system: can exchanges under the contract be automated?

For all exchanges with the contractors during the implementation of the contracts resulting from this call for tenders as well as for future possible subsequent proceedings, including, but not limited to, for the purposes of EDES (European Union's Early Detection and Exclusion System), the contracting authority may use an electronic exchange system meeting the requirements of Article 148 of the Financial Regulation. At the request of the contracting authority, the use of such a system shall become mandatory for the contractors at no additional cost for the contracting authority. Details on specifications, access, terms and conditions of use will be provided in advance.

1.10 Security

When performing tasks for the contracting authority in execution of the contract, the contractor and its personnel shall comply with the contracting authority's applicable security requirements.

For the Commission (and, when relevant - for the Executive Agencies), the applicable security requirements include:

- ✓ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission, as well as all its subsequent versions.

2 GENERAL INFORMATION ON TENDERING

2.1 Legal basis: what are the rules?

This call for tenders is governed by the provisions of the Financial Regulation.

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. In an open procedure any interested economic operator (any natural or legal person who offers to supply products, provide services or execute works) may submit a tender.

2.2 Entities subject to restrictive measures and rules on access to procurement: who may submit a tender?

Tenderers must ensure that no involved entities (see Section 2.4) nor any subcontractors, including those which do not need to be identified in the tender (see Section 2.4.2), 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)[21], 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.

Participation in this call for tenders is open on equal terms to all natural and legal persons 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.[22]

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[21] Please note that the EU Official Journal contains the official list and, in case of conflict, its content prevails over that of the EU Sanctions Map.

[22] EEA Agreement:

Under the EEA Agreement, economic operators established in Iceland, Norway and Liechtenstein have access to all procurement procedures of the EU executive agencies, subject to the limitations set out in Annex XVI.

Stabilisation and Association Agreements:

Under the Stabilisation and Association Agreements (SAA) economic operators established in North Macedonia, Albania, Montenegro, Serbia, Bosnia and Herzegovina and Kosovo have access to the procurement procedures of the EU executive agencies, subject to the general security based restrictions.

Association Agreements:

The Agreement on Government Procurement[23] or the Bilateral Free Trade Agreements [24] concluded within the World Trade Organisation does not apply. Therefore, the participation to this call for tenders is not open to natural and legal persons established in the countries that have ratified this Agreement.

The rules on access to procurement do not apply to entities on whose capacity tenderers rely to fulfil the selection criteria nor to subcontractors. Subcontracting may not be used with the intent or effect to circumvent the rules on access to procurement. Participation in this call for tenders is also open on equal terms to natural and legal persons established in a third country eligible for funding under the *EU4Health programme*.

Third countries negotiating association to the programme will be treated as associated countries provided that the association agreement with the third country concerned applies at the time of the award of the contract.

To enable the contracting authority to verify the access, each tenderer must indicate its country of establishment (in case of a joint tender – the country of establishment of each group member) and must present the supporting evidence normally acceptable under the law of that country. The same document(s) could be used to prove the country/-ies of establishment and the delegation(s) of the authorisation to sign, as described in Section 4.3.

2.3 Registration in the Participant Register: why register?

Any economic operator willing to participate in this call for tenders must be registered in the Participant Register - an online register of organisations and natural persons (participants)

Under the Association Agreements with Georgia, Moldova and Ukraine economic operators established in those countries have access to procurement procedures of the EU executive agencies, subject to general exceptions.

Association Agreements to Union Funding Programmes:

Association Agreements of third countries for participation in Union Funding Programmes regularly provide that entities established in the third country may participate in actions funded by the programme under conditions equivalent to those applicable to entities established in the European Union. Accordingly, economic operators established in third countries associated to a relevant Union programme under which the call is launched, have the right to participate in procurement procedures funded under that programme unless those Agreements and the rules of the relevant spending programme (the basic act, the work programme, the call text, etc.) have specific provisions regulating or restricting access to procurement.

Overseas Countries and Territories:

Economic operators established in Overseas Countries and Territories (OCT) have the right to participate in EU procurement procedures under Article 176 FR as the OCTs (listed in the Annex II of the TFEU) fall within the scope of the Treaties (under the association regime of Part IV of the TFEU).

[23] The full text of the GPA and its annexes per country:
https://www.wto.org/english/tratop_E/gproc_e/gp_gpa_e.htm
https://e-gpa.wto.org/en/Agreement/Latest

[24] The full text of the FTAs and the annexes per country
https://www.wto.org/english/tratop_E/gproc_e/gp_gpa_e.htm.

participating in calls for tenders or proposals of the European Commission and other EU institutions/bodies.

On registering each participant obtains a Participant Identification Code (PIC, 9-digit number), which acts as its unique identifier in the Participant Register. A participant needs to register only once – the information provided can be further updated or re-used by the participant in other calls for tenders or calls for proposals of the European Commission and other EU institutions/bodies.

☝ **Each participant needs to ensure that its SME status in the Participant Register is registered and kept up to date.**

At any moment during the procurement procedure, the Research Executive Agency Validation Services (hereafter *the EU Validation Services)* may contact the participant and ask for supporting documents on legal existence and status [and financial capacity]. The requests will be made through the register's messaging system to the e-mail address of the participant's contact person indicated in the register. It is the responsibility of the participant to provide a valid e-mail address and to check it regularly. The documents that may be requested by *the EU Validation Services* are listed in the EU Grants and Tenders Rules on Legal Entity Validation, LEAR appointment and Financial Capacity assessment.

☝ **Please note that a request for supporting documents by the *EU Validation Services* in no way implies that the tenderer has been successful.**

2.4 Ways to submit a tender: how can economic operators organise themselves to submit a tender?

Economic operators can submit a tender either as a sole economic operator (sole tenderer) or as a group of economic operators (joint tender)[25]. In either case subcontracting is permitted.

Tenders must be drawn and submitted in complete independence and autonomously from the other tenders. A declaration in this regard by each tenderer (in case of a joint tender, by each of its members) shall be requested.

A natural or legal person cannot participate at the same time and for the same lot within the same procedure either as member of two or more groups of economic operators or as a sole tenderer and member of another group of economic operators. In such case, all tenders in which that person has participated, either as sole tenderer or as member of a group of economic operators, will be rejected.

Economic operators linked by a relationship of control or of association (e.g. belonging to the same economic/corporate group) are allowed to submit different and separate tenders provided that each tenderer is able to demonstrate that its tender was drawn independently and autonomously.

A natural or legal person may act as subcontractor for several tenderers as long as the tenders are drawn and submitted in complete independence and autonomously from each other. However, cross subcontracting among tenderers is forbidden, more precisely an entity "A" may

[25] Each economic operator participating in the joint tender is referred to as "group member".

participate as tenderer (either as sole tenderer or as member of a group of economic operators) and as subcontractor to another tenderer "B" for the same lot within the same procurement procedure. However, in this case it is forbidden that tenderer "B" (or any of its participating members in case of a group of economic operators) is at the same time subcontractor for tenderer "A" (or for the group of economic operators in which "A" participates) for the same lot within the same procurement procedure. In this case, both tenders A and B shall be rejected.

In order to fulfil the selection criteria, set out in Section 3.2 the tenderer can rely on the capacities of subcontractors (see Section 2.4.2) or other entities that are not subcontractors (see Section 2.4.3).

An **"involved entity**" is any economic operator involved in the tender. This includes the following four categories of economic operators:

- sole tenderer,
- group members (including group leader),
- identified subcontractors (see Section 2.4.2), and
- other entities (that are not subcontractors) on whose capacity the tenderer relies on to fulfil the selection criteria.

The role of each entity involved in a tender must be clearly specified in the eSubmission application: i) sole tenderer, ii) group leader (in case of a joint tender), iii) group member (in case of a joint tender), or iv) subcontractor[26].

For an entity on whose capacities the tenderer relies to fulfil the selection criteria (that is not a subcontractor), this role is defined in the commitment letter (***Annex 5.2***).

2.4.1 Joint tenders

A joint tender is a situation where a tender is submitted by a group (with or without legal form) of economic operators regardless of the link they have between them in the group. The group as a whole is considered a tenderer[27].

All group members assume joint and several liability towards the contracting authority for the performance of the contract as a whole.

Group members must appoint from among themselves a group leader (the group leader) as a single point of contact authorised to act on their behalf in connection with the submission of the tender and all relevant questions, clarification requests, notifications, etc., that may be received during the evaluation, award and until the contract signature. All group members (including the group leader) must sign an Agreement/Power of attorney drawn up in the model attached in ***Annex 3.***

The joint tender must clearly indicate the role and tasks of each group member, including those of the group leader who will act as the contracting authority's contact point for the contract's administrative or financial aspects and operational management. The group leader will have full authority to bind the group and each of its members during contract execution.

[26] Only identified subcontractors (see Section 2.4.2) must be specified in the eSubmission application.
[27] References to *tenderer* or *tenderers* in this document shall be understood as covering both sole tenderers and groups of economic operators submitting a joint tender.

If the joint tender is successful, the contracting authority shall sign the contract with the group leader, authorised by the other members to sign the contract also on their behalf via the Agreement/Power of attorney drawn up in the model attached in ***Annex 3***.

Changes in the composition of the group during the procurement procedure (after the deadline for submission of tenders and before contract signature) shall lead to rejection of the tender, with the exception of the following cases:

- case of a merger or takeover of a group member (universal succession), provided that the following cumulative conditions are fulfilled:

    - the new entity is not subject to restrictive measures, has access to procurement (see Section 2.2) and is not in an exclusion situation (see Section 3.1),
    - all the tasks assigned to the former entity are taken over by the new entity member of the group,
    - the group meets the selection criteria (see Section 3.2),
    - the change must not make the tender non-compliant with the procurement documents,
    - the terms of the originally submitted tender are not altered substantially and the evaluation of award criteria of the originally submitted tender are not modified,
    - the new entity undertakes to replace the former entity for the implementation of the contract, in case of an award.

- case where a group member is subject to restrictive measures or does not have access to procurement (see Section 2.2) or is in an exclusion situation (see Section 3.1), provided the following cumulative conditions are fulfilled:
    - none of the remaining group members is subject to restrictive measures (see Section 2.2),
    - all the remaining group members have access to procurement (see Section 2.2),
    - the remaining group members meet the selection criteria (see Section 3.2),
    - the change must not make the tender non-compliant with the procurement documents,
    - the terms of the originally submitted tender are not altered substantially and the evaluation of award criteria of the originally submitted tender are not modified,
    - the continuation of the participation of the remaining group members in the procurement procedure does not put the other tenderers in a competitive disadvantage,
    - the remaining group members undertake to implement the contract, in case of an award, without the excluded group member.

    The replacement of the group member not having access to procurement or in a situation of exclusion is not allowed.

2.4.2 Subcontracting

Subcontracting is the situation where the contractor enters into legal commitments with other economic operators, which will perform part of the contract on its behalf. The contractor retains full liability towards the contracting authority for performance of the contract as a whole.

The following shall not be considered subcontracting:

a) Use of workers posted to the contractor by another company owned by the same group and established in a Member State ("intra-group posting" as defined by Article 1, 3, (b) of Directive 96/71/EC concerning the posting of workers in the framework of the provision of services).
b) Use of workers hired out to the contractor by a temporary employment undertaking or placement agency established in a Member State ("hiring out of workers" as defined by Article 1, 3, (c) of Directive 96/71/EC concerning the posting of workers in the framework of the provision of services).
c) Use of workers temporarily transferred to the contractor from an undertaking established outside the territory of a Member State and that belongs to the same group ("intra-corporate transfer" as defined by Article 3, (b) of Directive 2014/66/EU on the conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer) .
d) Use of staff without employment contract ("self-employed persons working for the contractor"), without the tasks of the self-employed persons being particular well-defined parts of the contract.
e) Use of suppliers and/or transporters by the contractor, in order to perform the contract at the place of performance, unless the economic activities of the suppliers and/or the transporting services are within the subject of this call for tenders (see Section 1.4).
f) Performance of part of the contract by members of an EEIG (European Economic Interest Grouping), when the EEIG is itself a contractor or a group member.

The persons mentioned in points a), b), c) and d) above will be considered as "personnel" of the contractor as defined in the contract.

All contractual tasks may be subcontracted unless the procurement documents expressly reserve the execution of certain critical tasks to the sole tenderer itself, or in case of a joint tender, to a group member.

By filling in the form available in ***Annex 4*** (List of identified subcontractors), tenderers are required to give an indication of the proportion of the contract that they intend to subcontract, as well as to identify and describe briefly the envisaged contractual roles/tasks of subcontractors meeting any of these conditions (hereafter referred to as *identified subcontractors*):

- subcontractors on whose capacities the tenderer relies upon to fulfil the selection criteria as described under Section 3.2;
- subcontractors whose intended individual share of the contract, known at the time of submission, is above 10 % .

Any such subcontractor must provide the tenderer with a commitment letter drawn up in the model attached in ***Annex 5.1*** and signed by its authorised representative.

☝ Each tenderer shall identify *such* subcontractors and provide the commitment letters with its tender. The information must be true and correct at the time of submitting the tender. Any changes or additions regarding the envisaged subcontractors after the deadline for submission of tenders must be justified to the contracting authority.

The above rules apply also where the economic operators, which will perform part of the contract on behalf of a successful tenderer, belong to the same economic/corporate group as the sole tenderer or a member of the group submitting the joint tender.

Changes concerning subcontractors identified in the tender (withdrawal/replacement of a subcontractor, additional subcontracting) during the procurement procedure (after the submission deadline and before contract signature) require the prior written approval of the contracting authority subject to the following verifications:

- any new subcontractor is not subject to restrictive measures, has access to procurement if the rules on access to procurement apply also to subcontractors (see Section 2.2) and is not in an exclusion situation (see Section 3.1),
- the tenderer still fulfils the selection criteria and the new subcontractor fulfils the selection criteria applicable to it individually, if any;
- the terms of the originally submitted tender are not altered substantially, i.e. all the tasks assigned to the former subcontractor are taken over by another involved entity, the change does not make the tender non-compliant with the tender specifications, and the evaluation of award criteria of the originally submitted tender is not modified.

Subcontracting to subcontractors identified in a tender that was accepted by the contracting authority and resulted in a signed contract, is considered authorised.

2.4.3 Entities (not subcontractors) on whose capacities the tenderer relies to fulfil the selection criteria

In order to fulfil the selection criteria a tenderer may also rely on the capacities of other entities (that are not subcontractors), regardless of the legal nature of the links it has with them. It must in that case prove that it will have at its disposal the resources necessary for the performance of the contract by producing a commitment letter in the model attached in ***Annex 5.2,*** signed by the authorised representative of such an entity, and the supporting evidence that those other entities have the respective resources[28].

☝ The above rules apply also where the economic operators on whose capacities the tenderer relies to fulfil the selection criteria (that are not subcontractors) belong to the same economic/corporate group as the sole tenderer or a member of the group submitting the joint tender.

2.4.4 Rules common to subcontractors and entities (not subcontractors) on whose capacities the tenderer relies to fulfil the selection criteria

If a successful tenderer intends to rely on another entity to meet the minimum levels of economic and financial capacity, the contracting authority may require the entity to sign the contract or, alternatively, to provide a joint and several first-call financial guarantee for the performance of the contract.

With regard to technical and professional selection criteria, a tenderer may only rely on the capacities of other entities where the latter will perform the works or services for which these capacities are required, i.e. the latter will either assume the role of subcontractors or will fall within the exceptions listed in Section 2.4.2 and will then assume the role of entities (not subcontractors) on whose capacities the tenderer relies to fulfil the selection criteria.

[28] This does not apply to subcontractors on whose capacity the tenderer relies to fulfil the selection criteria – for these the documentation required for subcontractors must be provided.

☝ Relying on the capacities of other entities is only necessary when the capacity of the tenderer is not sufficient to fulfil the required minimum levels of capacity. Abstract commitments that other entities will put resources at the disposal of the tenderer will be disregarded.

3 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;
- Selection of tenderers on the basis of selection criteria;
- Verification of compliance with the minimum requirements specified in the procurement documents;
- Evaluation of tenders on the basis of the award criteria.

The contracting authority will evaluate the abovementioned elements in the order that it considers to be the most appropriate.

If the evaluation of one or more elements demonstrates that there are grounds for rejection, the tender will be rejected and will not be subjected to further full evaluation. The unsuccessful tenderers will be informed of the ground for rejection without being given feedback on the non-assessed content of their tenders. Only tenderers for whom the verification of all elements did not reveal grounds for rejection can be awarded the contracts resulting from this call for tenders.

The evaluation will be based on the information and evidence contained in the tenders and, if applicable, on additional information and evidence provided at the request of the contracting authority during the procedure. If any of the declarations or information provided proves to be false, the contracting authority may impose administrative sanctions (exclusion or financial penalties) on the entity providing the false declarations/information.

For the purposes of the evaluation related to exclusion and selection criteria the contracting authority may also refer to publicly available information, in particular evidence that it can access on a national database free of charge.

The contracting authority may reject abnormally low tenders, in particular if it established that the tenderer or an identified subcontractor does not comply with applicable obligations in the fields of environmental, social and labour law.

3.1 Exclusion criteria

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[29] needs to submit with its tender a Declaration on Honour[30] in the model available in ***Annex 2***[31]. The declaration must be signed by an authorised representative of the entity providing the declaration. Where the declaration has been signed by hand, the original does not need to be submitted to the contracting authority, but the latter reserves the right to request it from the tenderer at any time during the record-keeping period specified in Section 4.3.

The initial verification of non-exclusion of tenderers will be done on the basis of the submitted declarations and consultation of the European Union's Early Detection and Exclusion System.

At any time during the procurement procedure[32], the contracting authority may request the documents mentioned in the Declaration on Honour as supporting evidence on non-exclusion (the documentary evidence). It may also request information on natural or legal persons that are members of the administrative, management or supervisory body or that have powers of representation, decision or control, including legal and natural persons within the ownership and control structure and beneficial owners, and appropriate evidence that none of those persons are in one of the exclusion situations referred to in Section A point (1) (c) to (f) of the Declaration on Honour.

All tenderers are **invited to prepare in advance the documentary evidence**, since they may be requested to provide such evidence within a short deadline. In any event, the tenderers proposed by the evaluation committee for the award of the contracts will be requested to provide such evidence.

☝ If the tenderer does not provide valid documentary evidence within the deadlines set by the contracting authority, the latter reserves the right to reject the tender. In any event, in case a tenderer proposed for the award of the contract fails to comply with the above evidence requirement, its tender will be rejected, unless the tenderer can justify the failure on the grounds of material impossibility to provide such evidence.

Annex 1 specifies which of the involved entities participating in a tender need to provide the Declaration on Honour and, when requested by the contracting authority, the supporting evidence.

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[29] See Annex 1 which of the involved entities participating in a tender need to provide the Declaration on Honour.
[30] The European Single Procurement Document (ESPD) may not be used yet in European Commission's calls for tenders.
[31] Unless the same declaration has already been submitted for the purposes of another award procedure of HaDEA, the situation has not changed, and the time elapsed since the issuing date of the declaration does not exceed one year.
[32] The obligation to provide the supporting evidence will be waived in the following situations:
- if the same documents have already been provided in a previous award procedure of the European Commission, have been issued no more than one year before the date of their request by the contracting authority and are still valid at that date;
- if such evidence can be accessed by the contracting authority on a national database free of charge, in which case the economic operator shall provide the contracting authority with the internet address of the database and, if needed, the necessary identification data to retrieve the document;
- if there is a material impossibility to provide such evidence.

Please note that a request for evidence in no way implies that the tenderer has been successful.

3.2 Selection criteria

The objective of the selection criteria is to assess whether the tenderer has the legal, regulatory, economic, financial, technical and professional capacity to perform the contract.

The selection criteria for this call for tenders, including the minimum levels of capacity, the basis for assessment and the evidence required, are specified in the following subsections.

Tenders submitted by tenderers not meeting the minimum levels of capacity will be rejected

When submitting its tender each tenderer shall declare on honour that it fulfils the selection criteria for the lots for which it applies in this call for tenders. The model Declaration on Honour available in ***Annex 2*** shall be used.

The initial assessment of whether a tenderer fulfils the selection criteria will be done on the basis of the submitted declaration(s).

The subsections below specify which selection criteria evidence must be provided with the tender or may be requested later, at any time during the procurement procedure, within a deadline given by the contracting authority[33].

The evidence must be provided in accordance with the applicable basis for assessment of each criterion: in case of a consolidated assessment – only by the involved entities who contribute to the fulfilment of the criterion, and in case of individual assessment – by each entity to whom the criterion applies individually.

In case not all selection criteria evidence is requested with the tender, all tenderers are **invited to prepare in advance the documentary evidence**, since they may be requested to provide such evidence within a short deadline. In any event, the tenderers proposed by the evaluation committee for the award of the contracts will be requested to provide such evidence.

☝ If the tenderer does not provide valid documentary evidence within the deadlines set by the contracting authority, the contracting authority reserves the right to reject the tender. In any event, in case a tenderer proposed for the award of the contract fails to comply with the above evidence requirement, its tender will be rejected, unless there is a ground for a waiver.

Please note that a request for evidence in no way implies that the tenderer has been successful.

[33] The obligation to provide the supporting evidence will be waived in the following situations:
- if the same documents have already been provided in a previous award procedure of the European Commission and are still up-to-date;
- if such evidence can be accessed by the contracting authority on a national database free of charge, in which case the economic operator shall provide the contracting authority with the internet address of the database and, if needed, the necessary identification data to retrieve the document.

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.

Where tenderers submit a tender through an entity, which lacks legal personality (e.g., a branch), the compliance with the exclusion criteria, selection criteria, the rules on access to procurement as well as the absence of restrictive measures shall be assessed at the level of the tenderers.

Tenderers must prove that they have legal capacity to perform the contract and the regulatory capacity to pursue the professional activity necessary to carry out the work subject to this call for tenders.

The legal and regulatory capacity shall be proven by the evidence listed below:

- For lots 1, 2 and 3:
  - Copy of the clinical trial authorisation for the Phase I in EU Member States, EEA or third countries.
  - Copy of EU Clinical Trial register or equivalent for Phase I clinical trial.
  - Publication or manuscript of the successful clinical trial results.
- For lot 4:
  - Proof of successfully completed, at least, Phase I of the medical device development (see Figure 2).
- For all lots:
  - Any other proof of completing further Phases should only be submitted if applicable to the state of development of the candidate medical countermeasure.
  - Proof of authorisation that the tenderer is authorised to perform the contract in its country of establishment, if applicable.
  - Proof of compliance with the manufacturing processes for vaccines/antivirals or in-vitro medical devices (as appropriate for the lot) in the European Union (self-declaration or national authorisation).

☝ All of the above-specified evidence of legal and regulatory capacity must be provided with the tender.

In addition, involved entities (see Section 2.4) and all subcontractors, including those which do not need to be identified in the tender (see Section 2.4.2), must not be 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)[34] that constitute a legal impediment to perform the contract. This requirement will be assessed by reference to the EU restrictive measures in force. Therefore, the tenderer is not required to submit any evidence of not being subject to EU restrictive measures.

[34] Please note that the EU Official Journal contains the official list and, in case of conflict, its content prevails over that of the EU Sanctions Map.

3.2.2 Economic and financial capacity

Tenderers for each lot must comply with the following selection criteria in order to prove that they have the necessary economic and financial capacity to perform the contract.

Criterion F1	
Description and minimum level of capacity	Average yearly sum of turnover and other operating income (including e.g. government subsidies or donations excluding variation in stocks) of the last two financial years above: - EUR 5 million for Lot 1 - EUR 3.5 million for Lot 2 - EUR 3.5 million for Lot 3 - EUR 5 million for Lot 4
Basis for assessment	This criterion applies to the candidate as a whole, i.e. a consolidated assessment of the combined capacities of all involved entities will be carried out.
Evidence	Copy of the balance sheet and profit and loss accounts, for the last two years for which accounts have been closed from each concerned involved entity or, failing that, appropriate statements from banks. The most recent year must have been closed within the last 18 months.

The minimum level of economic and financial capacity on criterion F1 for tenderers submitting tenders for two or more lots, should be the average yearly sum of turnover and other operating income (excluding variation in stocks) of the last two financial years above the aggregate of the respective lots. I.e. if applying for Lot 1 and 2, must be above EUR 8.500 000 (Lot 1 and Lot 2 individually EUR 5 000 000 and Lot 4 EUR 3 500 000).

Criterion F2	
Description and minimum level of capacity	Quick ratio: current assets – stocks – receivables > 1 year / current liabilities above 0,5.
Basis for assessment	The criterion will be checked against one member, in case of joint tender, or the sole tenderer.
Evidence	Copy of the profit and loss accounts and balance sheets for the last two years for which accounts have been closed from each concerned involved entity, or, failing that, appropriate statements from banks. The most recent year must have been closed within the last 18 months.

Criterion F3	
Description and minimum level of capacity	Solvency Ratio between total debt and equity: i = Total debt / Equity. Acceptable value: $i < 8$ and $i \geq 0$
Basis for assessment	The criterion will be checked against one member, in case of joint tender, or the sole tenderer.
Evidence	Copy of the balance sheet and profit and loss accounts, for the last two years for which accounts have been closed from each concerned involved entity or, failing that, appropriate statements from banks. The most recent year must have been closed within the last 18 months.

☝ **All of the above-specified evidence of economic and financial capacity must be provided with the tender.**

3.2.3 Technical and professional capacity

☝ With regard to technical and professional selection criteria, a tenderer may only rely on the capacities of other entities where the latter will perform the works or services for which these capacities are required. The entity on whose capacity the tenderer relies, will either assume the role of a subcontractor or fall within the exceptions listed in Section 2.4.2.

Tenderers must comply with the following selection criteria in order to prove that they have the necessary technical and professional capacity to perform the contract:

For Lot 1 - Vaccines to combat antimicrobial resistance (AMR),

Lot 2 – Broad spectrum antivirals (respiratory RNA viral families) andLot 3 – Broad spectrum antivirals (viral haemorrhagic fever)

Criterion T1	
The tenderer must prove experience in clinical development of medicines/medicinal product	
Minimum level of capacity	At least one past similar clinical trial (in scope and complexity) in scientific product life cycle and procedure management for the development of medicines in the Phases II and/or III[35] of the proposed services, completed in the last 10 years preceding the tender submission deadline.
Basis for assessment	This criterion applies to the tenderer as a whole, i.e. the combined capacities of all *involved entities*.
Evidence	A list of clinical trials protocols/projects/activities meeting the minimum level of capacity. The list shall include details

[35] When relevant and duly justified (e.g. lack of commercial interest or another type of market failure that leads to crowding out investments and partnerships), tenderers may only cover the assessment of a primary efficacy endpoint of Phase III trials.

	of their start and end date, the summary of the clinical trial protocols, the authorisation of the clinical trial by at least one regulatory authority, total project/activity amount and scope, role and amount invoiced/activity costs.

For Lot 4 – Point of care metagenomic sequencing for universal pathogen detection.

Criterion T1	
The tenderer must prove experience in the research and development of diagnostics.	
Minimum level of capacity	At least one past similar development (in scope and complexity) concerning scientific product life cycle and procedure management in the area of diagnostics, completed in the last 10 years preceding the tender submission deadline. Overall, the tenderer must prove that they are able to achieve the necessary steps to develop and bring to market a device which complies with the In Vitro Diagnostic Medical Device Regulation.
Basis for assessment	This criterion applies to the tenderer as a whole, i.e. the combined capacities of all *involved entities*.
Evidence	A list of past development protocols meeting the minimum level of capacity. The list shall include details of their start and end date, total project/activity amount and scope, role and amount invoiced/activity costs. As supporting documents for each project reference the *contracting authority* may request statements issued by the clients and take contact with them.

3.3 Compliance with the conditions for participation and minimum requirements specified in the procurement documents

By submitting a tender, a tenderer commits to perform the contract in full compliance with the terms and conditions of the procurement documents for this call for tenders. Particular attention is drawn to the minimum requirements specified in Section 1.4 of these specifications and to the fact that tenders must comply with applicable data protection, environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to Directive 2014/24/EU.

The minimum requirements shall be observed throughout the entire duration of the contract. Compliance with these requirements is mandatory and cannot be subject to any assumptions, limitations, conditions, or reservations on the part of a tenderer.

Tenderers must declare when submitting their tenders in eSubmission whether their tenders comply with the minimum requirements specified in the procurement documents.

☝ **Tenders that are not compliant with the applicable minimum requirements shall be rejected.**

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:

1. 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.

2. Quality - 70%

The quality of the tender will be evaluated based on the criteria described in the section below:

3.4.1 Lot specific award criteria

The award criteria aim at evaluating the technical offers' alignment with public health challenges, real innovation, robust developments activities and priority right to purchase, appropriate organisation of the work and resources and high-quality risk assessment.

3.4.1.1 Lot 1 – Vaccines to combat antimicrobial resistance (AMR)

Award criteria for selecting vaccines to combat antimicrobial resistance (AMR)			
Quality award criterion	**Explanation of the criterion's scope**	**Maximum number of points per criterion (weighting)**	**Minimum points to be obtained (60% per criterion)**
Award criterion 1 (with 3 sub-criteria based on the elements laid down in section 1.4.2.1 and 1.4.2.2): **Relevance and Innovation**	The criterion will assess the information submitted in the minimum requirements: how the medical countermeasure addresses the EU added value, the public health challenges, innovation and promising activity based on the information provided in the offer.	**45**	**26**
	Sub-criterion 1.1 - Relevance to Public Health Challenges and EU added value This sub-criterion will assess the relevance of the proposed product and the foreseen improvement of health outcomes (e.g. expected impact on mortality and morbidity rates in the EU and in the world). This sub-criterion will also assess the EU added value[4] and how the tender will ensure EU market	15	8

	readiness and access for the product once its development is completed and/or close to commercialisation. This sub-criterion will also assess the technical details for the European Commission and the contracting authority to exercise the priority right to purchase the related volume of doses.		
	Sub-criterion 1.2 – Innovation This sub-criterion will assess the level of clinical development, the product description and indication, the implementation plan for the development, breakthrough innovation description of the proposed product (e.g. lack of alternative vaccines, alternative delivery mechanisms and innovative administration mode, innovative platform technologies, simplified clinical protocols or other innovative approaches.)	20	12
	Sub-criterion 1.3 - Promising Biological Activity and Safety This sub-criterion will assess the quality and results of the supplied evidence, which shall confirm of promising biological activity and the safety of the proposed product: • Proof of principle demonstrating promising biological activity meeting the immuno-focusing challenge against one of the bacterial pathogens under the scope of this lot • Evidence of safety, reactogenicity, and tolerability in healthy adult volunteers, including data on haematological and biochemical parameters, suspected adverse reactions, local/system adverse effects, and serious adverse effects.	10	6
Award criterion 2: **Methodology for conducting the clinical and concurrent non-clinical development activities**	This criterion will assess the appropriateness of the clinical and concurrent non-clinical development activities of the product and the detailed data management plan for the clinical trials. This encompasses the technological measurement, and a statistical analysis plan of the study/clinical trial, trial activities and all related tasks requested in the process of submission of the market authorisation in the EU and the preliminary roadmap for placing the product on the market.	**30**	**18**

	The methodology shall provide detailed description of the plans for Clinical Development and Trial Design**.** This criterion will assess the quality and feasibility of the tenderers plans for the clinical development and trial activities. It will rely on a detailed description of the clinical trial design, including location, infrastructure, study protocol, sample size, and workflow; approval (or in the process of obtaining) to conduct clinical trials in at least one country and preferably an EU/EEA Member State; incentivised multi-country clinical trials and inclusion of diverse populations to ensure representation across different populations; comprehensive data management plan, technological measurement methodology, and statistical analysis plan. All the activities must demonstrate alignment with EU regulatory requirements. Within the methodology description, the tender shall demonstrate in-house or easy access to an accredited clinical laboratory[11].		
Award criterion 3: **Appropriateness of the organisation of the work and resources**	This criterion will assess elements related to the organisation of the work plausible allocation of time and human resources for the implementation of the tasks. The tender shall describe clearly the project management structure, the team composition, the allocation of resources and the work method (definition and distribution of roles and responsibilities for each task) in relation to the proposed implementation plan of the development of the product using Gantt charts outlining the timeframe of the foreseen activities and deliverables foreseen during the period of the contract. The tender shall also describe the continuity of the service in case of absence of the member(s) of the team dedicated to a particular task. The supervision of the project and communication with the contracting authority shall also be defined. In the case of joint tenders, tenderers must also define the structure set up to coordinate the work between group members and explain how each member will provide its best expertise.	**15**	**8**

Award criterion 4: **Quality of the measures implemented for a continuous high performance, including quality control and data protection**	This criterion will assess the quality the measures proposed for data protection, project risk assessment and project mitigating measures of the risks associated to the implementation of the tasks. This criterion will also assess the quality and soundness of the procedure proposed to deal with data breaches and requests of data subjects.	**10**	**6**
Total		**100**	**60**

3.4.1.2 Lot 2 – Broad Spectrum antivirals (respiratory RNA viral families)

Award criteria for selecting broad-spectrum antivirals – Lot 2 **antivirals targeting respiratory RNA viral families**			
Quality award criterion	**Explanation of the criterion's scope**	**Maximum number of points per criterion (weighting)**	**Minimum points to be obtained (60% per criterion)**
Award criterion 1 (with 3 sub-criterion based on the elements laid downs in section 1.4.2.1 and 1.4.2.3): **Relevance and Innovation**	The criterion will assess the information submitted in the minimum requirements: how the medical countermeasure addresses the EU added value, the public health challenges, innovation and promising activity based on the evidence provided in the offer.	**40**	**24**
	Sub-criterion 1.1 - Relevance to Public Health Challenges and EU added value: This sub-criterion will assess the relevance of the proposed product and the foreseen improvement of the health outcomes described in section 1.4.2.1. This sub-criterion will also assess the EU added value[4] and how the tender will ensure EU market readiness and access for the product once its development is completed and/or close to commercialisation. This sub-criterion will also assess the technical details for the European Commission and the contracting authority to exercise the priority right to purchase the related volume of doses.	10	6
	Sub-criterion 1.2 – Innovation: Broad-spectrum antiviral (BSA), and **BSA-containing drug combinations** ('*antiviral cocktails*') This sub-criterion will assess the level of clinical development, the product	20	12

	description and indication, the implementation plan for the development, and breakthrough innovation description of the product. The proposed product: • shall directly block viral targets and functions • have an anticipated efficacy against multiple species or genera in at least one, preferably several RNA viral families of pandemic potential, focusing on respiratory RNA viral families of concern, such as *Paramyxo-, Orthomyxo and Coronaviruda*e • preferably to be new chemical entities which include small molecules and small biotherapeutics like nucleic acids or peptides that are directly acting against viral targets and functions, i.e. not through the modulation of the host responses • preferably have safety profiles and suitable routes of administration (e.g. oral or intranasal) for broad use in the outpatient setting to treat early stages of infection by reducing viral burden • preferably addressing unmet need, and/or therapeutic added value (*e.g. no active treatment available for condition; current treatment is suboptimal, e.g., existing treatment has challenging adherence or delivery; new treatment has the potential to provide substantial additional benefits over existing treatment options; new treatment targets different aspects of the condition*)		
	Sub-criterion 1.3 - Safety profile and overall soundness of the scientific approach and technology used This sub-criterion will assess the quality and results of the supplied evidence: • Evidence of safety, reactogenicity, and tolerability in healthy adult volunteers, including data on haematological and biochemical parameters, suspected adverse reactions, local/system adverse effects, and serious adverse effects.	10	6

	• Furthermore, available evidence should suggest potential therapeutic activity and be supportive of the proof of principle. This should derive from pre-clinical studies (in vitro and in vivo used animal models) or early clinical studies related to the appropriate mechanism of action, safety and efficacy of new medicinal products, or for repurposed medicinal products. Evidence that is already known should be available from existing use.		
Award criterion 2: **Methodology for conducting the clinical and non clinical activities**	This criterion will assess the appropriateness of the tasks described in these tender specifications, related to the clinical and concurrent non-clinical development activities of the product, the detailed data management plan of the clinical trials and regulatory activities including all related tasks requested in the process of submission of the market authorisation in the EU. This encompasses the technological measurement, and a statistical analysis plan of the study/clinical trial, trial activities and all related tasks requested in the process of submission of the market authorisation in the EU and the preliminary roadmap for placing the product on the market. The methodology shall provide detailed description of the plans for Clinical Development and Trial Design**.** This criterion will assess the quality and feasibility of the tenderers plans for the clinical development and trial activities. It will rely on a detailed description of the clinical trial design, including location, infrastructure, study protocol, sample size, and workflow; approval (or in the process of obtaining) to conduct clinical trials in at least one country and preferably one EU/EEA Member State; incentivised multi-country clinical trials and inclusion of diverse populations to ensure representation across different populations; comprehensive data management plan, technological measurement methodology, and statistical analysis plan. All the activities must demonstrate alignment with EU regulatory requirements. Within the methodology description, the tender shall demonstrate in-house or	**30**	**18**

	easy access to an accredited clinical laboratory[11].		
Award criterion 3: **Appropriateness of the organisation of the work and resources**	This criterion will assess elements related to the organisation of the work and plausible allocation of time and human resources for the implementation of the tasks. The tender shall describe clearly the project management structure, the team composition, the allocation of resources and the work method (definition and distribution of roles and responsibilities for each task) in relation to the proposed implementation plan of the development of the product using Gantt charts outlining the timeframe of the foreseen activities and deliverables foreseen during the period of the contract. The tender shall also describe the continuity of the service in case of absence of the member(s) of the team dedicated to a particular task. The supervision of the project and communication with the contracting authority shall also be defined. In the case of joint tenders, tenderers must also define the structure set up to coordinate the work between group members and explain how each member will provide its best expertise.	**20**	**12**
Award criterion 4: **Quality of the measures implemented for a continuous high performance, including quality control and data protection**	This criterion will assess the quality the measures proposed for data protection, project risk assessment and project mitigating measures of the risks associated to the implementation of the tasks. This criterion will also assess the quality and soundness of the procedure proposed to deal with data breaches and requests of data subjects.	**10**	**6**
Total		**100**	**60**

3.4.1.3 Lot 3 - Broad-spectrum antivirals (VHF-associated RNA viral families)

Award criteria for selecting broad-spectrum antivirals – Lot 3 **antivirals targeting RNA viral families causing viral hemorrhagic fevers**			
Quality award criterion	**Explanation of the criterion's scope**	**Maximum number of points per criterion (weighting)**	**Minimum points to be obtained (60% per criterion)**
Award criterion 1 (with 3 sub-criteria based on the elements laid down in sections 1.4.2.1 and 1.4.2.3): **Relevance and Innovation**	The criterion will assess the information submitted in the minimum requirements: how the medical countermeasure addresses the EU added value, the public health challenges, innovation and promising activity based on the evidence provided in the offer.	**40**	**24**
	Sub-criterion 1.1 - Relevance to Public Health Challenges and EU added value: This sub-criterion will assess the relevance of the proposed product and the foreseen improvement of the health outcomes described in section 1.4.2.1. This sub-criterion will also assess the EU added value[4] and how the tender will ensure EU market readiness and access for the product once its development is completed and/or close to commercialisation. This sub-criterion will also assess the technical details for the European Commission and the contracting authority to exercise the priority right to purchase the related volume of doses.	10	6
	Sub-criterion 1.2 – Innovation: Broad-spectrum antiviral (BSA), and **BSA-containing drug combinations** ('*antiviral cocktails*') This sub-criterion will assess the level of clinical development, the product description and indication, the implementation plan for the development, and the breakthrough innovation description of the proposed product. The product : • shall directly block viral targets and functions • have an anticipated efficacy against multiple species or genera in at least one, preferably several RNA viral families of pandemic potential, focusing on RNA viral families of concern causing VHF, such	20	12

	as *Arena-, Bunya-, Flavi-, Filoviridae* • preferably to be new chemical entities which include small molecules and small biotherapeutics like nucleic acids or peptides that are directly acting against viral targets and functions, i.e. not through the modulation of the host responses • preferably have safety profiles and suitable routes of administration (e.g. oral or intranasal) for broad use in the outpatient setting, to treat early stages of infection by reducing viral burden • preferably addressing unmet need, and/or therapeutic added value (*e.g. no active treatment available for condition; current treatment is suboptimal, e.g., existing treatment has challenging adherence or delivery; new treatment has the potential to provide substantial additional benefits over existing treatment options; new treatment targets different aspects of the condition*)		
	Sub-criterion 1.3 - Safety profile and overall soundness of the scientific approach and technology used This sub-criterion will assess the quality and results of the supplied evidence, which shall confirm of the safety of the proposed product: • Evidence of safety, reactogenicity, and tolerability in healthy adult volunteers, including data on haematological and biochemical parameters, suspected adverse reactions, local/system adverse effects, and serious adverse effects. • Furthermore, available evidence should suggest potential therapeutic activity and be supportive of the proof of principle. This should derive from pre-clinical studies (in vitro and in vivo used animal models) or early clinical studies related to the appropriate mechanism of action, safety and efficacy of new medicinal products, or for repurposed medicinal products. Evidence	10	6

	that is already known should be available from existing use		
Award criterion 2 : **Methodology for conducting the clinical and concurrent non-clinical development activities**	This criterion will assess the appropriateness of the tasks described in these tender specifications, related to the clinical and concurrent non-clinical development of the product, the detailed data management plan for the clinical trial, and the regulatory activities including all related tasks requested in the process of submission of the market authorisation in the EU. This encompasses the technological measurement, and a statistical analysis plan of the study/clinical trial, trial activities and all related tasks requested in the process of submission of the market authorisation in the EU and the preliminary roadmap for placing the product on the market. The methodology shall provide detailed description of the plans for Clinical Development and Trial Design**.** This criterion will assess the quality and feasibility of the tenderers plans for the clinical development and trial activities. It will rely on a detailed description of the clinical trial design, including location, infrastructure, study protocol, sample size, and workflow; approval (or in the process of obtaining) to conduct clinical trials in at least one country and preferably one EU/EEA Member State; incentivised multi-country clinical trials and inclusion of diverse populations to ensure representation across different populations; comprehensive data management plan, technological measurement methodology, and statistical analysis plan. All the activities must demonstrate alignment with EU regulatory requirements. Within the methodology description, the tender shall demonstrate in-house or easy access to an accredited clinical laboratory[11].	**30**	**18**
Award criterion 3: **Appropriateness of the organisation of the work and resources**	This criterion will assess elements related to the organisation of the work and plausible allocation of time and human resources for the implementation of the tasks. The tender shall describe clearly the project management structure, the team composition, the allocation of resources and the work method (definition and distribution of roles and responsibilities for each task) in relation to the proposed	**20**	**12**

	implementation plan of the development of the product using Gantt charts outlining the timeframe of the foreseen activities and deliverables foreseen during the period of the contract. The tender shall also describe the continuity of the service in case of absence of the member(s) of the team dedicated to a particular task. The supervision of the project and communication with the contracting authority shall also be defined. In the case of joint tenders, tenderers must also define the structure set up to coordinate the work between group members and explain how each member will provide its best expertise.		
Award criterion 4: **Quality of the measures implemented for a continuous high performance, including quality control and data protection**	This criterion will assess the quality the measures proposed for data protection, project risk assessment and project mitigating measures of the risks associated to the implementation of the tasks. This criterion will also assess the quality and soundness of the procedure proposed to deal with data breaches and requests of data subjects.	**10**	**6**
Total		**100**	**60**

3.4.1.4 Lot 4 – Point of care metagenomic sequencing for universal pathogen detection

Award criteria for selecting Point of care metagenomic sequencing for universal pathogen detection			
Quality award criterion	**Explanation of the criterion's scope**	**Maximum number of points per criterion (weighting)**	**Minimum points to be obtained (60% per criterion)**
Award criterion 1 (with 2 sub-criterion based on the elements laid down in section 1.4.2.1 and 1.4.2.4): **Relevance and Innovation**	The criterion will assess the information submitted in the minimum requirements: how the medical countermeasure addresses the EU added value, the public health challenges, innovation and promising activity based on the evidence provided in the offer.	**50**	**30**
	Sub-criterion 1.1 - Relevance to Public Health Challenges and EU added value: This sub-criterion will assess the relevance of the proposed product and the foreseen improvement of health outcomes (e.g. expected impact on	10	6

	mortality and morbidity rates in the EU and in the world). This sub-criterion will also assess the EU added value[4] and how the tender will ensure EU market readiness and access for the product once its development is completed and/or close to commercialisation. This sub-criterion will also assess the technical details for the European Commission and the contracting authority to exercise the priority right to purchase the related volume of doses.		
	Sub-criterion 1.2 – Innovation: This sub-criterion will assess the level of innovation of the suggested solution, the implementation plan for the developments against the requirements outlined in Table 1 of Lot 4, and the breakthrough innovation description of the proposed product. Especially relevant or this criterion will be: • Complexity of workflows • Time to answer • Per-sample cost • Interpretability by clinicians • Sensitivity, specificity, PPV, NPV (see details in table 1)	40	26
Award criterion 2: **Methodology**	This criterion will assess the appropriateness and quality of the proposed methodologies and tools to carry out the tasks described in these tender specifications, related to the clinical and product development activities and all related tasks requested in the process of submission of the application for conformity assessment in the EU. This encompasses the technological measurement, and a statistical analysis plan of the development activities and all related tasks requested in the process of submission of the certification in the EU and the preliminary roadmap for placing the product on the market. This criterion will assess the quality and feasibility of the tenderers plans for the product development activities, performance studies of the product and preparation of the conformity assessment procedure. All the activities must demonstrate alignment with EU regulatory requirements.	**25**	**15**

Award criterion 3: **Appropriateness of the organisation of the work and resources**	This criterion will assess elements related to the organisation of the work and plausible allocation of time and human resources for the implementation of the tasks. The tender shall describe clearly the project management structure, the team composition, the allocation of resources and the work method (definition and distribution of roles and responsibilities for each task) in relation to the proposed implementation plan of the development of the product using Gantt charts outlining the timeframe of the foreseen activities and deliverables foreseen during the period of the contract. The tender shall also describe the continuity of the service in case of absence of the member(s) of the team dedicated to a particular task. The supervision of the project and communication with the contracting authority shall also be defined. In the case of joint tenders, tenderers must also define the structure set up to coordinate the work between group members and explain how each member will provide its best expertise.	**15**	**9**
Award criterion 4: **Quality of the measures implemented for a continuous high performance, including quality control and data protection**	This criterion will assess the quality the measures proposed for data protection, project risk assessment and project mitigating measures of the risks associated to the implementation of the tasks. This criterion will also assess the quality and soundness of the procedure proposed to deal with data breaches and requests of data subjects.	**10**	**6**
Total		**100**	**60**

3.5 Award (ranking of tenders)

Tenders shall be ranked per lot according to the best price-quality ratio in accordance with the formula below for each lot:

$$\textbf{\textit{Score Tender X}} = \frac{\textbf{\textit{Cheapest price}}}{\textbf{\textit{Price of Tender X}}} \times \mathbf{100} \times \textbf{\textit{Price weigthing}}\ (\mathbf{30\%}) + \textbf{\textit{Total quality score Tender X}} \times \textbf{\textit{Quality weigthing}}\ (\mathbf{70\%})$$

Should the outcome of the formula lead to two or more tenders with the same result for the same lot, the tenderer who has been awarded the highest marks for quality within the same lot

will be deemed to be the most economically advantageous tender for this lot. This approach will continue to be applied to each of the award criteria in the descending order listed in below until a most economically advantageous tender can be determined:

- Award criterion 1 – Relevance and Innovation
- Award criterion 2 – Methodology
- Award criterion 3 – Appropriateness of the organisation of the work and resources
- Award criterion 4 – Quality of the measures implemented for a continuous high performance, including quality control and data protection strategy

☝ The contract shall be awarded to the tender ranked first for each lot, which complies with the minimum requirements specified in the procurement documents and is submitted by a tenderer not subject to restrictive measures, having access to procurement, not in an exclusion situation and fulfilling the selection criteria.

☝ **Detection of abnormally low tenders**

Tenderers must be aware of Point 23 of Annex I to the Financial Regulation on abnormally low tenders and of the possibility for rejection of the tender based on it.

4 FORM AND CONTENT OF THE TENDER

4.1 Form of the tender: how to submit the tender?

Tenders are to be submitted via the eSubmission application according to the instructions laid down in the Invitation letter and the eSubmission Quick Guide available at the link below:

https://wikis.ec.europa.eu/display/FTPortal/Open+procedures_EN

☝ Make sure you prepare and submit your tender in eSubmission early enough to ensure it is received within the deadline indicated under Section IV.2.2 of the contract notice and/or on TED eTendering.

4.2 Content of the tender: what documents to submit with the tender?

The documents to be submitted with the tender in eSubmission are listed in ***Annex 1.***

☝ 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.

The following requirements apply to the technical and financial tender to be uploaded in eSubmission:

- *Technical tender*.

The technical tender must provide all the information needed to assess the compliance with Section 1.4 of these specifications and the award criteria. Tenders deviating from the minimum requirements or not covering all the requirements may be rejected on the basis of non-compliance and not evaluated further.Tenderers are free to choose where the personal data will be processed or stored as long as they comply with the contractual obligations on data processing (Art.I.9.2 and Art. II.9) and, in particular, with the requirements for transfer of personal data to third countries and international organisations laid down in Chapter V of Regulation (EU) 2018/1725[36].

Tenderers must specify in their technical tender the location where the personal data will be processed and stored only where this location is outside the territory of the European Union or the European Economic Area. If no location is specified in the tender, the contracting authority will consider that the personal data will be processed and stored only within the territory of the European Union or the European Economic Area.

When submitting the technical tender it is highly recommended that the tenderer:

[36] Regulation (EU) 2018/1725 of 23 October 2018 Regulation (EU) 2018/1725 of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295/39, 21.11.2018, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN .

- limits the technical tender to a maximum of 70 pages, excluding evidence provided for the assessment of exclusion and selection criteria, such as CVs, past projects or profit and loss accounts, 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).]

Tenders shall be perfectly legible so that there can be no doubt as to words and figures. Tenders shall be clear and concise. They must be complete and consistent with all the requirements and instructions laid down in the tender specifications.

- *Financial tender.*

A complete financial tender, including the breakdown of the price, needs to be submitted. For this purpose, the Financial Model in ***Annex 6*** shall be used. **It is only the total price for the service in the financial offer form that will be considered in the application of the best price/quality formula, described under section 3.5 of the present tender specifications.**

The total amount of the tender as indicated in cell ***G25 (Lot 1, 2 and 3) or G26 (Lot 4)*** must be encoded in the field "Total amount" under the section "Tender data" in eSubmission. Is the "Total amount" that will be considered in the application of the best price-quality ratio described in section 3.5

It is the responsibility of each tenderer to ensure that the total amount of the tender inserted in the eSubmission field "Total amount" corresponds to the amount indicated in the uploaded financial tender. In case of discrepancies, only the amount indicated in the financial tender will be taken into account.

Any modification of the template of the financial tender may lead to rejection of the tender. The tenderer must not change, add, hide or eliminate any part of the template such as row, column or cell, or change the texts already prefilled in the template.

The financial tender must fulfil the following requirements:

- prices shall be all-inclusive - all costs associated with the completion of the work, including overheads such as infrastructure, administration costs and travel costs and other costs, even not mentioned, but necessary for the completion shall be included in the overall fixed price in the financial tender (no reimbursable variable costs).
- prices shall be calculated to cover all the expenditure borne by the contractor in the performance of the contract, including travel and subsistence expenses.
- prices shall be expressed in euros. Tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to bear the risks or the benefits deriving from any variation.
- prices should be expressed to a maximum of 2 decimal places.
- prices shall be quoted free of all duties, taxes and other charges, i.e. also free of VAT.

☝ The European Union Institutions are exempt from such charges in the EU under Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union of 8 April 1965 annexed to the Treaty on the Functioning of the European Union. Exemption is granted to the

Commission/Executive agency by the governments of the Member States, either through refunds upon presentation of documentary evidence or by direct exemption.

In case of doubt about the applicable VAT system, it is the tenderer's responsibility to contact its national authorities to clarify the way in which the European Union is exempt from VAT.

4.3 Signature policy: how can documents be signed?

Where a document needs to be signed, the signature must be either hand-written or, preferably, a qualified electronic signature (QES) as defined in Regulation (EU) No 910/2014 on electronic identification and trust services for electronic transactions in the internal market (the *eIDAS Regulation*).

Tenderers are strongly encouraged to sign with a QES[37] all documents requiring a signature and only exceptionally to sign such documents by hand as hand-written signatures lead to an additional administrative burden for both the tenderer and the contracting authority. The originals of any hand-signed documents (other than the contract) do not need to be submitted to the contracting authority but the tenderer must keep them for a period of five years starting from the notification of the outcome of the procedure or, where the tenderer has been awarded a contract resulting from this call for tenders and the contract has been signed, the payment of the balance.

All documents must be signed by the signatories (when they are individuals) or by their duly authorised representatives.

For the following documents, when signed by representatives, tenderers must provide evidence for the delegation of the authorisation to sign:

- The Declaration on Honour of the tenderer (in case of a joint tender – the Declarations on Honour of all group members);
- (in the case of a joint tender) the Agreement/Power(s) of attorney drawn up using the model attached in ***Annex 3***.

The delegation of the authorisation to sign on behalf of the signatories (including, in the case of proxy(-ies), the chain of authorisations) must be evidenced by appropriate written evidence (copy of the notice of appointment of the persons authorised to represent the legal entity in signing contracts (together or alone), or a copy of the publication of such appointment if the legislation which applies to signatory requires such publication or a power of attorney). A document that the contracting authority can access on a national database free of charge does not need to be submitted if the contracting authority is provided with the exact internet link and, if applicable, the necessary identification data to retrieve the document.

[37] See here how to apply a QES on a document exchanged with a European institution, body or agency.

4.4 Confidentiality of tenders: what information and under what conditions can be disclosed?

Once the contracting authority has opened a tender, it becomes its property and shall be treated confidentially, subject to the following:

- For the purposes of evaluating the tender and, if applicable, implementing the contract, performing audits, benchmarking, etc., the contracting authority is entitled to make available (any part of) the tender to its staff and the staff of other Union institutions, bodies and agencies, as well to other persons and entities working for the contracting authority or cooperating with it, including contractors or subcontractors and their staff, provided that they are bound by an obligation of confidentiality.
- After the signature of the award decision, tenderers whose tenders were received in accordance with the submission modalities, who are not subject to restrictive measures, have access to procurement, who are not found to be in an exclusion situation referred to in Article 136(1) of the FR, who are not rejected under Article 141 of the FR, whose tenders are not found to be incompliant with the procurement documents, and who make a request in writing, will be notified of the name of the tenderer to whom the contract is awarded for the lot(s) for which the tenderer applied, the characteristics and relative advantages of the successful tender and its total financial tender amount. The contracting authority may decide to withhold certain information that it assesses as being confidential, in particular where its release would prejudice the legitimate commercial interests of economic operators or might distort fair competition between them. Such information may include, without being limited to, confidential aspects of tenders such as unit prices included in the financial tender, technical or trade secrets[38].
- The contracting authority may disclose the submitted tender in the context of a request for public access to documents, or in other cases where the applicable law requires its disclosure. Unless there is an overriding public interest in disclosure[39], the contracting authority may refuse to provide full access to the submitted tender, redacting the parts (if any) that contain confidential information, the disclosure of which would undermine the protection of commercial interests of the tenderer, including intellectual property.

☝ The contracting authority will disregard general statements that the whole tender or substantial parts of it contain confidential information. Tenderers need to mark clearly the information they consider confidential and explain why it may not be disclosed. The contracting authority reserves the right to make its own assessment of the confidential nature of any information contained in the tender.

[38] For the definition of trade secrets please see Article 2 (1) of DIRECTIVE (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.

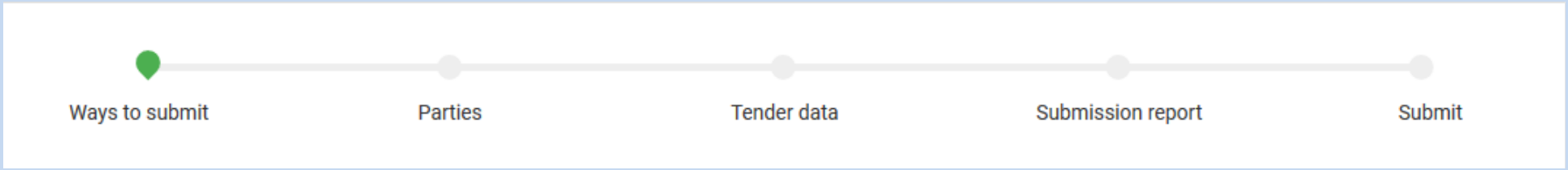
[39] See Article 4 (2) of the REGULATION (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents. See Article 4 (2) of the Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents.

APPENDIX: LIST OF REFERENCES

Award criteria	See Section 3.4
Contracting authority	See Section 1.1
Entities on whose capacities the tenderer relies to fulfil the selection criteria	See Section 2.4.3
EU Validation services	See Section 2.3 EU Grants and Tenders Rules on Legal Entity Validation, LEAR appointment and Financial Capacity assessment
Exclusion criteria	See Section 3.1
Financial Regulation	Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union
Group leader	See Section 2.4.1
Group member	See Section 2.4.1
Identified subcontractors	See Section 2.4.2
Involved entities	See Section 2.4
Joint tender	See Section 2.4.1
Participating entities	See Section 1.1
Participant Register	See Section 2.3 https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/participant-register
Selection criteria	See Section 3.2
Sole tenderer	See Section 2.4
Subcontracting/subcontractor	See Section 2.4.2
Treaties	The EU Treaties: https://europa.eu/european-union/law/treaties_en

ANNEXES

Annex 1. List of documents to be submitted with the tender or during the procedure

Description	Sole tenderer	Joint tender		Identified Subcontractor	Entity on whose capacity is being relied (that is not subcontractor)	When and where to submit the document?	Instructions for uploading in eSubmission (if applicable)	
		Group leader	Group member				How to name the file?	Where to upload?
1. Identification and information about the tenderer. *eSubmission view*  								
Declaration on Honour on Exclusion and Selection Criteria (see Section 3.1) *model in Annex 2*	☒	☒	☒	☒	☒	With the tender in eSubmission	'Declaration on Honour'	With the concerned entity under 'Parties' →'Identification of the participant' →'Attachments'→'Declaration on Honour'. For entities that are not subcontractors and on whose capacity the tenderer relies to fulfil the selection criteria, the document must be uploaded in the section of the sole tenderer or group leader:

								→'Identification of the participant' →'Attachments'→'Other documents'.
Evidence that the person signing the documents is **an authorised representative** of the entity[40] (see Section 4.3)	☒	☒	☒			With the tender in eSubmission	'Authorisation to sign documents'	With the concerned entity under 'Parties' →'Identification of the participant' →'Attachments'→'Other documents'.
Agreement/Power of attorney (see Section 2.4.1) *model in Annex 3*		☒	☒			With the tender in eSubmission	'Agreement_ Power of attorney'	In the group leader's section under 'Parties' →'Identification of the participant' →'Attachments'→'Other documents'.
List of identified subcontractors (see Section 2.4.2) *model in Annex 4*	☒	☒				With the tender in eSubmission	'List of identified subcontractors'	In the sole tenderer's or the group leader's section under 'Parties' →'Identification of the participant' →'Attachments'→'Other documents'.
Commitment letter (see Section 2.4.2 and 2.4.3)				☒ *(model in Annex 5.1)*	☒ *(model in Annex 5.2)*	With the tender in eSubmission	'Commitment letter'	With the concerned entity under 'Parties' →'Identification of the participant' →'Attachments'→'Other documents'.

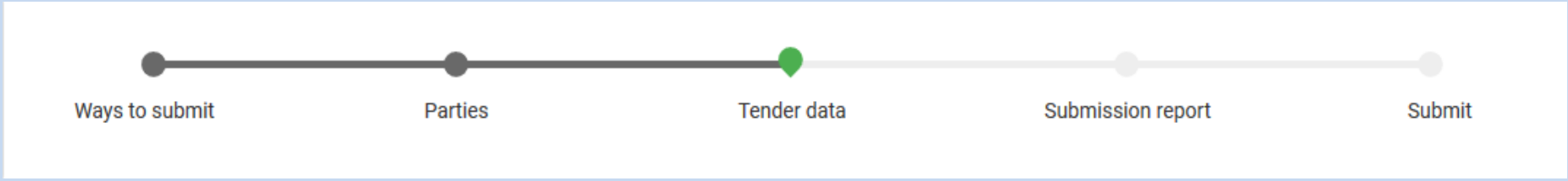
[40] A document that the contracting authority can access on a national database free of charge does not need to be submitted if the contracting authority is provided with the exact internet link and, if applicable, the necessary identification data to retrieve the document.

Evidence of non-exclusion (see Section 3.1)	☒	☒	☒	☒	☒	Tenderers (sole tenderers/all group members in case of a joint tender) must provide the evidence when requested by the contracting authority and, in any event, if a tenderer is successful, before the award of the contract. Subcontractors and entities on whose capacity a tenderer relies to fulfil the selection criteria must provide the evidence only upon request by the contracting authority.	n.a.	n.a.
Evidence of legal existence and status (see Section 2.3)	☒	☒	☒			Only upon request by *the EU Validation services* At any time during the procedure In the Participant Register	n.a.	n.a.
Evidence of legal and regulatory capacity (see Section 3.2.1)						With the tender in eSubmission	No specific requirements how to name the file(s).	With the concerned entity under 'Parties' →'Identification of the participant' →'Attachments'→'Legal and regulatory capacity'.
Evidence of economic and financial capacity F1-F3 (see Section 3.2.2)	**The documents must be provided**					With the tender in eSubmission	'Balance_sheet_ entity_year' 'Profit_Loss_ Account_entity_ year'	With the group leader or the sole tenderer under 'Parties' →'Identification of the participant' →'Attachments'→'Economic and financial capacity'.

	only by the involved entities **which contribute to reaching the minimum capacity level** **for criteria F1-F3**			
Evidence of technical and professional capacity T1 (see Section 3.2.3)	**The documents must be provided** **only by the involved entities** **who contribute to reaching the minimum capacity level** **for criterion T1**	With the tender in eSubmission	'Project_ reference_No.1" 'Project_ reference_No.2" …. (Project refers to clinical trial, developments protocols, etc. as described under Evidence for T1)	With the group leader or the sole tenderer under 'Parties' →'Identification of the participant' →'Attachments'→'Technical and professional capacity'.

2. Tender data.

eSubmission view



Failure to upload the following documents in eSubmission will lead to rejection of the tender.

Technical tender (see Section 4.2)	☒	☒				With the tender in eSubmission	'Technical tender'	Under section 'Tender Data' →'Technical tender'
Financial tender (see Section 4.2) *model in Annex 6*	☒	☒				With the tender in eSubmission	'Financial tender'	Under 'Tender Data' →'Financial tender'

Annex 2. Declaration on Honour on exclusion and selection criteria

Annex 2 is published as a separate document.

Annex 3. Agreement/Power of attorney

Call for tenders ***XXX/XX/XX/20XY/XYZ*** - ***[Lot X]***
[TITLE OF THE PROCEDURE]

AGREEMENT/POWER OF ATTORNEY

The undersigned:

[- Signatory 1 (Name, Function, Legal entity name, Registered address, VAT Number)]

- Signatory 2 (Name, Function, Legal entity name, Registered address, VAT Number)

- …

- Signatory N (Name, Function, Legal entity name, Registered address, VAT Number)]

having the legal capacity required to act on behalf of the entities they represent,

HEREBY AGREE TO THE FOLLOWING:

1) To submit a joint tender (the tender) as members of a group of tenderers (the group), constituted by ***[Insert names of Legal entity 1, Legal entity 2, ... Legal entity N – the name of the group leader must be included here!]*** (the group members), and led by ***[Insert name of Legal entity 1]*** (the group leader), in accordance with the conditions of the procurement documents and the terms of the tender to which this Agreement/Power of attorney is attached.
2) If the contracting authority awards a contract resulting from this call for tenders (the contract) to the group on the basis of the tender to which this Agreement/Power of attorney is attached, all group members (including the group leader) shall be considered parties to the contract in accordance with the following conditions:
   (a) All group members (including the group leader) shall be jointly and severally liable towards the contracting authority for the performance of the contract.
   (b) All group members (including the group leader) shall comply with the terms and conditions of the contract and ensure the proper delivery of their respective share of the services and/or supplies subject to the contract.
3) Payments by the contracting authority related to the services and/or supplies subject to the contract shall be made through the bank account of the group leader indicated in the contract.
4) The group members grant to the group leader all the necessary powers to act on their behalf in the submission of the tender and the conclusion of the contract, including:

(a) The group leader shall submit the tender on its own behalf and on behalf of the other group members and indicate in the "Contact Person" section in eSubmission the name and e-mail address of an individual as a single point of contact authorised to communicate officially with the contracting authority in connection with the submitted tender on behalf of all group members, including in connection with all relevant questions, clarification requests, notifications, etc., that may be received during the evaluation, award and until the contract signature.

(b) The group leader shall sign any contractual documents — including the contract,[specific contracts] and amendments thereto — and shall warrant the submission of any invoices related to the performance of the contract on behalf of all group members.

(c) The group leader shall act as a single contact point with the contracting authority in the delivery of the services and/or supplies subject to the contract. It shall coordinate the delivery of the services and/or supplies by the group to the contracting authority, and shall see to a proper administration of the contract.

This Agreement/Power of attorney may be executed in counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same document.

Any modification to the present Agreement/Power of attorney shall be subject to the contracting authority's express approval. This Agreement/Power of attorney shall expire when all the contractual obligations of the group have ceased to exist. The parties cannot terminate it before that date without the contracting authority's consent.

Name ***Function*** ***Name of the legal entity***	***Name*** ***Function*** ***Name of the legal entity***
signature[s]: _____	***signature[s]: _____***
Done at ……..…., on ……	***Done at ……..…., on ……***
Name ***Function*** ***Name of the legal entity***	***Name*** ***Function*** ***Name of the legal entity***
signature[s]: _____	***signature[s]: _____***
Done at ……..…., on ……	***Done at ……..…., on ……***

Annex 4. List of identified subcontractors and proportion of subcontracting

Identification details	Roles/tasks during contract execution	Proportion of subcontracting (% of contract volume)
[Full official name of the identified subcontractor, registered address, statutory registration number, VAT registration number]		
[Full official name of the identified subcontractor, registered address, statutory registration number, VAT registration number]		
[REPEAT AS MANY TIMES AS THE NUMBER OF IDENTIFIED SUBCONTRACTORS]		
Other subcontractors that do not need to be identified under Section 2.4.2[41]		
	TOTAL % of subcontracting	0,00%

[41] For this category of subcontractors, please provide in a general manner their intended roles/tasks during contract execution, as well as the aggregated % of contract volume for all non-identified subcontractors.

Annex 5.1. Commitment letter by an identified subcontractor

[Letterhead, if any]

[ ]

Call for tenders Ref. ***[reference number]***

Attn:

[Insert date]

Commitment letter by identified subcontractor

I, the undersigned,

Name:

Function:

Legal entity:

Registered address:

VAT Number:

having the legal capacity required to act on behalf of ***[insert name of the entity]***, hereby confirm that the latter agrees to participate as subcontractor in the tender of *[insert name of the tenderer]* for the call for tenders [***insert reference number]*** – ***[insert title of procedure]*** [Lot ***[insert lot number]]***.

In the event that the tender of the aforementioned tenderer is successful, ***[insert name of the subcontractor]*** commits itself to make available the resources necessary for performance of the contract as a subcontractor and to carry out the services that will be subcontracted to it in compliance with the terms of the contract. It further declares that it is not subject to conflicting interests, which may negatively affect the contract performance, and that it accepts the terms of the procurement documents for the above call for tenders, in particular the contractual provisions related to checks and audits.

Done at:

Name:

Position:

Signature:

Annex 5.2. Commitment letter by an entity on whose capacities is being relied

[Letterhead, if any]

[ ]

Call for tenders Ref. ***[reference number]***

Attn:

[Insert date]

Commitment letter by an entity on whose capacity is being relied

I, the undersigned,

Name:

Function:

Legal entity:

Registered address:

VAT Number:

having the legal capacity required to act on behalf of ***[insert name of the entity]***, hereby confirm that the latter **authorises the** ***[insert name of the tenderer]*** **to rely on its [financial and economic capacity] [technical and professional capacity] in order to meet the minimum levels** required for the call for tenders [***insert reference number]*** – ***[insert title of procedure]*** [Lot ***[insert lot number]]***.

In the event that the tender of the aforementioned tenderer is successful, ***[insert name of the entity]*** commits itself to make available the resources necessary for performance of the contract. It further declares that it is not subject to conflicting interests which may negatively affect the contract performance, and that it accepts the terms of the procurement documents for the above call for tenders, in particular the contractual provisions related to checks and audits.

Done at:

Name:

Position:

Signature:

Annex 6. Financial tender form

Annex 6 is published as a separate document.