

EMA/79061/2020

Invitation to tender to open procedures using e-Submission

Dear Madam/Sir

Subject: The provision of IT software development, configuration, implementation and maintenance services covering solutions based on Microsoft software, Microsoft technology services, Azure Platform and Software services and related technologies (Lot 1), in relation to Master Data Management (MDM) solutions based on Informatica technologies (Lot 2), and in relation to Enterprise Resource Planning (ERP) based on SAP technologies (Lot 3) - (EMA/2019/28/IT)

The European Medicines Agency (referred to below as 'EMA' or 'the Agency') is planning to award the contract(s) resulting from the above procurement procedure. The procurement documents consist of the contract notice in the Official Journal of the European Union, this invitation letter, the tender specifications and their annexes including the draft contract. All documents are available at the following TED e-Tendering website¹:

<https://etendering.ted.europa.eu/cft/cft-display.html?cftId=6049>

Economic operators interested in this contract are invited to submit a tender in one of the official languages of the European Union.

1. Submission of tenders

Tenders must be submitted exclusively via the electronic submission system (e-Submission) available from the above website. Tenders submitted in any other way (e.g. e-mail or by letter) will be disregarded.

For detailed instructions on how to submit a tender please consult the e-Submission Quick Guide available at: https://webgate.ec.europa.eu/esubmission/assets/documents/manual/quickGuide_en.pdf. In case of technical problems, please contact the e-Submission Helpdesk (see contact details in the Quick Guide) as soon as possible. In case of broken links: E-mail DIGIT-EPROUREMENT-SUPPORT@ec.europa.eu; Tel +32 (0) 229 71063.

In order to submit a tender using e-Submission, tenderers (each member of the group in the case of a joint tender) will need to register in the European Commission's [Participant Register](#)² - an online register of organisations participating in EU calls for tenders or proposals. On registering each

¹ Subscription to the call for tender at the above link allows interested economic operators to receive e-mail notifications when new information or documents are published. Subscription is free of charge and does not involve any commitment to submit a tender.

² <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home>



organisation obtains a Participant Identification Code (PIC, 9-digit number) which acts as its unique identifier in the above register. Instructions on how to create a PIC can be found in the PIC-management [Quick Guide for Economic Operators](#)³. Tenderers already registered in the Participant Register shall reuse their existing PICs when preparing tenders in e-Submission.

The time-limit for receipt of tenders is indicated under Heading IV.2.2 of the contract notice where local time shall be understood as local time at the Agency's location (the location indicated under Heading I.1 of the contract notice).

A tender received after the time-limit for receipt of tenders will be rejected. The tender reception confirmation provided by e-Submission with the official date and time of receipt of the tender (timestamp) constitutes proof of compliance with the time-limit for receipt of tenders.

Tenderers must ensure that their submitted tenders contain all the information and documents required by the Agency at the time of submission as set out in the procurement documents.

The following documents shall be dated and signed, either by hand or by applying an electronic signature based on a qualified certificate, by an authorised representative of the signatory:

- Declaration(s) on honour (template available in the tender specifications).
- The tender report (a document generated by e-Submission and listing all the documents included in the tender, to be signed by the tenderer or the group leader in case of a joint tender).

When the declaration(s) on honour and/or the tender report are signed by hand, a scanned copy must be attached to the tender in e-Submission.

After submitting a tender, but before the deadline for receipt of tenders, a tenderer may definitively withdraw its tender, or withdraw it and replace it with a new one⁴. In these cases the tenderer must send a withdrawal/replacement notification, clearly specifying the call for tender's reference and the e-Submission ID of the tender⁵ being withdrawn/replaced. The notification must be dated, signed by the tenderer or the group leader in case of a joint tender and sent as follows:

- if signed using an electronic signature based on a qualified certificate: by e-mail sent before the deadline for receipt of tenders to the Agency's e-mail address indicated under Heading I.1 of the contract notice;
- if signed by hand: a scanned copy by e-mail, sent before the deadline for receipt of tenders to the Agency's e-mail address indicated under Heading I.1 of the contract notice.

All costs incurred for the preparation and submission of tenders are to be borne by the tenderers and will not be reimbursed.

Please note only one tender per tenderer can be submitted (this includes only one financial tender (costing sheet)). Any tenderer submitting more than one tender shall be eliminated from the procedure.

2. Legal effects of the invitation to tender and submission of a tender

This invitation to tender is in no way binding on the Agency. EMA's contractual obligation commences only when the contract with the successful tenderer is signed by both parties.

³ https://webgate.ec.europa.eu/supplier_portal_toolbox/quickGuide/SP_quickGuide_en.pdf

⁴ To submit a new version, the tenderer must create a new tender in e-Submission and include all the information and documents required in the procurement documents with the submission of a tender, even if some of them have already been included in the replaced tender.

⁵ The e-Submission ID of the tender can be found on the left-hand side of the screen of the tender in e-Submission as well as in the tender reception confirmation.

Up to the signature of the contract the Agency may cancel the procurement procedure without tenderers being entitled to claim any compensation. Any such decision must be substantiated and tenderers notified.

The validity period of the tender, during which tenderers may not modify the terms of their tenders in any respect, is indicated under Heading IV.2.6 of the contract notice.

Submission of a tender implies acceptance of all the terms and conditions set out in the procurement documents and, where appropriate, waiver of the tenderer's own general or specific terms and conditions. The submitted tender is binding on the tenderer to whom the contract is awarded for the duration of the contract.

3. Contacts during the procurement procedure

Contacts between the Agency and tenderers are prohibited throughout the procedure save in exceptional circumstances and under the following conditions only:

a. Submission phase (before the time-limit for receipt of tenders)

Upon request, the Agency may provide additional information solely for the purpose of clarifying the procurement documents.

Any request for additional information must be made in writing only through the above TED e-Tendering website in the "Questions & answers" tab, by clicking "Create a question" (registration on TED e-Tendering is required to be able to create and submit a question).

The Agency is not bound to reply to requests for additional information received less than six working days⁶ before the time-limit for receipt of tenders.

The Agency may, on its own initiative, inform interested parties of any error, inaccuracy, omission or any other type of clerical error in the text of the procurement documents.

Any additional information will be published on the above TED e-Tendering website. The website will be updated regularly, and it is the tenderer's responsibility to check for updates and modifications during the submission period.

b. Opening of tenders

Tenders will be opened in public at the time and place indicated under Heading IV.2.7 of the contract notice. A maximum of one representative per tender may attend the opening session. For organisational and security reasons the tenderer must provide the full name, date of birth, nationality and ID or passport number of the representative⁷ at least two working days in advance to contracts@ema.europa.eu. The representatives will be required to present the tender reception confirmation generated by e-Submission and to sign an attendance sheet. The Agency reserves the right to refuse access to its premises if the above information or the tender reception confirmation are not provided as required.

The public part of the opening session will be strictly limited to the following aspects:

- verification that each tender has been submitted in accordance with the submission requirements of the call for tender;

⁶ Working days at the Agency's location indicated under Heading I.1 of the contract notice.

⁷ This data is necessary to ensure access to the Agency building. Details concerning the processing of personal data for visitors to the European Medicines Agency are available in the privacy statement at: <https://www.ema.europa.eu/en/about-us/legal/privacy-statement>.

- announcement of the tenders received: the names of the tenderers (all members in the case of a joint tender) will be announced.

Tenderers not present at the opening session may send an information request to contracts@ema.europa.eu if they wish to be provided with the information announced during the public opening.

Once the Agency has opened the tender, it shall become its property and will be treated confidentially.

c. Evaluation phase (after the opening of tenders)

Except in duly justified cases, tenderers who have failed to submit evidence or to make statements as required in the procurement documents, shall be contacted by the Agency to provide the missing information or clarify supporting documents.

EMA may correct obvious clerical errors in the tender after confirmation of the correction by the tenderer.

Such information, clarification or confirmation shall not substantially change the tender.

d. Award phase

Tenderers will be notified of the outcome of this procurement procedure by e-mail. The notification will be sent to the e-mail address provided in the e-Submission application for the tenderer (group leader in case of a joint tender) under the section *Tender Contact Info*. The same e-mail address will be used by EMA for all other communications with the tenderer. It is the tenderer's responsibility to provide a valid e-mail address and to check it regularly.

4. Data protection

If processing a reply to the invitation to tender involves the recording and processing of personal data (such as name, contact details, addresses and Curricula Vitae), such data will be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the European Union institutions and bodies and on the free movement of such data. Unless indicated otherwise, your replies to the questions and personal data requested are required to evaluate your tender in accordance with the specifications of the invitation to tender and will be processed solely for that purpose. The data controller for this processing is the Head of the Information Management Division; the contact details for the data controller can be obtained from contracts@ema.europa.eu. Details concerning the processing of your personal data are available on the privacy statement on the Agency's website at:

https://www.ema.europa.eu/documents/other/privacy-statement-processing-personal-data-context-public-procurement-procedures_en.pdf

The tenderer's personal data may be registered in the Early Detection and Exclusion System (EDES) if you are in one of the situations mentioned in Article 136 of the Financial Regulation⁸. For more information, see the Privacy Statement at:

http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm

5. Means of redress

Tenderers may submit any observations concerning the procurement procedure to the Agency using the contact details under Heading I.1 of the contract notice. If tenderers believe that there is maladministration, they may lodge a complaint to the European Ombudsman within two years of the

⁸ 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.

date from which they become aware of the facts which form the basis for the complaint (see <https://www.ombudsman.europa.eu>).

Within two months of notification of the outcome of the procedure (*award decision*), tenderers may launch an action for its annulment. Any request tenderers may make and any reply from the Agency, or any complaint for maladministration, will have neither the purpose nor the effect of suspending the time-limit for launching an action for annulment nor open a new period for launching an action for annulment. The body responsible for hearing annulment procedures is indicated under Heading VI.4.1 of the contract notice.

Yours faithfully

Nerimantas Steikūnas
Authorising Officer
(*e-signed*)

Annex to the invitation to tender:

- Tender specifications and annexes