

Call for tenders' details

Title: Provision of External Service Providers for IT Software Development, Implementation and Maintenance Services for the Clinical Trials Information System

Start date: 07/05/2020

Time limit for receipt of tenders: 03/07/2020

Contracting authority: European Medicines Agency (EMA)

Status: Closed

Call for tenders question list

| # | Submission date | Publication date | Question subject | Question | Answer |
|---|---------------------|---------------------|-------------------------|--|--|
| 1 | 08/05/2020 13:26 | 14/05/2020 12:53 | Criterion 3.3 Reporting | In the award criteria questionnaire in criterion 3.3, you request a sample monthly report. (a) Could you please confirm if EMA is expecting a fun blown sample report or only a table of contents is sufficient ? If it is the first case, our understanding is that we need the required sample is to be considered separately and in addition to the 10-page response for Criterion 3. Could you please confirm that our understanding is correct? | 14/05/2020 Under Annex 6 – Award criteria questionnaire, Criterion 3.3. the Tenderer is expected to provide a sample monthly report for the execution of the services including service quality indicators and service levels. Table of content is not sufficient. Response for Criterion 3.3 should be included within the maximum pages allocated for this criterion. CORRECTION: Please note, for Annex 6. – Award Criterion 3 – Maintenance approach; the maximum pages have now been increased from 10 to 15. |

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| 2 | 08/05/2020 13:27 | 14/05/2020 12:55 | Criterion 3 Reporting | In Criterion 3, question 3 Reporting is listed as 2.3. Could you please confirm that this is a clerical mistake and that it should be 3.3? | 14/05/2020 Your understanding is correct, Annex 6. – Award criteria questionnaire, Criterion 3, 2.3. should be read as Criterion 3, 3.3. |
| 3 | 08/05/2020 13:30 | 14/05/2020 12:57 | Criterion 3 Reporting | In the award criteria questionnaire in criterion 3.3, you request a sample monthly report. Could you please confirm if EMA is expecting a sample report regarding the provision of a maintenance service or of the overall FwC? | 14/05/2020 Annex 6 – Award criteria questionnaire, Criterion 3 – Maintenance approach. The Tenderer is expected to submit a sample report regarding the provision of maintenance services. |
| 4 | 08/05/2020 13:31 | 14/05/2020 12:58 | Award Criteria | Could you please confirm if the Award Criteria needs to be submitted in a unique document or in a separate document per Criterion? | 14/05/2020 Response for Annex 6 – Award criteria questionnaire should be submitted as one single document. |
| 5 | 08/05/2020 13:35 | 14/05/2020 13:00 | Criterion 2.1 and Criterion 3.1 | Our understanding is that EMA is expecting a description of the profiles in Criterion 2.1 and a FTEs estimation in Criterion 3.1. Could you please confirm that our understanding is correct? | 14/05/2020 Your understanding is not correct. Under Annex 6 – Criterion 2.1, the tenderer is not expected to provide a description of the profiles. Under Criterion 3.1, the tenderer is not expected to provide a FTE estimation. |

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| 6 | 12/05/2020 14:35 | 14/05/2020 13:01 | Extra Muros Services | Does EMA exclude any geographical location for the delivery of the extra muros services? | 14/05/2020 Tenderer's offsite work location must reside within the EEA only if the work at that location involves processing of personal data. This is unless there is an adequacy decision in place whereby the European Commission, on the basis of Article 45 of Regulation (EU) 2016/679, has determined that the country outside the EEA where the offsite work location is placed, offers an adequate level of data protection. |
| 7 | 14/05/2020 12:48 | 19/05/2020 17:16 | COVID - extension | Given the exceptional situation, causing delays on different levels e.g. employees are combining work and family-school life, especially the last weeks of June, we would like to request for an extension of 3 weeks? | 19/05/2020 Tenderers to note, taking into account the current COVID-19 exceptional situation, the Agency has decided to extend the tender submission deadline to 3 July 2020 at 12:00 CET. |
| 8 | 14/05/2020 11:21 | 21/05/2020 09:42 | References of Software Development projects (Tender Specs 19.2, 2.b) | The tenderer is required to provide references of Software Development projects of a similar scale. Please can you quantify the scale of the projects executed within the ongoing FWC at EMA (in value or persons.days). Indeed the indicative volume of 45,936 person-days is for the whole four-year contract, not for projects executed within the contract. Thank you. | 21/05/2020 Your assumption is correct. The Agency estimates, without this being binding, that the volume of services (development and maintenance) required under the contract is 45,936 days of the various profiles. Project references submitted must fulfil all criteria as set under 19.2. and 19.2.2b. Reference requirements are set in line with the estimated contract volume. |

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| 9 | 14/05/2020 11:45 | 21/05/2020 09:43 | References contracts / projects (Tender Specs 19.2) | Please explain why tenderers are required to provide references of contracts in 2.a and of projects in 3.b. Being understood that a project can be the object of a contract, of a single specific contract within a FWC, of a series of specific contracts within a FWC or even of a series of specific contracts within several FWCs. Thank you. | 21/05/2020 Your understanding is correct. Tenderer is requested to submit references that fulfil all criteria as stated under 19.2.2. References provided for maintenance should be based on completed contracts that fulfil all criteria under 19.2 and 19.2.2a. References provided for software development should be based on completed projects that fulfil all criteria under 19.2 and 19.2.2b. In that respect a project reference can be a single direct contract, a single specific contract under a FwC, series of specific contracts under a FwC, series of specific contracts under multiple FwC provided that the referenced project fulfils all criteria under 19.2 and 19.2.2b. |

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| 10 | 14/05/2020 11:51 | 21/05/2020 09:46 | References : value of the projects (Tender Specs 19.2, 2b) | Please confirm that the requirement is to provide references of SW development projects for at least 15 M€ per year (at least 3 projects, each with a value of more than 5,000,000 EUR per annum). Thank you. | <p>21/05/2020 Your understanding is not correct. Tenderers are required to demonstrate that within the past three years they delivered (the project may have started before) at least three IT Software Development projects of a similar scale. Each project must have had a continuous duration of a minimum of 18 months with a value in excess of 5,000,000 EUR per annum. At least two software development reference should demonstrate the ability to deliver end to end IT Software Development product. Details of the Tenderer's current and previous experience of three major IT Software Development projects of a similar type that has been awarded by public or private sector clients and delivered by the Tenderers in the past three years, including dates and sums. Each must have been undertaken for a different client (departments, divisions, directorates etc. are regarded as the same client).</p> |

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| 11 | 14/05/2020 11:54 | 21/05/2020 09:49 | References of maintenance contracts (Tender Specs 19.2, 2b) | Please confirm that a maintenance contract of 80,000 € per year is a valid reference provided that it had a continuous duration of a minimum of 12 months. Thank you. | 21/05/2020 Your understanding on 19.2, 2a is correct. In addition, at least one maintenance reference should demonstrate the implementation of "DevOps" practices to automate delivery processes. |
| 12 | 19/05/2020 12:53 | 21/05/2020 09:52 | Selection criteria - references | Our understanding is that each EU institution (including an EU Agency) are considered a different client. Could you please confirm our understanding is correct? | 21/05/2020 Your understanding is correct. |
| 13 | 19/05/2020 13:52 | 21/05/2020 10:07 | Response to the Award Criteria Questionnaire TOC, cover page | The Response for Annex 6 – Award criteria questionnaire must be submitted as one single document (Q&A#4) of max 60 pages (including the sample report) inclusive of any pictures, tables, graphs or diagrams. Are we allowed to add, on top of the 60 pages, a Table of Contents which conveys no actual element of response and which would ease the navigation in the document? And a cover page? Thank you. | 21/05/2020 Yes, Tenderers may add a cover page and table of contents to the award criteria questionnaire response, provided that such additions convey no actual element of response and which only serve the purpose of navigation in the document. Those pages then will not be counted in the maximum pages. |

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| 14 | 19/05/2020 14:51 | 22/05/2020 10:21 | Page limitation per critarion | Response for Annex 6 – Award criteria questionnaire should be submitted as one single document (Q&A#4) but on page 2 of EN-Annex 06 - Award criteria questionnaire.pdf, "For example: a tenderer submits a 12 pages document for criterion 2, the document will only be evaluated up to page 10." Please can you confirm that the example becomes "a tenderer submits 12 pages for criterion 2, the response will only be evaluated up to page 10"? Thank you | 22/05/2020 Your understanding is correct. |
| 15 | 18/05/2020 13:08 | 25/05/2020 21:30 | Certificates of satisfactory execution. | Due to the COVID-19 situation, our Consortium is facing difficulties in getting the customers' signatures on some Certificates of satisfactory execution. Is it possible to propose the all references at the submission, and provide any missing Certificate of satisfactory execution only when the contract is awarded? | 25/05/2020 Certificates of satisfactory execution are requested to be submitted at the tender submission. As an exceptional alternative to the certificates signed by the client, the Agency will except documents with a certified digital signature, or alternatively an email from the reference client containing all required details on the reference projects and digital signature. |
| 16 | 19/05/2020 11:22 | 25/05/2020 21:33 | Annex 05 Profiles | Regarding the IT Domain Expert profile, could you please confirm that the required professional certificates will be defined in the request for services and not at the tendering stage? | 25/05/2020 Your understanding is correct. |

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| 17 | 19/05/2020 11:27 | 26/05/2020 13:40 | Tender specifications - Selection criteria - Relevant experience | Regarding the evidences to provide for the relevant experience, for point B (Software development services), we understand that each project must have had a continuous duration of a minimum of 18 months OR with a value in excess of 5,000,000 EUR per annum. Please confirm our understanding. | 26/05/2020 Your understand is not correct. Each project must have had a continuous duration of a minimum of 18 months with a value in excess of 5,000,000 EUR per annum |
| 18 | 21/05/2020 12:26 | 26/05/2020 13:44 | Technical and professional capacity | With reference to the evidence required to fulfil the technical and professional criteria, section 19.2, point 2.b, "Each project must have had a continuous duration of a minimum 18 months with a value in excess of 5,000,000 EUR per annum". It is our understanding that a referenced project with either a continuous duration of 18 months within the last 3 years OR 5,000,000 EUR per annum would fulfil this requirement. Could you please confirm our understanding or clarify further? | 26/05/2020 Your understanding is not correct. Each project must have had a continuous duration of a minimum 18 months with a value in excess of 5,000,000 EUR per annum. |

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| 19 | 21/05/2020 12:27 | 26/05/2020 13:47 | Technical and professional capacity | With reference to the evidence required to fulfil the technical and professional criteria, section 19.2, point 2, "Relevant experience in provision of similar services to comparable clients in the past three years" is requested. We understand that we may demonstrate reference projects that started before 06/2017 and/or still on-going, as long as they fulfil the rest of the requirements stated in points 19.2.2a and 19.2.2.b. Could you please confirm our understanding or clarify further? | 26/05/2020 Your understanding is not correct. Under 19.2.2.a), Tenderers are required to demonstrate that within the past three years they managed at least three IT Software Maintenance contracts of a similar scale. Under 19.2.2.b), Tenderers are required to demonstrate that within the past three years they delivered (the project may have started before). Tenderers may use completed/delivered contracts, projects as reference provided, that they fulfil the relevant requirement as specified in the technical specification. All references must be accompanied by certificates of satisfactory execution issued by the clients. |
| 20 | 21/05/2020 12:27 | 26/05/2020 13:48 | Technical and professional capacity | We understand that the projects we will provide as evidence to fulfil the technical and professional criteria, as described in section 19.2, point a & b, may refer to a) Time and Means services, or Quoted Time and Means services or Fixed Price services, b) Services delivered by intra-muros, or extra-muros, or a combination of both. Could you please confirm our understanding or clarify further? | 26/05/2020 The client references should demonstrate the tenderer's ability to deliver whilst responsible for delivery. For this reason, it is required that these relate to Fixed Price or Quoted Time and Means mode of delivery. References relating to Time and Means delivery in that case would not be accepted. Services delivered by intra-muros, extra-muros or the combination of both are accepted. |

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| 21 | 21/05/2020 12:28 | 26/05/2020 13:49 | Technical and professional capacity | According to section 19.2, point 2.b, "At least two software development reference should demonstrate the ability to deliver end to end IT software development product". We understand that a Framework contract relevant to the provision of Software Development services through which several products are delivered end-to-end, is eligible for covering this requirement. Could you please confirm our understanding or clarify further? | 26/05/2020 Your understanding is not correct. Under 19.2.2.b) Tenderers are required to demonstrate that within the past three years they delivered at least three IT Software Development projects of a similar scale. Provided references should relate to delivered projects and must fulfil all requirements as specified in the technical specification. |
| 22 | 21/05/2020 12:28 | 26/05/2020 13:51 | Technical and professional capacity | With reference to the evidence required to fulfil the technical and professional criteria, section 19.2, point 2.b, "Each project must have had a continuous duration of a minimum 18 months with a value in excess of 5,000,000 EUR per annum". We understand that a software development project that had minimum duration of 18 months within the last 3 years and value in excess of 7,500,000 EUR within these 18 months is eligible for covering this requirement. Could you please confirm our understanding or clarify further? | 26/05/2020 Your understanding is correct. |

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| 23 | 21/05/2020 12:28 | 26/05/2020 13:52 | Different clients | According to page 32 of the tender specifications, section 19.2 "Each must have been undertaken for a different client". We understand that we must demonstrate projects for at least 3 different clients per project category (Development/Maintenance). In other words, we may demonstrate a development project and a maintenance project for the same client. Could you please confirm our understanding or clarify further? | 26/05/2020 Your understanding is correct. |

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| 24 | 21/05/2020 12:29 | 26/05/2020 13:54 | Technical and professional capacity | <p>With reference to the evidence required to fulfil the technical and professional criteria, section 19.2, point 2.a,” Each contract must have had a continuous duration of a minimum of 12 months or with a value in excess of 2.000.000 EUR per annum”. We understand that the following project examples are eligible for covering this requirement: a) An IT Software maintenance project with duration of more than 12 months within the period 06/2017 until today, regardless its value b) An IT Software maintenance project with 6 months duration within the period 06/2017 until today, with value in excess of 1.000.000 for these 6 months. Could you please confirm our understanding or clarify further?</p> | <p>26/05/2020 Your understanding is partially correct. Tenderers to note that for 19.2.2.a.) reference submitted should relate to a specific contract or a direct contract that otherwise fulfil all requirements as specified in the technical specification and not to a “project”. Your understanding on point a.) is correct. Your understanding on point b.) is not correct. A reference covering 6 months period must have a value in excess of 2,000,000 EUR.</p> |

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| 25 | 21/05/2020 12:31 | 26/05/2020 13:55 | ISO Certifications | Since the selection criteria as evaluated as a whole for all Consortium members, we understand that ISO certification should be possessed by the Consortium as whole. In other words in case of a Consortium it is sufficient that one Consortium member possess the certification and all certifications are covered by the Consortium. Could you please confirm? | 26/05/2020 Your understanding is correct. |
| 26 | 25/05/2020 15:51 | 26/05/2020 13:57 | Documents signing | It is our understanding that in case the administrative forms/ declarations/ statements are hand-signed by an authorized representative, scan copies must be uploaded in e-submission and no original hand-signed documents need to be sent to EMA's premises. Could you please confirm our understanding or clarify further? | 26/05/2020 Your understanding is correct |

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| 27 | 25/05/2020 15:51 | 26/05/2020 13:58 | Electronic Signature | According to the instructions of Annex 02 – Response questionnaire, “In respect of the signed declarations upon honour and statements, taking into account the current COVID-19 exceptional situation, electronic signatures are acceptable”. We understand that this applies to all the forms/statements that require signature (Annexes 01, 03, 12, 14, 15, 16). Could you please confirm our understanding or clarify further? | 26/05/2020 Your understanding is correct. Documents which are signed with a certified electronic signature are accepted, provided the signature meets the requirements for advanced electronic signature or qualified electronic signature in the meaning of eIDAS Regulation (Regulation 910/2014). If the signature does not meet those requirements, then the alternative of providing wet signature remains. |
| 28 | 25/05/2020 15:52 | 26/05/2020 14:00 | Annex 02 - Response questionnaire | For Annex 02 could you please indicate in case of joint tender, whether each consortium member (and subcontractors) should fill in their own questionnaire or do you prefer to add extra sheets (where appropriate) in the same questionnaire and submit one document? | 26/05/2020 Annex 02 – Response questionnaire is requested to be submitted as a single document in both Excel and PDF formats. In case of joint tender, the tenderer is requested to add additional worksheets to the document as required. |
| 29 | 15/05/2020 15:34 | 29/05/2020 20:26 | Criterion 3.2 | Our understanding is that in our answer to question 3.2 we should address the change request management cycle and not the acceptance of these changes from a business point of view. Could you confirm that our understanding is correct? | 29/05/2020 Your understanding is NOT correct. In your answer you should cover the complete lifecycle of managing change requests and making these changes available to business colleagues, including the user acceptance aspect. |

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| 30 | 18/05/2020 16:48 | 29/05/2020 20:39 | Software development reference (Tenders Specs 19.2.2.b), end to end IT Software Development product | Tenderers are required to submit at least 3 IT Software Development projects among which at least 2 should demonstrate the ability to deliver end to end IT Software Development product. Please can you specify what is meant with "the ability to deliver end to end IT Software Development product"? What is a 'IT Software Development product'? Do you mean an Software Development project (not product), from the inception to the deployment in production? What would differentiate in your eyes a project resulting in the delivery of a 'end to end IT Software Development product' from the other IT Software Development project? | 29/05/2020 Successful projects have a start and an end, after which a new project can start to continue the work. Contrary to that, the product management paradigm encompasses all the efforts and resources needed to field and maintain a long-lived capability for the organisation. In the context of delivering a software development product delivers functionality between regular intervals, based on an evolving roadmap aligned with business/product strategy. Teams last as long as the roadmap has business relevance, typically several years. Roadmaps are prioritised by Product Owners and their business counterparts and cross-cutting initiatives are prioritised by the business or IT leadership. Delivery of new functionality and maintenance is managed by the same team and delivery process. |

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| 31 | 21/05/2020 12:26 | 29/05/2020 20:41 | DevOps practices | With reference to the evidence required to fulfil the technical and professional criteria, section 19.2, point 2.a, "At least one maintenance reference should demonstrate the implementation of "DevOps" practices to automate delivery process". We understand that a relevant project that incorporates tools such as Git, Jenkins, Nexus, Maven, Selenium, etc. for service delivery for implementing DevOps with CI/CD practices would fulfil this requirement. Could you please confirm our understanding or clarify further? | 29/05/2020 The Tenderer is requested to provide a maintenance reference that demonstrates the implementation of DevOps practices. Reference should demonstrate how DevOps practices were implemented in delivery process. Tools used shall be described, however the focus of the reference is about the DevOps practices implemented to automate delivery process. |
| 32 | 21/05/2020 12:29 | 29/05/2020 20:45 | Profiles – Product Manager (Annex 05 of tender specifications) | It is our understanding that CSPO (Certified Scrum Product Owner) certificate is considered equivalent to CPM and ACPMPO, thus would cover the Product manager's profile certification requirement. Could you please confirm our understanding or clarify further? | 29/05/2020 Your understanding is correct. |

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| 33 | 21/05/2020 12:29 | 29/05/2020 20:46 | Profiles – Business Analyst (Annex 05 of tender specifications) | It is our understanding that IQBBA (Certified Foundation Business Analyst) and IREB (Certified Professional for Requirements Engineering Foundation Level) are considered equivalent to BCS, CCBA, CBAP, IIBA certificates, thus would cover the Business Analyst's profile certification requirement. Could you please confirm our understanding or clarify further? | 29/05/2020 Your understanding is correct. |
| 34 | 21/05/2020 12:30 | 29/05/2020 20:47 | Profiles (Annex 05 of tender specifications) | It is our understanding that AWS DevOps Engineer certificate is considered equivalent to the DevSecOps Engineering certificate requested for the DevOps Engineer profile. Could you please confirm our understanding or clarify further? | 29/05/2020 Your understanding is correct. AWS DevOps covers DevSecOps aspects. |
| 35 | 21/05/2020 12:30 | 29/05/2020 20:48 | Profiles (Annex 05 of tender specifications) | With reference to the professional certificates related to Java EE required for the Technical Architect, Developer and SaaS Developer profiles, we understand that similar certificates in Java SE are considered equivalent. Could you please confirm our understanding or clarify further? | 29/05/2020 Your understanding is NOT correct. The curriculum for the Java SE certification is different from the curriculum for the JEE certification. We require JEE certification since it covers enterprise aspects, such as persistence (JPA) and messaging (JAXB, JAX-WS, JAX-RS). |

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| 36 | 21/05/2020 12:30 | 29/05/2020 20:50 | Profiles (Annex 05 of tender specifications) | With reference to the professional certificates related to Azure for the Technical Architect and Developer, we understand that similar certificates in AWS (AWS Solution Architect Associate, AWS Developer Associate, etc) are considered equivalent. Could you please confirm our understanding or clarify further? | 29/05/2020 Your understanding is correct. |
| 37 | 21/05/2020 12:31 | 29/05/2020 20:52 | Profiles (Annex 05 of tender specifications) | With reference to the certifications requested for the User eXperience and User Interface Designers, we understand that certificates of attendance to relevant UI/ UX trainings provided by accredited organisations are considered equivalent for covering the profiles' requirements. Could you please confirm our understanding or clarify further? | 29/05/2020 Your understanding is correct. In case of a university/college degree the educational organisation should certify that: • the user experience curriculum is equivalent to a professional accreditation and • the candidate has completed successfully the user experience designer subject. NB Courses providing a certificate of attendance are not acceptable. |
| 38 | 25/05/2020 15:52 | 29/05/2020 21:04 | Power of Attorney | With reference to section 8.2 of the tender specifications, "the Agency will require them to formalize the collaboration before the contract is signed". It is our understanding that the duly filled-in and signed Annex 13 - Power of Attorney should be submitted upon award of the contract and not at the tender stage along with our offer. Could you please confirm our understanding or clarify further? | 29/05/2020 Tenderer may submit the duly signed POA at the tenderer submission stage, however it is not mandatory at that stage. |

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| 39 | 21/05/2020 12:31 | 02/06/2020 11:32 | Criterion 2 | In relation to your question “i. Software delivery process you would follow for the analysis, design, implementation, deployment and testing of the product, including management of technical debt”. Could you please elaborate further on the term “technical dept”? Do you refer to rework required in case of development? | 02/06/2020 Tenderer may find a link below that describes the concept of technical debt: https://resources.sei.cmu.edu/asset_files/WhitePaper/2012_019_001_58818.pdf |
| 40 | 25/05/2020 15:54 | 02/06/2020 11:41 | Number of staff break down | According to section 19.2.1.b of the tender specifications, “A break down per profile, level and employment type is required”. It is our understanding that (a) a break down per year (2019, 2018, 2017) should also be provided; (b) break down per employment type refers to the distinction between staff directly employed by the tenderer (consortium members) or subcontractors. Could you please confirm our understandings or clarify further? | 02/06/2020 For 19.2.1 of the ITT; the Tenderer is requested to provide the following documents: a. Statement on the average annual manpower and the number of managerial staff covering the period of 2017-2019; and b. Statement on the number of staff per employment type, profile and level (as described in Annex 05), covering the period of 2017-2019 is required. The statement is required to cover all profiles described in Annex 05 of the technical specification. |

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| 41 | 26/05/2020 11:56 | 02/06/2020 11:44 | Timeline – current state of the contract | With reference to Section 3.3.3 of Tender Specifications, “The Audit is planned for the end of 2020 with audit findings being resolved and new functionality being implemented during 2021, in preparation for the Go-live.”, can you please provide the timeline of this contract i.e. a) when the incumbent’s contract end, b) when is the transition-in overlap (incumbent – upcoming contractor), c) when are the roll-out activities planned? | 02/06/2020 Transition is planned to happen during first half of 2021. Planned duration is 3 months and shall be completed by end of June 2021. |
| 42 | 26/05/2020 17:23 | 02/06/2020 11:57 | Annex 02 - Response questionnaire | It is our understanding that the consolidated Annex 02 - Response questionnaire excel file as well as the duly signed sheets will be submitted in e-Submission application under “Other” tab of the sole tenderer or the consortium leader’s in case of joint tender. Please confirm our understanding or clarify further. | 02/06/2020 Your understanding is correct. |
| 43 | 27/05/2020 14:48 | 02/06/2020 12:00 | Question 2.1 - Planning | In order to facilitate comprehension and clarity, are we allowed to submit a planning diagram in A3 format to question 2.1? | 02/06/2020 For Annex 06, Criterion 2. Question 2.1 the Tenderer may submit a planning diagram in A3 format. |

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| 44 | 18/05/2020 08:35 | 04/06/2020 10:04 | Disproportional selection criteria | <p>Criterion 19.2.2.b requires 3 IT SW Development projects with an annual budget of 5 M€. EU institutions, agencies and European public authorities implement projects with a much smaller budget. The same is true for criterion 19.2.2.a. These criteria exclude most of the European IT firms. EMA should not exclude them, since the minimum turnover is 11 M€ (section 18.1). The criteria have to be adapted accordingly. EU directives stipulate that selection criteria must be proportionate and reasonable. Moreover, in EU there are markets operating with a manday (md) rate of 800 € and others with 100 €. With criteria 19.2.2.a/b, those who offer low prices are disadvantaged. E.g., a project of 800 K€ at 100 €/md uses more mds and demonstrates a higher expertise than a project of 5 M€ at 800 €/md. In some cases, projects have a high budget because they comprise hardware and software licenses. In ESP DIMSIS II with more than double the volume of CTIS, the same criterion required</p> | <p>04/06/2020 The evidence required under section 19.2.2.b) of the technical specifications refers to delivery of at least three IT Software Development projects, whereas each project must have had a continuous duration of a minimum of 18 months with a value in excess of 5,000,000 EUR per annum (for details - please see the technical specifications). It means that under section 19.2.2.b) both duration and value have to be met for each of the projects. Whereas the evidence indicated in section 19.2.2.a) of the technical specifications requires demonstration of management of at least three IT Software Maintenance contracts of a similar scale within past 3 years, whereas each contract must have had a continuous duration of a minimum of 12 months or with a value in excess of 2,000,000 EUR per annum (for details - please see the technical specifications). Please note that for purposes of demonstrating compliance with section 19.2.2.b) the tenderers are expected to refer to minimum 3 projects, however one project may consist of more than one concluded contract. The indicated selection criteria have been considered with due care by the Agency in order to reflect the needs of the Agency with respect to the subject</p> |

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| | | | | <p>CTIS, the same criterion required references of at least 6 months duration and 2 M€/year vs 18 months and 5 M€/year in CTIS. Please amend as follows: 1. The references should be adapted to a minimum yearly value, comparable to ESP DIMSIS II and EU directives. 2. Tenderers should be allowed to present more than one references totaling the minimum value for a single reference. E.g. if the budget for each reference is X M€, a tenderer may present for each reference three other references totaling X M€ or more. 3. The volume of references must be expressed in terms mds and not in €, so that HW & SW can be excluded.</p> | <p>the Agency with respect to the subject of the procurement, and ensure proportionality. Please note that the selection criteria indicated in ESP DIMSIS II were different solely in the context of IT software development, since the tasks expected to be covered under that procurement are different. In particular, the tasks within the current procurement are expected to be of higher complexity and intensity. The requirements in question aim, thus, to address the capacity of the tenderer to perform work of scale similar to the one envisaged for this to-be-procured project (Clinical Trial Information System). In the light of the above clarification the Agency does not intend to change the requirements indicated in section 19.2.2. a) and b).</p> |
| 45 | 28/05/2020 17:59 | 04/06/2020 10:11 | Disproportional selection criteria - Our question of 18/05/2020 | <p>On 18 May 2020 we submitted a question to EMA. So far many questions which were submitted later, were answered. Our question remains unanswered. Could you please confirm that our question was received and that it will be answered?</p> | <p>04/06/2020 Tenderers' question has been received and response has been published.</p> |

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|----|---------------------|---------------------|-------------------------------------|--|---|
| 46 | 20/05/2020 09:14 | 04/06/2020 11:11 | Signature of documents | Can another person (that has the signature authority to represent a company) than the LEAR taken back in the registration participant sign the documents? | 04/06/2020 Submitted tender documents are requested to be signed by either the appointed consortium leader in case of joint tender or the appointed person authorised representing the tenderer in case of a single entity. No other signatory is accepted. |
| 47 | 21/05/2020 12:28 | 04/06/2020 11:29 | Technical and professional capacity | With reference to the evidence required to fulfil the technical and professional criteria, it is our understanding that we may demonstrate the same contract for covering points (a) and (b) of section 19.2, point 2 of the tender specifications, including both IT software development and IT software maintenance projects, as long as each project category fulfils the relevant requirements (stated in points (a) and (b) of the referenced section). Could you please confirm our understanding or clarify further? | 04/06/2020 Your understanding is correct. A reference that otherwise fulfils all relevant requirements as described under 19.2.2.a) and 19.2.2.b) may be submitted for both. Tenderer is requested to clearly demonstrate the fulfilment of each relevant requirement. The submission of Annex 07-Reference Template is requested to be provided for both contract and project referenced. Furthermore, the provided client's certificate must confirm the satisfactory execution of both contract and project. |

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| 48 | 22/05/2020 15:53 | 04/06/2020 11:44 | References | With reference to Section 19.2 Evidence required, 2.a/2b of the open tender specifications, page 33 of 35, the tenderer should provide references to relevant experience in provision of similar services to comparable clients in the past three years. We understand that the same reference can be provided for both IT software maintenance (evidence 2.a.) and IT software (evidence 2.b) as long as it satisfies all the minimum requirements under 19.2.2.a and 19.2.2.b. Please confirm our understanding or clarify further. | 04/06/2020 Your understanding is correct. A reference that otherwise fulfils all relevant requirements as described under 19.2.2.a) and 19.2.2.b) may be submitted for both. Tenderer is requested to clearly demonstrate the fulfilment of each relevant requirement. The submission of Annex 07-Reference Template is requested to be provided for both contract and project referenced. Furthermore, the provided client's certificate must confirm the satisfactory execution of both contract and project. |
| 49 | 26/05/2020 17:21 | 04/06/2020 14:16 | Declaration on honour - Exclusion criteria Evidence | Can you please clarify whether the tenderer must provide the supporting Evidence for Annex 03, at the tender stage or at the award stage upon request? | 04/06/2020 Tenderer is requested to provide Annex 03 and its supporting evidence at the tenderer stage. In addition, Tenderer is requested to provide a completed Annex 03 for each subcontractor if the overall envisaged subcontracting is greater than 10%. |

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| 50 | 25/05/2020 15:54 | 04/06/2020 16:00 | Client Letters | <p>We understand that in case we submit as evidence to our relevant experience an IT Software Development project executed under a Framework Contract, a certificate issued by the client, confirming satisfactory execution of the Framework Contract as a whole would suffice as documentation accompanying the project reference. Could you please confirm our understanding or clarify further?</p> | <p>04/06/2020 Your understanding is not correct. Under 19.2.2.b.) the Tenderer may provide a single contract or multiple specific contracts under one or more framework contracts for a referenced project. Certificate of satisfactory execution can be provided on a Framework Contract level, provided; that a.) the specific contract or specific contracts under a FwC are undoubtedly linked to a specific project that is otherwise further described in Annex07-Reference template; and b.) the certificate confirms the satisfactory execution of the referenced project.</p> |

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| 51 | 25/05/2020 15:53 | 04/06/2020 16:43 | Documentation provided by subcontractors | <p>With reference to section 8.3 of the tender specifications, "A completed Annex 03 is required by each subcontractor where more than 10% of the contract shall be executed by subcontractors". Also, in sheets 02b.1 and 02b.2 of Annex 02 – Response questionnaire "documentation must be provided in relation to any subcontractors unless 10% or less of the total volume of services is expected to be subcontracted and in this case documentation for any subcontractor is not required". It is our understanding that a subcontractor must provide filled-in and signed Annex 03 and sheets 02b.1, 02b.2 and 02b.3 of Annex 02 only in case more than 10% of the contract is envisaged to be subcontracted to this specific subcontractor. Could you please confirm our understanding or clarify further?</p> | <p>04/06/2020 It is important to note, the 10% subcontracting volume refers to the total envisaged subcontracting volume and not per subcontractor. Should the Tenderer rely on the capacity of a subcontractor or several subcontractors, and the total volume of envisaged subcontracting is greater than 10%, then the submission of documents are required for each subcontractor. Should the total volume of envisaged subcontracting is equal or less than 10%; then the submission of such documents are not required.</p> |

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| 52 | 25/05/2020 15:53 | 04/06/2020 17:01 | Financial and economic capacity | <p>According to section 18.2 of the tender specifications, page 31, "In case of joint tenders the financial and economic capacity shall be evaluated as a whole". We understand that in case a consortium member or subcontractor does not obtain a score of at least 4 points when calculating its financial feasibility, the financial capacity of the tenderer is not being necessarily affected, since the financial feasibility requirement will be evaluated as a whole. In other words,</p> <p>EMA will score the liquidity, solvency and profitability of the tenderer based on the consolidated numbers of the consortium members and subcontractors. Could you please confirm our understanding or clarify further?</p> | <p>04/06/2020 Your understanding is partly correct. In case of joint tenders the financial and economic capacity is evaluated as a whole. Please note the evaluation of the financial and economic capacity of joint tenders is not based on consolidated financial figures but on individual assessments. The conclusion of the evaluation is then formed on the joint tenders as a whole.</p> |

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| 53 | 25/05/2020 15:53 | 04/06/2020 17:03 | Financial and economic capacity | <p>With reference to section 18. Selection criteria: Financial and economic capacity and specifically to 18.2 Evidence required, the tenderer, including subcontractors if more than 10% of the contract is intended to be subcontracted, shall provide “a statement of overall turnover for the last two financial years available”. It is our understanding that worksheet “02. a Turnover” of Annex 02 – Response questionnaire corresponds to this form and no extra documentation needs to be provided as evidence to cover the quoted criterion. Could you please confirm our understanding or clarify further?</p> | <p>04/06/2020 Your understanding is correct.</p> |

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| # | Submission date | Publication date | Question subject | Question | Answer |
|----|---------------------|---------------------|-----------------------------------|--|--|
| 54 | 25/05/2020 15:52 | 04/06/2020 17:12 | Annex 02 - Response questionnaire | <p>With reference to Annex 02 – Response questionnaire, we understand that in case the tenderer is a consortium/ group and more than 10% of the total volume of services is expected to be subcontracted: (a) Pdf versions of sheets 01a, 01c, 02a must be signed by the consortium leader</p> <p>(b) Additional copies of worksheets 01b, 02b.1, 02b.2, 02b.3 will be created for consortium members and subcontractors and the respective authorized representative should sign the pdf version) (c) Annex 02 in MS Excel 10 and the signed pdf files should be uploaded in e-submission under the tab “other” of the consortium leader. Could you please confirm our understandings or clarify further?</p> | <p>04/06/2020</p> <p>a.) 01a and 01c must be signed by the Consortium leader. 02a must be filled by the consortium leader, however, does not require a signature. b.) Your understanding is correct. Signature of those sheets are not required. c.) Your understanding is correct.</p> |

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|----|---------------------|---------------------|-----------------------|---|--|
| 55 | 22/05/2020 15:53 | 04/06/2020 17:14 | References | With reference to subsection 19.2.2.b of the open tender specifications, page 33 of 35, it is stated that "Each project must have had a continuous duration of a minimum of 18 months with a value in excess of 5,000,000 EUR per annum.". We understand that a reference with a continuous duration of 18 months fulfilling the 5Mio Euros for at least 1 year during the past three years is eligible. Please confirm our understanding or clarify further. | 04/06/2020 Tenderer please refer to Q&A no. 22. Tenderer is required to demonstrate that within the past three years it delivered (the project may have started before) at least three IT Software Development projects that had a minimum duration of 18 months and value in excess of 7,500,000 EUR. |
| 56 | 26/05/2020 17:21 | 04/06/2020 18:02 | Statement of Turnover | Can you please confirm that the requested statement of overall turnover for the last two financial years in page 30 of the main specifications pdf file corresponds to the sheet 02a Turnover of the Annex 02 excel file? | 04/06/2020 Your understanding is correct. |

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| 57 | 26/05/2020 15:22 | 04/06/2020 18:35 | Section 19.2.1.a | With reference to section 19.2.1.a of the tender specifications, describing the necessary proof of sufficient level of manpower, we understand the following: (a) We must provide a document presenting the requested numbers and no signed statement needs to be submitted. (b) We may also count freelancers that had a contractual relationship with the tenderer during 2017/ 2018/ 2019. Could you please confirm our understandings or clarify further? | 04/06/2020 For selection criterion 19.1.1. and 19.2.1. the Tenderer is requested to provide: a.) Statement on the average annual manpower and the number of managerial staff covering the period of 2017-2019; and b. Statement on the number of staff per employment type, profile and level (as described in Annex 05), covering the period of 2017-2019. The statement is required to cover all profiles described in Annex 05 of the technical specification. Statements may be signed but is not mandatory. Statements for point a.) and b.) must include staff members = permanent staff (directly employed by the tenderer) + subcontractors that fulfil all requirements as described in 19.1.1 and 19.2.1. Freelancers are excluded. |
| 58 | 29/05/2020 12:18 | 04/06/2020 18:48 | Annex 02 - Response questionnaire / 01a Legal Entity Form | It is our understanding that in case of electronic signature is used, the company stamp could be omitted. Kindly note that due to the circumstances arising from COVID19 pandemic, most of the employees are working remotely with no access to such means. Please confirm that our understanding is correct or clarify further. | 04/06/2020 Your understanding is correct. Considering the COVID-situation, electronic signature is accepted, and company stamps are not required. |

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| 59 | 28/05/2020 17:25 | 04/06/2020 19:00 | Annex 02 - Response questionnaire / Signed Sheets | <p>According to the instructions of Annex 02, point 9 "In addition, once this file is completed, tenderers are required to print all worksheets and submit the original signed electronic copy of the documents." It is</p> <p>our understanding that the final consolidated excel file can be converted in one pdf file and can be signed with an advanced electronic signature or qualified electronic signature in the meaning of eIDAS Regulation (Regulation 910/2014), and not each excel sheet separately. Please confirm our understanding or clarify further.</p> | <p>04/06/2020</p> <p>Tenderer is requested to submit the completed Annex 02 – Response questionnaire in both excel and pdf formats. Considering the COVID-19 situation, Tenderer may include a cover page to the converted pdf format and sign it with a certified electronic signature that meets the requirements for advanced electronic signature or qualified electronic signature in the meaning of eIDAS Regulation (Regulation 910/2014).</p> |

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|----|---------------------|---------------------|------------------|--|---|
| 60 | 26/05/2020 14:07 | 04/06/2020 20:47 | References | Concerning technical capacity, p.33 Relevant experience, under point a) it is stated that experiences in the area of software maintenance "Each contract must have had a continuous duration of a minimum of 12 months or with a value in excess of 2,000,000 EUR per annum". Under point b) it is stated " Each project must have had a continuous duration of a minimum of 18 months with a value in excess of 5,000,000 EUR per annum." In the first a) it is stated "or". Could you confirm that in b) both criteria must be applied (there is no "or")? The criteria of a value of 5,000,000 EUR only for development seems very high. | 04/06/2020 Your understanding is correct. 19.2.2. a.) is stated "or" 19.2.2. b.) is stated "with" |

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| 61 | 21/05/2020 12:31 | 04/06/2020 21:22 | Criterion 2 | <p>In relation to your request for “v. The proportion of on-site/off-site profiles as required; and vi. The proportion of on-site/off-site resources as required.”. Could you please clarify the following? • We understand that you refer to the proportion of profiles and resources for the management of the contract and not for the actual implementation (which will be defined at SC level). Could you please confirm or further clarify? • We understand that for v) we need to describe only the managerial profiles and their distribution per location while for vi) we need to present the number of FTEs per profile defined in v). Could you please confirm or further clarify the difference between profiles and resources?</p> | <p>04/06/2020 For Criterion 2, Q.2.3 the Tenderer is requested to provide details of a proposed delivery approach by addressing several aspects. Under v. and vi., the Tenderer is requested to address the proportion of the team as a whole, including management. v.) Tenderer is requested to describe the proportion (in %) of on-site and off-site profiles to be used for the proposed delivery approach. The description should cover in detail each profile proposed. i.e. Developer; 20% on-site and 80% off-site). vi.) Tenderer is requested to describe the proportion (in %) of on-site/off-site resources proposed for the delivery approach. Response must cover the team as a whole, including management. i.e. Entire Delivery team 35% on-site and 65% off-site. Tenderer is requested to describe the proportion of the management team i.e. 10%. And how the management team is distributed across on-site and off-site. i.e. 40% on-site and 60% off-site.</p> |

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| 62 | 21/05/2020 12:32 | 04/06/2020 21:23 | Criterion 3 | <p>In relation to your request for “iii. The proportion of on-site/off-site profiles as required; and iv. The proportion of on-site/off-site resources as required..”. Could you please clarify the following? • We understand that you refer to the proportion of profiles and resources for the management of the transition and not for the actual implementation (which will be defined at SC level). Could you please confirm or further clarify? • We understand that for iii) we need to describe only the managerial profiles and their distribution per location while for iv) we need to present the number of FTEs per profile defined in iii). Could you please confirm or further clarify the difference between profiles and resources?</p> | <p>04/06/2020 Your understanding is not correct. For Criterion 3, Q.3.1 the Tenderer is requested to provide details on the smooth transition approach to production (“go-live” milestone) of CTIS by addressing several aspects. Under iii. and iv., the Tenderer is requested to address the proportion of the team as a whole, including management. iii.) Tenderer is requested to describe the proportion (in %) of on-site and off-site profiles to be used for the proposed transition approach. The description should cover in detail each profile proposed. i.e. Developer; 20% on-site and 80% off-site). iv.) Tenderer is requested to describe the proportion (in %) of on-site/off-site resources proposed for the transition approach. Response must cover the team as a whole. i.e. Entire Delivery team 35% on-site and 65% off-site. Tenderer is requested to describe the proportion of the management team i.e. 10%. And how the management team is distributed across on-site and off-site. i.e. 40% on-site and 60% off-site.</p> |

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| 63 | 02/06/2020 16:16 | 04/06/2020 21:29 | Section 3.3.2. Governance and stakeholders in Open tender specification | Section 3.3.2 describes responsibilities of Implementing Partner as: "Is the contractor responsible for the final delivery of the product and direct interaction with users" Could you please explain more about "users" here? | 04/06/2020 User groups are described in section 3.3.2. of the technical specification, under: Member States Product Owners; MS Rapporteurs; and Sponsor Product Owners. |
| 64 | 02/06/2020 16:17 | 05/06/2020 11:13 | Criterion 4.1 - Refactoring | We understand that we need to provide the strategy & solution to refactor the current CITS system to meet the target platforms followed by EMA strategic technology/Consolidated Technological Platforms. We don't need to take care of technology choices/platform. Please confirm our understanding. Besides, Is there required to provide case studies/project references? | 05/06/2020 Under Criterion 4, Q 4.1. the Tenderer is requested to provide an approach for the refactoring of the CTIS system. Under point ii. High level architecture, the tenderer should justify their technology choice in either case, i.e. maintaining the current technology architecture or changing it. No case study/project reference is required. |

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| 65 | 26/05/2020 17:20 | 05/06/2020 13:41 | Declaration on honour | According to the template that EMA provides, Section VII SELECTION CRITERIA, points 1b and 1c should be N/A in case of joint tenders. In case of a tenderer (sole or joint tender) who uses subcontractors submits a tender, please confirm that the following approach is acceptable: the subcontractors will choose the option YES only if they contribute in fulfilling the capacity as indicated in sections 18 and 19 of the tender specifications; otherwise the answer of the subcontractors should be N/A. | 05/06/2020 Annex 03-Declaration of honour on exclusion criteria and selection criteria is only requested to be filled by subcontractors if the total envisaged subcontracting is foreseen to be greater than 10%. In such case, Section VII. Point 1b and 1c should be marked as N/A by the subcontractor. The Sole Tenderer or Consortium Leader will then need to declare the compliance with the selection criteria for the Tenderer as a whole including members and subcontractors under Section VII. Point 2. |

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| 66 | 28/05/2020 17:15 | 05/06/2020 13:43 | Selection criteria - ISO/IEC 20000:2005 | Regarding the ISO/IEC 20000:2005 policy, we understand that in order to meet this requirement, we need to provide a certified copy of valid accreditation of the standard/s or an equivalent policy. In particular, ISAE3402 is an acceptable equivalent policy in order to replace the ISO/IEC 20000:2005 policy. Could you please confirm our understanding? | <p>05/06/2020</p> <p>Tenderer is requested to provide a certified copy of valid accreditation held by the Tenderer of the following standard/s or equivalent policies: ISO 9001:2000 accreditation or later version; • ISO/IEC 20000:2005 accreditation or later version; and • ISO/IEC 27001:2013 accreditation or later version. In case the tenderer does not have access to such accreditation within the relevant time limit, the Agency will consider “equivalent quality assurance measures” policies. The tenderer must provide the following: • Valid reasons, not attributable to the tenderer, for not having access to such accreditations within the relevant time limits; • Equivalent quality assurance measures policies to the listed standards under 19.1.3 of the technical specification; and • Evidence provided by a third party, such as an accreditation body/external audit report, that the proposed quality assurance measures policies comply with the required quality assurance standards listed under 19.1.3 Please note the tenderer may rely on another entity’s capacity in order to demonstrate meeting selection criteria. This other entity – if not related to the tenderer shall be either a partner within joint tender</p> |

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| | | | | | a partner within joint tender (consortium) or a subcontractor (with all consequences thereof). If the said entity is related to the tenderer (e.g. being the tenderer's parent company or sister company), the letter of intent provided by this entity shall be deemed sufficient. |
| 67 | 01/06/2020 15:31 | 05/06/2020 14:21 | Power of Attorney | Power of Attorney template contains in section 1 "(1) The European Medicines Agency (EMA) has awarded the Framework Contract resulting from the Call for Tender EMA/2020/02/IT to [complete]...". Our understanding is that we should change the sentence to "(1) The European Medicines Agency (EMA) in case of award of the Framework Contract resulting from the Call for Tender EMA/2020/02/IT [complete]...". Could you please confirm our understanding is correct or further clarify? | 05/06/2020 Tenderer may change the form as suggested. However please note, should the Tenderer be awarded the POA will be then requested to be signed again with the wording as per the published template. |

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| 68 | 01/06/2020 15:44 | 05/06/2020 14:22 | Power of Attorney / Signature in counterparts | <p>It is our understanding that the Annex 13- Power of Attorney can be signed in counterparts, each of which shall be deemed to be an original.</p> <p>All the identical signed documents by each consortium member, together will constitute one and the same document. Each consortium member can sign the document in hand-written or by using the company's advanced electronic signature. Can you please confirm that the described way of signing is acceptable by the authority? We kindly request you to take into consideration the difficult conditions that we are facing lately due to COVID-19 pandemic and this way of signing will facilitate/expedite the whole procedure.</p> | <p>05/06/2020</p> <p>Considering the COVID-19 situation, the POA may be signed with certified electronic signatures, provided signatures meet the requirements for advanced electronic signature or qualified electronic signature in the meaning of eIDAS Regulation (Regulation 910/2014). If the signatures do not meet those requirements, then the alternative of providing wet signatures remains.</p> |

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| 69 | 26/05/2020 15:23 | 05/06/2020 16:26 | Section 19.1.1 | With reference to section 19.1.1 of the tender specifications “The tenderer must have had during 2019, 2018, 2017 on average a minimum of 40 staff members per year in total covering all the profiles”. Is the certifications mandatory? E.g. an individual with several years of experience in the profile requested demonstrating the required experience and expertise can be counted in the average manpower numbers? | 05/06/2020 For selection criterion 19.1.1 the tenderer is requested to submit the following: a.) Statement on the average annual manpower and the number of managerial staff covering the period of 2017-2019; and b.) Statement on the number of staff per employment type, profile and level (as described in Annex 05), covering the period of 2017-2019. The statement is required to cover all profiles described in Annex 05 of the technical specification. For point a.) it is not required to fulfil the profile requirements as described in Annex05-Profile description. For point b.) it is required to fulfil the profile requirements as described in Annex05-Profile description. |

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| 70 | 26/05/2020 15:22 | 05/06/2020 17:00 | Section 19.1.1 | <p>With reference to section 19.1.1 of the tender specifications “The tenderer must have had during 2019, 2018, 2017 on average a minimum of 40 staff members per year in total covering all the profiles”. It is our understanding that a profile is covered if we may demonstrate at least 1 staff member, regardless the seniority level. For example, the Project Manager profile will be covered if we demonstrate 5 advanced profiles and no standard profiles and vice-versa. Could you please confirm our understanding or clarify further?</p> | <p>05/06/2020 Your understanding is correct. Please note for criterion 19.1.1 and its evidence required under 19.2.1.b., a break down per profile, level and employment type (employee and subcontractor) is required.</p> |

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| 71 | 26/05/2020 15:22 | 05/06/2020 17:15 | Criterion 2 | With reference to your question “ii. Estimation method you will apply along with your duration and effort estimates, including profiles and effort per profile for the needs of the development stream for this project.” Could you please clarify the following: • Our understanding is that Tenders should describe their estimation method including how they calculate the duration and effort estimates including profiles and effort per profile. Could you please confirm or clarify? • We understand that we do need to provide detailed estimations for the development stream since this will be part of the SC where more details will become available to the Tenderer. Could you please confirm or clarify? | 05/06/2020 For Criterion 2, Q.2.2. ii. 1.) Your understanding is correct. 2.) The Tenderer does NOT need to provide detailed estimations for the development stream. |

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| 72 | 04/06/2020 15:26 | 05/06/2020 17:18 | Endorsement letter | Could EMA confirm that when a tenderer relies on the capacity of a 'sister company' to comply with the selection criteria on the technical and professional capacity it is sufficient to provide an endorsement letter signed by a person who has the legal mandate to represent that company | <p>05/06/2020</p> <p>Pursuant to point 18.6 Annex I of Financial Regulation (Regulation 2018/1046) an economic operator may, where appropriate and for a particular contract, rely on the capacities of other entities, regardless of the legal nature of the links which it has with them. It shall in that case prove to the contracting authority that it will have at its disposal the resources necessary for the performance of the contract by producing a commitment by those entities to that effect. If the tenderer considers relying on another entity's capacity in order to demonstrate meeting selection criteria on technical and professional capacity, this other entity – if not related to the tenderer shall be either a partner within joint tender (consortium) or a subcontractor (with all consequences thereof). If the said entity is related to the tenderer (e.g. being the tenderer's parent company or sister company), the letter of intent provided by this entity shall be deemed sufficient.</p> |

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| 73 | 04/06/2020 15:27 | 07/06/2020 09:58 | 8.3. Subcontracting: intra-muros services | Point 8.3. Subcontracting in the document of open tender specifications, it is mentioned that 'In case of intra-muros services, the names, contacts and authorised representatives of subcontractors involved in the performance of the contract must also be stated.' Could EMA clarify in which field/s the tenderer should add this information in Annex 02? | 07/06/2020 Tenderer may add an additional sheet to the excel or an additional page to the pdf format of Annex 02 for the provision of such information. |
| 74 | 04/06/2020 15:25 | 07/06/2020 10:02 | Project references | Could EMA confirm our understanding that project references from countries that were part of the EU at the time of execution of the project would be accepted by EMA? | 07/06/2020 Tenderer may provide references from countries that were part of the EU at the time of execution of the project, provided, that references fulfil all requirements as described in 19.1.2 and 19.2.2 of the technical specification. |
| 75 | 04/06/2020 14:31 | 07/06/2020 10:04 | Selection criteria - References | Can a project reference be considered as valid if the project is implemented outside the EU, provided that the project covers all the requirements as these are presented in the tender specifications document? | 07/06/2020 Tenderer may provide references implemented outside the EU, provided, that such references fulfil all requirements as described in 19.1.2 and 19.2.2 of the technical specification. |

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|----|---------------------|---------------------|--|---|--|
| 76 | 04/06/2020 10:55 | 07/06/2020 10:24 | Financial and Economic Capacity / Ratios | If a tenderer obtains the requested score for the financial year 2018 and not for 2017, could you please advise what other means the contracting authority considers as acceptable in order the tenderer to provide a favourable picture of its financial status in 2017? | 07/06/2020 Tenderer to note, the financial and economic capacity evaluation is based on the last two financial years as a whole. Falling behind the threshold in the previous or current financial periods does not automatically disqualify a tenderer. |
| 77 | 27/05/2020 14:48 | 09/06/2020 19:02 | Question 2.3 – Product Owners | We understand that “Product Owners” in question 2.3 refer only to “Member States Product Owners” and “Sponsor Product Owners” (i.e. the rest of stakeholders such as EC are not considered Product Owners). Can you please confirm our understanding? | 09/06/2020 User groups are described in section 3.3.2. of the technical specification, under: Member States Product Owners; MS Rapporteurs; and Sponsor Product Owners. The European Commission is a key stakeholder and does participate in key events with Product owners providing their view, therefore in terms of stakeholder engagement EC should be considered as a Product Owner. |

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| 78 | 27/05/2020 17:09 | 09/06/2020 19:05 | Managed Services | With reference to your answer to Question #20, "The client references should demonstrate the tenderer's ability to deliver whilst responsible for delivery". It is our understanding that a contract/ project delivered in Managed Services mode, where the contractor retains full liability for the service delivery and is imposed to an SLA, is an eligible reference, even if the service ordering was performed in Time and means mode. Could you please confirm our understanding or clarify further? | 09/06/2020 The client references should demonstrate the tenderer's ability to deliver whilst responsible for delivery. For this reason, it is required that these relate to Fixed Price or Quoted Time and Means mode of delivery. References relating to Time and Means delivery in that case would not be accepted. |

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| 79 | 26/05/2020 15:22 | 09/06/2020 19:07 | Criterion 3 | With reference to your question “ii. ensure continuity of the maintenance support including relevant policies and processes and how these would be managed together with the first release.” Could you please clarify the following? • We understand that continuity of maintenance support refers to the measures applied in order to provide maintenance in the appropriate levels (i.e. according to SLA). Could you please confirm or clarify? • The term “together with the first release.” actually refers to the provision of maintenance services “after” the deployment of the first release. Could you please confirm or clarify? | 09/06/2020 Criterion 3 “ii. ensure continuity of the maintenance support including relevant policies and processes and how these would be managed together the first release”, refers to ensuring continuous maintenance of the system while new releases (after Go-Live) with new features are continuing to be delivered to production. |
| 80 | 02/06/2020 10:18 | 09/06/2020 19:14 | Criterion 3.2.Maintenance of a live system | Please expand what is meant by this statement - "Please reflect in your answer that the first release will have to be adopted by all National Competent Authorities (NCAs)" | 09/06/2020 First release in production and following releases after Go-Live will be adopted by the National Competent Authorities. Governance of the delivery will remain after Go-Live; Product Owners continue to have a role in definition and acceptance of scope of Releases as well as acceptance of Releases into production. |

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| 81 | 04/06/2020 18:35 | 09/06/2020 19:18 | References | Our understanding is that project references need have been delivered during the minimum duration required within the past three years, but projects may still be on-going taking into account that big maintenance and development contracts have a duration of 4 years and renewals. Could you please confirm? | 09/06/2020 Your understanding is not correct. References provided for 19.1.2 and 19.2.2. must refer to completed/delivered contracts (19.2.2a), projects (19.2.2.b), the project may have started before provided, that they fulfil the relevant requirement as specified in the technical specification. At least two software development reference should demonstrate the ability to deliver end to end IT Software Development product. All references must be accompanied by certificates of satisfactory execution issued by the clients. |
| 82 | 05/06/2020 09:01 | 09/06/2020 19:20 | Criterion 2 - Delivery approach - > 2.4 Ensuring quality | From our understanding, the "quality assurance" is to ensure the project and project members follow the agreed process and approach (service and human resource process, delivery approach, communication plan, etc.) while the "quality control" is to ensure the product itself follows the agreed requirements and design and have been thoroughly tested. Is this correct? | 09/06/2020 Your understanding is correct. For Criterion 2 – Delivery approach – 2.4, we request the tenderer to describe: i. The proposed approach to implement quality assurance for a system such as CTIS taking into consideration your delivery approach. ii. The proposed approach to implement quality control for a system such as CTIS taking into consideration your delivery approach. |

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| 83 | 05/06/2020 17:15 | 09/06/2020 19:28 | Selection criteria – Manpower | <p>With reference to section 19.2.1.b of the tender specifications, page 32, the tenderer shall provide a statement on the number of staff for the last three years for all the profiles and levels described under Annex 05, including permanent staff directly employed by the tenderer and subcontractors. In addition to this, in section 8.3.2 concerning the freelancers, page 25 of the tender specifications, it is stated that “one-person-companies (or freelancers) could be authorised as subcontractors”. We understand that one-person-companies (or freelancers) can be added in the manpower statement on the profiles as long as they are declared as identified subcontractors. Please confirm our understanding or clarify further.</p> | <p>09/06/2020 Your understanding is not correct. For the evidence requested for 19.1.1 selection criteria, the tenderer requested to provide a statement on the number of staff (permanent staff directly employed by the tenderer + subcontractors), that have worked continuously within the relevant business area of the tenderer for the last three years for all the profiles and levels described under (Annex 05 - Profile description). A break down per profile, level and employment type is required. For the provision of such statement freelancers are not considered and therefore should be excluded.</p> |

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| 84 | 08/06/2020 17:47 | 09/06/2020 20:01 | Award question 4.2, standard platform | <p>For question 4.2 of the award criteria questionnaire, the tenderer is requested to describe how he would undertake a transformation of the application to a standard platform. What a standard platform is not explicitly defined in the RFP (but may be well known to the current contractor). The only clue seems to be the sentence "This includes the design of solutions based on low code or SaaS/aPaaS application development platforms" found in the Tender Specs, section 5 " Subject of the tender". Please can you further specify what is meant by "standard platform" so that we can elaborate a sound response? What is missing from the currently developed application to be considered as a standard platform? On what basis is such a transformation considered to be an alternative to refactoring? Shall it be also assumed that it cannot include any kind of refactoring or DevOps-related transformations? Thank you.</p> | <p>09/06/2020 Examples of low-code SaaS/PaaS application platforms are Azure Dynamics365, Salesforce and SAP. The difference between the above examples and the current application is that at present, user requirements are being developed from the ground-up. Using a low-code platform will mainly require configuration of the platform's technical capabilities to satisfy the user needs. In doing so, it is expected that user requirements would need to be adapted to fit the capabilities of the platform. Given the above, adopting a standard platform will require changes to the external behaviour of the system. Such changes are not considered refactoring.</p> |

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| 85 | 09/06/2020 16:51 | 09/06/2020 20:08 | Statement on the IT Domain Experts | Since the technical competencies and certificates of an IT Domain Expert will only be defined in the request for services, we assume that a number of staff for this profile must not be provided in the statement required as evidence for the criterion specified 19.1.1. Is that correct? | 09/06/2020 Your understanding is correct. |
| 86 | 02/06/2020 16:18 | 10/06/2020 11:51 | Criterion 4.2 Transformation to a standard platform. | The document states that "describe how you would undertake a transformation of the application to a standard platform". Please help to explain why there is a specific need for "a standard platform"? Do you mean one of the pain points of the current system is that it consists of separated sub-systems which you want to transform to a centralized platform? | 10/06/2020 EMA's long-term vision is to transform its' overall IT-architecture towards software packages or software services that provide higher level outcomes. Transitioning to less bespoke development and towards more configuration of software packages or software services. EMA's objective is to reduce the operating effort and the effort of introducing new capabilities. |

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| 87 | 02/06/2020 16:19 | 10/06/2020 11:52 | Current status of the CTIS system | Can you please share with us the idea of refactoring the CTIS system in term of technology shifting. i.e, what are the pain points of the current CTIS system(s)? such as following example: - Pain points of the current architecture (performance, integration, etc.) - Pain points of the user experience - Functionalities - Maintenance of the current code (bugs, ability to customise and manage code, etc.) - etc. | 10/06/2020 EMA's long-term vision is to transform its' overall IT-architecture towards software packages or software services that provide higher level outcomes. Transitioning to less bespoke development and towards more configuration of software packages or software services. EMA's objective is to reduce the operating effort and the effort of introducing new capabilities. |
| 88 | 05/06/2020 15:04 | 10/06/2020 12:00 | Criterion 4 – Alternative technical architecture options | Regarding to Sponsor and Authority UI (Angular) and Sponsor and Authority workspace (J2EE7), is it individual applications or a merged application? | 10/06/2020 Sponsor UI and Authority UI are deployed as two web applications. They have separate URLs, and each has a dedicated codebase. Common UI aspects are implemented in a different codebase (Common UI) which is used by Sponsor UI and Authority UI. |
| 89 | 05/06/2020 15:04 | 10/06/2020 12:03 | Criterion 4 – Alternative technical architecture options | In term of database, would you have the any database migration tool? Could you show us how you guys is managing the database's schema? | 10/06/2020 We do not have a data migration tool. In the context of CTIS it will not be required to migrate Clinical Trials from the existing system. Changes to the physical data model are deployed using Flyway. Management of CTIS database is not relevant in the context of the response to this tender. |

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| 90 | 05/06/2020 15:06 | 10/06/2020 12:04 | Criterion 4 – Alternative technical architecture options | In term of Workflow Engine, Is Activiti Workflow 6.0 kind of system running individually on seperated server? Could you show us about how to deploy rules? | 10/06/2020 Activiti is not deployed in a separate application server. Activiti is deployed as a library of the CTIS application and is using a dedicated database schema including the process definitions. The process of deploying business processes/rules is not required in order to respond to this tender. |
| 91 | 05/06/2020 15:07 | 10/06/2020 12:06 | Criterion 4 – Alternative technical architecture options | How would it be about system/application configuration? Would you inject directly system/application configuration in the application or not? | 10/06/2020 The system's configuration is managed in Java property files. |
| 92 | 08/06/2020 16:28 | 10/06/2020 12:08 | Regarding Criterion 4 – Alternative technical architecture options. | Considering EMA uses function points for deriving SQL and relate with the current Effort Implementation: A) Does EMA have a current value in Function Points of the system to be refactor/transformed? B) Does EMA have a current value of the productivity ratio up to date for the development of the system to be refactor/transformed? C) Does EMA have a breakdown of Functions per Function Type (ILF, EIF, EI, EO, EQ) and Complexity? | 10/06/2020 EMA is not consistently applying Function Point Analysis in this project at this point in time. |

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| 93 | 03/06/2020 10:31 | 10/06/2020 12:22 | Regarding Criterion 4 - Alternative technical architecture options. | A) Can you further describe the main problems that the current architecture raises? B) Can you describe the main modules of the current CTIS application from a technical point of view? C) Can you describe the current deployment model of the system, including different components installed, their responsibility, and how they are packaged (EAR, WAR, JAR)? D) Does it exist any Service Bus, or communication orchestrator, between the application components? E) What is the degree of customisation of the COTS components (activiti, Liferay, IAM)? F) What are the main domain objects in the CTIS system? G) What is the actual Test Coverage of the existing Test Suite? | 10/06/2020 A.) EMA's objective is to reduce the operating effort and the effort of introducing new capabilities. B.-G.) Sections 3.3.5 – 3.3.8 provide all the necessary information required to respond to this tender. |
| 94 | 03/06/2020 18:41 | 10/06/2020 12:24 | Regarding Criterion 4 - Alternative technical architecture options. | Is the Public Website described in section 3.3.5 of the Tender Specification as part of the CTIS system the same as the EU Portal (implemented with Liferay) that is mentioned in section 3.3.6? | 10/06/2020 Your understanding is correct, see also diagram in p.16 of the technical specification. |

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| 95 | 08/06/2020 10:04 | 10/06/2020 12:38 | Endorsement Letter | Could EMA confirm our understanding of the Agency's response to Question# 72 that when a tenderer relies on the capacity of a 'sister company' to comply with the selection criteria on technical and professional capacity it is sufficient to provide an endorsement letter signed by a person who has the legal mandate to represent that sister company and it is not required to add the sister entity as a subcontractor? | 10/06/2020 Your understanding is correct |
| 96 | 09/06/2020 18:57 | 10/06/2020 13:11 | Selection criteria – Profiles | With reference to Annex 05 of tendering specifications, the following certifications are specified for the profile of Data Architect: TOGAF 9 Certification, IBM Certified Data Architect or other equivalent and valid certificates. We understand that “IBM Certified Solution Architect - Cloud Computing Infrastructure” certificate is considered equivalent. Please confirm our understanding or clarify further. | 10/06/2020 Your understanding is correct |

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| 97 | 09/06/2020 18:58 | 10/06/2020 13:12 | Selection criteria – Profiles | With reference to Annex 05 of tendering specifications, the following certifications are specified for the profile of DevOps Engineer: DevSecOps Engineering (DSOE) or other equivalent and valid certificates. We understand that “Certified SAFe 4 DevOps Practitioner” certificate is considered equivalent. Please confirm our understanding or clarify further. | 10/06/2020 Your understanding is correct |
| 98 | 10/06/2020 10:45 | 10/06/2020 13:16 | References - Evidence | Taking into account the difficult times most of the countries are going through and the fact that in many countries offices still aren't opened, it is difficult to reach some of our clients. Our understanding is that to provide invoices (together with the signed contract) should be enough proof of delivery of a project. Could you please confirm if we can present invoices together with the signed contracts as evidence for the references? Please take into account that due to the current situation most of our clients are working under exceptional circumstances. | 10/06/2020 Your understanding is not correct. Tenderer is requested to provide a certificate of satisfactory execution signed by the client. Due to the COVID-19 situation, the Agency will accept client certificates with a certified digital signature, provided, that it meets the requirements for advanced electronic signature or qualified electronic signature in the meaning of eIDAS Regulation (Regulation 910/2014). Alternatively, an email from the reference client containing all required details on the reference projects and digital signature. |

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| 99 | 10/06/2020 11:48 | 10/06/2020 13:18 | Opening Session | Could EMA consider the participation of tenderers in the opening session of the tenders possible through video conference as well, due to the COVID-19 pandemic? | 10/06/2020 Tenderer to note, due to the COVID-19 pandemic, participation in the tender opening session is only offered through video conference. |
| 100 | 09/06/2020 18:57 | 10/06/2020 13:23 | Selection criteria – References | With reference to section 19.2.2 of the tender specifications, tenderers are required to demonstrate that within the past three years they managed at least three IT Software Maintenance contracts of a similar scale. We understand that contracts which started before the past three years' period but have been delivered within this time period are eligible provided that they cover all the necessary requirements for maintenance contracts (section 19.2.2.a). Please confirm our understanding or clarify further. | 10/06/2020 Your understanding is correct. References for 19.1.2 a.) 19.2.2 a.) that started either before or within the three-year reference period and were delivered/completed during the past three years are eligible, provided, that they fulfil either the relevant continuous duration or the relevant monetary requirement as specified in the technical specification. |

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| 10 1 | 10/06/2020 12:20 | 10/06/2020 13:32 | References | Regarding the evidence required for the references the tenderer should provide evidence on relevant experience in provision of similar services to comparable clients in the past three years. We understand that contract references that start before the three-year reference period and were delivered/completed during the past three years are eligible. Please confirm our understanding or clarify further. | 10/06/2020 Your understanding for the provision of references for 19.1.2 a) 19.2.2 a) is correct. As described in the technical specification, the subject of references provided for 19.1.2 b) 19.2.2 b) are to focus on projects and products rather than contracts. For these references a project may have started before the three-year reference period and were delivered/completed during the past three years. |
| 10 2 | 10/06/2020 15:34 | 10/06/2020 19:17 | Annex 02 - Response questionnaire / 01b Joint Applicants | It is our understanding that in case a sole tenderer submits an offer, the sole tenderer should fill in the worksheet "01a Legal Entity Form" while the worksheet "01b Joint Applicants" should be left blank. The worksheet "01b Joint Applicants" applies only to the consortium members or to an identified subcontractor. Please confirm our understanding or clarify further. | 10/06/2020 Your understanding is correct. |

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| 103 | 08/06/2020 09:48 | 10/06/2020 19:22 | References | Our understanding is that a project that fulfils the minimum duration requirement within the last three years but that has not finished yet (for example a development project that has developed some applications and now is still on-going due to maintenance services) is valid. Could you please confirm? | 10/06/2020 References for software development projects that otherwise fulfil all requirements as described in 19.1.2 and 19.2.2 are considered acceptable in the following cases: 1.) a software development project that has developed an application and the project is now closed; or 2.) a software development project that has released to production a software development product. |
| 104 | 10/06/2020 16:53 | 10/06/2020 19:46 | eSubmission / Tender Data / Total amount | It is our understanding that in the eSubmission application, under the Tender Data section, Total amount field, we should fill in an indicative amount, i.e. 1, since the actual financial offer (signed in pdf format and in xlsx format) will be uploaded under the Financial offer field, and no amount should be disclosed anywhere else, since it is a confidential document. Please confirm our understanding or clarify further. | 10/06/2020 For the submission of the offer via e-Submission, please refer to the 'quick guide' available here: https://webgate.ec.europa.eu/digit/ops/ys/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: By E-mail: DIGIT-EPROCUREMENT-SUPPORT@ec.europa.eu Telephone: +32 (0) 229 71063 |
| 105 | 09/06/2020 16:50 | 12/06/2020 09:52 | Question 3.2 of EN-Annex 06 | In 3.2.ii, in the phrase "how these would be managed together with the first release", we interpret the first release to refer to the delivery project's "first release after go-live". Is this correct? | 12/06/2020 Your understanding is correct. |

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| 106 | 09/06/2020 16:50 | 12/06/2020 09:53 | Question 3.2 of EN-Annex 06 | In the sentence that follows 3.2.ii, "Please reflect in your answer that the first release will have to be adopted by all National Competent Authorities (NCAs).", we interpret the significance of this sentence to be that the userbase of the maintenance service will include the NCAs from the "first release after go-live" onward. Is this correct? | 12/06/2020 Your understanding is correct. |
| 107 | 09/06/2020 18:56 | 12/06/2020 09:55 | Selection criteria – References | With reference to section 19.2.2 of the tender specifications, we understand that a contract that has been delivered/ accepted within the past three years and is currently on warranty period is an eligible reference provided that it covers all the necessary requirements for maintenance or development (sections 19.2.2.a, 19.2.2.b respectively). Please confirm our understanding or clarify further. | 12/06/2020 Your understanding is correct |
| 108 | 11/06/2020 14:32 | 12/06/2020 09:57 | Language of Company's Certificates | It is our understanding that any company's certificate related to the exclusion criteria evidence can be submitted in any EU language without being accompanied by an English translation. Please confirm our understanding or clarify further. | 12/06/2020 Your understanding is correct |

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| 109 | 11/06/2020 10:20 | 12/06/2020 10:55 | Annex 02 - Response questionnaire / 02b.1, 02b.2 and 02b.3 | It is our understanding that we should add additional worksheets for each consortium member and subcontractor (in case the overall envisaged subcontracting is greater than 10%) in order to be presented the financial figures of each concerned entity. Kindly note that if we insert in the excel file additional sheets (02b.1, 02b.2 and 02b.3) the formula in the additional 02b.3 sheet is not correct. Can you please advise how can we deal with it? | 12/06/2020 Tenderers shall create a separate sheet in the file for each concerned entity. The Agency will adjust the formulas in the sheet 02b.3 itself accordingly. |

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| 110 | 12/06/2020 10:07 | 12/06/2020 11:03 | Selection criteria – References | <p>According to the tendering specifications, tenderers shall provide at least three major IT Software Development projects of a similar type that have been awarded by public or private sector clients and delivered by the Tenderers in the past three years, including dates and sums. In addition, in QA#9 it is stated that “a project reference can be a single direct contract, a single specific contract under a FwC, series of specific contracts under a FwC, series of specific contracts under multiple FwC provided that the referenced project fulfils all criteria under 19.2 and 19.2.2b”. Our understanding is that a single Framework Contract with multiple specific contracts is accepted provided that the reference fulfils all criteria under 19.2.2.b. Can you please confirm or clarify?</p> | <p>12/06/2020 Under 19.2.2.b.) the Tenderer may provide a single contract or multiple specific contracts under one or more framework contracts for a referenced project. Certificate of satisfactory execution can be provided on a Framework Contract level, provided; that a.) the specific contract or specific contracts under a FwC are undoubtedly linked to a specific project that is otherwise further described in Annex07-Reference template; and b.) the client certificate confirms the satisfactory execution of the referenced project.</p> |
| 111 | 13/06/2020 07:16 | 15/06/2020 12:14 | CVs to be submitted | <p>Our understanding is that there are no CVs to be submitted at tender submission deadline, Could you please confirm our understanding is correct?</p> | <p>15/06/2020 Your understanding is correct</p> |

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| 11 2 | 05/06/2020 09:02 | 15/06/2020 12:26 | Criterion 2 - Delivery approach - > 2.4 Ensuring quality | With reference to "What would be the main risks and issues around testing CTIS?", could you elaborate more on why among different kinds of risks and issues (project plan risks, turnover rate, technology limitation, etc.) you are only interested in the testing of CTIS? What are the concerns that you want us to solve or show capability to solve. | 15/06/2020 The question should be read as follows: What would be the main risks and issues around testing a system such as CTIS? |
| 11 3 | 08/06/2020 15:38 | 15/06/2020 12:27 | Annex 06 - Section 2.1. Criterion 1 – Service and Resource Management - 1.1. Set up of Service/team | Topics i. - about recruitment and securing resources - and subsequent topics a), b), c), d) e) - all focused on knowledge transfer - do not seem to match. Do we have to explain how we recruit people for knowledge transfer activities? Or should we rephrase the initial i. sentence to "Describe the measures taken to secure a proper knowledge transfer for the team, in particular: a) b) ..." Please advise. | 15/06/2020 Criterion 1 – Service and Resource Management- 1.1 Set up of Service/team, covers estimating and securing right resources to provide the service, including but not limited to, planning, execution and control of transferring knowledge to those resources. |

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| 114 | 08/06/2020 16:36 | 15/06/2020 14:06 | Draft Framework Contract - Article I.10.2 - Pre-existing rights | <p>“Article I.10.2 of the Draft Framework Contract in its first paragraph says, that all pre-existing rights incorporated in the results, if any, are licensed to the contracting authority as set out in Article II.13.2. However, second paragraph says, that in this particular contract, by way of derogation, Article II.13.2 would not apply and EMA would acquire fully and irrevocably all pre-existing rights incorporated in the results. To us, it seems that those two provisions are contradictory. Could you please clarify if the pre-existing rights incorporated in the results are fully vested to EMA or are they licensed?”.</p> | <p>15/06/2020 Tenderers to note the following correction to Annex 04.a – Draft Framework contract: Article I.10.2 – Pre-existing rights should read as follows: I.10.2. Licence or transfer of pre-existing rights All pre-existing rights incorporated in the results, if any, are licensed to the contracting authority as set out in Article II.13.2.</p> |
| 115 | 11/06/2020 14:54 | 15/06/2020 14:09 | Selection criteria – References | <p>With reference to your answer to QA#20, we understand that completed projects used as project references under 19.2.2.b, including mixed modes of delivery (Fixed Price, Quoted Time and Means, Time and Means), are eligible provided that they cover all the necessary conditions as set out in the respective section. Please confirm our understanding or clarify further.</p> | <p>15/06/2020 Your understanding is not correct. Client's references for 19.2.2.b should demonstrate the tenderer's ability to deliver whilst responsible for delivery. For this reason, it is required that these relate to Fixed Price or Quoted Time and Means mode of delivery. References relating to Time and Means delivery in that case would not be accepted. Services delivered by intra-muros, extra-muros or the combination of both are accepted.</p> |

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| 116 | 12/06/2020 11:26 | 15/06/2020 14:17 | Criterion - Service & Resource Management, §1.1 Set up of Service/team, i) Describe the measures... : ... e. The evidence ... to demonstrate the quality of the knowledge transfer | <p>The question asks the tenderer to provide a proposal on the concrete measures and proposed implementation for all points listed below i, but the wording of point e) "The evidence the tenderer will provide to the Agency to demonstrate the quality of the knowledge transfer" points to the responsibility of the Handover party, not the Takeover party, which is responsible for knowledge acquisition (as in point d).</p> <p>Not being the incumbent, we find it difficult to answer this question. Can you please clarify how we are supposed to understand this question as a takeover party? Thank you in advance.</p> | <p>15/06/2020 Annex 6, Criterion 1, 1.1.e. "The evidence the tenderer will provide to the Agency to demonstrate the quality of the knowledge transfer" In their response tenderer should describe how they will monitor and demonstrate the quality (sufficient quality/insufficient quality) of Knowledge transfer received, from the incumbent. So that the tenderer can provide evidence in case the quality of knowledge transfer is not at an adequate level.</p> |

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| 11 7 | 12/06/2020 13:32 | 15/06/2020 14:31 | Technical and professional capacity - certificate of satisfactory execution | <p>We have a reference from a Directorate General of the European Commission that fulfils all the requirements as specified both in the technical specifications and the previous answers of the Contracting Authority for this procurement procedure. The client accepts to provide us a certificate of satisfactory execution for this reference but their standard policy is to provide such certificates only in their standard template, which clearly and undoubtedly indicates the referenced project but does not contain the totality of the required details/wording. Given that a) the client is a Directorate General of the European Commission, b) the certificate is provided in a standard template of the European Commission that is commonly accepted in similar procurement procedures, and c) the contact details of the signatory are indicated and they can therefore be contacted by the Contracting Authority, we understand that such a certificate can be accepted by the Contracting Authority. Can you please confirm our understanding?</p> | <p>15/06/2020 Your understanding is correct. Tenderer is requested to provide detailed description of the contract (19.1.2.a) project (19.1.2.b), using Annex 07 – Reference template of which does not require signature of the client. Such reference template must be accompanied with the signed client's certificate on satisfactory execution. The certificate of satisfactory execution indeed to be provided using the client's own template.</p> |

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| 118 | 13/06/2020 07:17 | 15/06/2020 15:10 | Proof of sufficient level of manpower | <p>please confirm our understanding?</p> <p>With reference to Section “Evidence required” of tender specifications, the tenderer should provide a manpower statement with the number of staff for the last three for all the profiles and levels described under Annex 5. In Annex 5, we also read that “the tender should be based on the profiles requested. By providing the CVs, the tenderer must prove its capacity to reply to any seniority request during contract execution following the needs of the service.”. Considering that the evidence to show sufficient level of manpower to perform tender’s services, as specified in tender specifications, is the manpower statement with all the profiles of Annex 5, we understand that no CVs are required in the tendering procedure. Please confirm our understanding or clarify further.</p> | <p>15/06/2020 Your understanding is correct</p> |

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| 119 | 15/06/2020 13:11 | 15/06/2020 15:28 | Selection criteria – References | <p>With reference to your answer to QA#110, the client certificate should confirm the satisfactory execution of the referenced project. However, the certificates we have in place or have already been requested from the clients have the typical structure of these statements issued by EU Institutions, i.e. they cover the whole Framework Contract without mentioning specific project, certify the award of the referenced contract to the concerned entity, its execution in accordance with the contractual terms and include the maximum awarded amount, the date of signature and the duration. Considering that 3 weeks remain until the deadline of submission of the tender and the COVID-19 situation, it is not feasible to have new certificates on time. For these reasons, we kindly ask you to accept the certificates described.</p> | <p>15/06/2020 Under 19.1.2.b 19.2.2.b of the tender specification the tenderer is requested to provide references on successfully delivered software development project and products that otherwise fulfil all requirements as described in the tender specification. The client's certificate on satisfactory execution must confirm the successful delivery of the project/product. For further information and clarification on client's certificate, please refer to previously published answers.</p> |

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| 120 | 12/06/2020 15:24 | 16/06/2020 14:28 | Project Reference | Could EMA clarify our understanding of Agency's response to Question No 30, regarding the requirement for end to end software development product that a reference should comply with Agency's description of System Development Life Cycle in 5.1 (Service Lines) and 5.2 (Software Development) which includes Analysis and Design, Development, Testing & Build and Deployment to be considered as end to end. | 16/06/2020 For 19.1.2.b. 19.2.2.b., the Tenderer is requested to provide 3 references. At least two software development reference should demonstrate the ability to deliver end to end IT Software Development product. References for software development projects that otherwise fulfil all requirements as described in 19.1.2 and 19.2.2 are considered acceptable in the following cases: 1.) a software development project that has developed an application and the project is now closed. In this context the reference is not required to cover end to end delivery. Tenderer is requested to provide 1 reference of this kind; or 2.) a software development project that has released to production a software development product. In this context the reference is considered "end to end" once maintenance of the product is ongoing. Tenderer is requested to provide 2 references of this kind. |
| 121 | 12/06/2020 15:46 | 16/06/2020 14:29 | Section 3.3.4 Delivery process | Could you please share with us EMA's maturity in Agile? | 16/06/2020 A consistent assessment of Agile maturity for the delivery of CTIS has not been done. |

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| 12 2 | 13/06/2020 07:17 | 16/06/2020 14:32 | Maintenance managed service - Support | Can we consider that the ticket volume mentioned here covers only the expert level support (L3) expected from contractors? Please clarify. b. If this is not the case, can you please provide the market with split of ticket by level (L1, L2, L3) ? | 16/06/2020 Please further clarify your question to a particular section, point of the technical specification and its annexes. |
| 12 3 | 13/06/2020 07:18 | 16/06/2020 14:33 | Maintenance managed service - Support | To design maintenance services aligned to the Agency needs, can you provide us with the hourly distribution of tickets per service desk hours during working days ? | 16/06/2020 Please further clarify your question to a particular section, point of the technical specification and its annexes. |
| 12 4 | 13/06/2020 07:18 | 16/06/2020 14:43 | Annex - 6 | As per the "delivery-time-frame-eu-portal-eu-database_en.pdf", CTIS was to go live by September 2018. Please confirm if the system has gone-live, if so , please provide the date of go-live? | 16/06/2020 The system has not gone live. |
| 12 5 | 13/06/2020 07:19 | 16/06/2020 14:44 | Annex - 6 | As per our understanding, most of the functionality of CTIS has already been developed. Can you please let us know the incumbent vendor. | 16/06/2020 The name of the incumbent vendor is not relevant information. |

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| 126 | 13/06/2020 07:22 | 16/06/2020 14:45 | Annex - 6 | Are the requirements for further upgrade /enhancements already captured? | 16/06/2020 Backlog for further development exists, as usual for Agile delivery it will evolve and be further detailed together with the Product Owners as the delivery progresses towards Go-live. |
| 127 | 13/06/2020 07:22 | 16/06/2020 15:03 | Annex - 6 | What are the service requirements of CTIS? a. Support window(24*7,16*5. on desk or on-call ?). b. SLA levels (response/resolution times and adherence %) | 16/06/2020 Tenderer to please refer to: Annex 4b-Draft framework contract- Service level agreement for further information. |

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| 128 | 15/06/2020 13:09 | 16/06/2020 15:04 | Criterion 3.1 i | We are requested to provide “the proposed governance structure for the maintenance stream” in order to provide “a smooth transition to production (go-live milestone) of CTIS”. We understand that until we produce a system that is ready from our side to “go live”, (i.e. implement all required functionality), only the development stream is active. Hence, the proposed in 3.1 (i) transition concerns the setup of the maintenance team that will become active during the period between the delivery from our side of the “go live ready” system, until the actual go-live date (i.e. after the audit and the Commission acceptance). Please confirm our understanding or clarify further. | 16/06/2020 Your understanding is correct. |

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| 129 | 13/06/2020 07:18 | 16/06/2020 15:19 | Tender specifications, section - Evidence required | The RFP reads: "Statement on the average annual manpower and the number of managerial staff for the last three years." Please clarify whether such figures should include (a) permanent staff directly employed by the tenderer or subcontractors OR (b) permanent staff only. | 16/06/2020 Statement on the average annual manpower and the number of managerial staff for the last three years shall only be provided for the tenderer; provided that the tenderer is not relying on the capacity of other legal entities (e.g. subcontractors) to meet the selection criteria on technical and professional capacity. In case of joint tenders, the statement must cover all members of the consortium. |

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| 130 | 14/06/2020 07:48 | 16/06/2020 15:41 | Section : 19.1.1 | "The tenderer must have minimum of 40 staff members covering all the profiles", can the 40 resources should be only from the company which we have bid (EU entity) or from group of companies linked to EU entity (like Other Development Centers in India/US/Australia)? | 16/06/2020 Please note the tenderer may rely on another entity's capacity in order to demonstrate meeting selection criteria. This other entity – if not related to the tenderer shall be either a partner within joint tender (consortium) or a subcontractor (with all consequences thereof). If the said entity is related to the tenderer (e.g. being the tenderer's parent company or sister company), the letter of intent provided by this entity stating that it will place at the disposal of the tenderer all the necessary resources for the performance of the contract. shall be deemed sufficient. In case of joint tender, the statement must cover all members of the consortium and provided data should be presented for the consortium as a whole. |
| 131 | 15/06/2020 18:05 | 16/06/2020 15:46 | Letter enclosing the tender | Page 35 of the tender specifications reads that the tenderer should submit a "Letter enclosing the tender on the official letter headed paper of the tenderer". Could the contracting authority please provide more information on what content this letter should include? | 16/06/2020 The sole purpose of the letter as described in section 21. of the technical specification is to serve as a "cover letter" to the tender submission as a whole. |

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| 13 2 | 16/06/2020 10:26 | 16/06/2020 15:48 | Questions 4.1 & 4.2 | For questions 4.1 and 4.2 you request a plan providing "Schedule including resourcing and the estimation approach". Since an effort estimate for a refactoring or a transformation of CTIS would require much more detailed information than the one provided as part of the RFO we assume that we need to provide only the approach we would follow for estimating such refactoring or transformation. A detailed estimate of effort is not expected as part of this plan. Is our assumption correct? | 16/06/2020 Your understanding is correct. |

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| 133 | 16/06/2020 10:37 | 16/06/2020 16:09 | Project reference requirements, page 33 par. b), | Can you please confirm whether you can accept as a valid reference a project that has already passed the testing phase, with full acceptance by the customer in the PreProduction environment, but scheduled to be delivered in Production by the end of July 2020? | <p>16/06/2020</p> <p>For 19.1.2.b. 19.2.2.b., the Tenderer is requested to provide 3 references. At least two software development reference should demonstrate the ability to deliver end to end IT Software Development product. References for software development projects that otherwise fulfil all requirements as described in 19.1.2 and 19.2.2 are considered acceptable in the following cases: 1.) a software development project that has developed an application and the project is now closed. In this context the reference is not required to cover end to end delivery. Tenderer is requested to provide 1 reference of this kind; or 2.) a software development project that has released to production a software development product. In this context the reference is considered “end to end” once maintenance of the product is ongoing. Tenderer is requested to provide 2 references of this kind. In this context, and in the view of the Tenderer’s scenario; assuming that the referenced project is now being closed and that it fulfils all requirements as described in the technical specification, the project can be accepted for point 1.) above. In case the referenced project is still ongoing, then it does not fulfil the</p> |

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| | | | | | ongoing, then it does not fulfil the criteria and therefore it is not considered acceptable. |
| 134 | 16/06/2020 17:37 | 17/06/2020 13:31 | Criterion 3.3 | Are we allowed to submit a sample report using one page in A3 format to question 3.3? | 17/06/2020 Tenderer to please refer to Q&A 1 for further information. Sample report must be submitted in A4 format. |
| 135 | 18/06/2020 18:05 | 22/06/2020 09:15 | Maintenance | Would EMA be willing to consider maintenance contracts which are ongoing and for which a letter of satisfactory execution has been signed by the client albeit they meet the requirements under 19.1.2 and 19.2.2 (a) as acceptable evidences. | 22/06/2020 References provided for maintenance must be based on completed/ fully delivered contracts that fulfil all criteria under 19.1.2. and 19.2.2a. |
| 136 | 18/06/2020 17:41 | 22/06/2020 09:16 | Annex 07 | Can EMA confirm that for a client who does not want to be named, can the tenderer redact the client name in Annex 07 and the signed client statement of satisfactory execution? | 22/06/2020 In case the tenderer has been requested not to disclose the client's name, the tenderer is requested to provide a valid justification. The tenderer must provide certificate of satisfactory execution issued by the client; however, the tenderer can redact the name of the client from the certificate. |

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| 13 7 | 18/06/2020 16:15 | 22/06/2020 09:17 | Selection criteria – References of a development project (19.2.2.b) | Please can you confirm that is it NOT required that the project has lasted 18 months in the last three years. In other words, a project which had a continuous duration of more than 18 months with a value in excess of 5,000,000 EUR per annum and which ended in March 2018 is eligible. Thank you. | 22/06/2020 Your understanding is correct. |

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| 138 | 16/06/2020 15:11 | 22/06/2020 09:21 | Internal subcontractor Outside EEA, binding corporate rules | <p>In question 6, EMA answered that the tenderer's offsite work location must reside within the EEA only if the work at the location involved processing of personal data. This is unless there's an adequacy decision in place, on the basis of Article 45 of Regulation (EU) 2016/679. In the absence of the adequacy decision, a controller or processor may transfer personal data to a third country or an international organisation only if the controller or processor has provided appropriate safeguards, and on condition that enforceable data subject rights and effective legal remedies for data subjects are available (Article 46 of the GDPR). One of the appropriate safeguards is having an adopted binding corporate rules in accordance with the Article 47 of the GDPR. Tenderer have the binding corporate rules in place, applicable to all entities within the group. Tenderer might use one of its internal subcontractor, located outside of EEA. That internal subcontractor adheres to the adopted binding corporate rules. Could you please confirm, if that subcontractor can be used also in cases where personal data will be processed by</p> | <p>22/06/2020 If the tenderer would like to transfer personal data processed on behalf of EMA to one of its internal subcontractors (i.e. subsidiary belonging to a company group) residing outside of EEA, this can only be allowed if compliance with Chapter V of Regulation (EU) 2018/1725 ("EUDPR", which is the counterpart of GDPR applicable to EMA) on international transfers is clearly verified. The EUDPR explicitly recognises compliance of international transfers based on an adequacy decision adopted in accordance with Article 45 GDPR. In addition, the EUDPR also recognises as appropriate safeguards binding corporate rules as referenced by Article 46(2)(b) GDPR. Accordingly, binding corporate rules must be approved by the competent supervisory authority in accordance with the consistency mechanism (set out in Article 63 GDPR), therefore the approval of the competent supervisory authority should be based on the opinion of the EDPB. It follows from the above, that if the tenderer intends to transfer personal data to an internal subcontractor falling under the scope of such binding corporate rules, this may be acceptable to EMA provided that the tenderer verifies: -</p> |

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| | | | | personal data will be processed by that internal subcontractor?" | that the tendered verifies: · compliance with binding corporate rules as adopted under the above referenced provision; and · that the concerned subcontractor(s) are subject to those binding corporate rules. |
| 139 | 22/06/2020 08:32 | 22/06/2020 09:32 | Deadline Extension | Would EMA consider extending the deadline from the 3rd of July until the 8th or 10th of July. We believe that it may be beneficial for the quality of the submission, cross regional co-ordination of teaming and as result project output to allow a little more time for contributors to hone the response? | 22/06/2020 Given the planning for the procurement and bearing in mind that the time limit for submission of offers is already longer than the minimum period required, the due date for submission of offers cannot be further extended. |
| 140 | 15/06/2020 13:09 | 22/06/2020 09:37 | Criterion 2.1 ii | In order to provide a product planning, especially considering "that the time between event a and event b might be very limited", can you please provide us with the indicative timeline of this contract i.e. a) when it is envisioned that we should provide a system that is ready from our side to "go live"? b) after go live, when the first release is envisioned to take place? | 22/06/2020 Criterion 2.1 ii is more about the product planning process instead of a specific plan or a schedule. Timing for Go-Live or the first release after Go-Live has not been determined. |

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| 14 1 | 16/06/2020 10:27 | 22/06/2020 09:38 | Criterion 4.1 | Does the scope of the refactoring of the system considered for question 4.1 includes the refactoring of the Public Website or should we only focus on the refactoring of the Sponsor and Authority workspaces? | 22/06/2020 Criterion 4.1 Describe the approach for the refactoring of the system considering, but not limited to, the EMA strategic technologies, including putting in place DevOps practices, with the view to reduce the operating effort and the effort of introducing new functionality, (e.g. increasing velocity, adaptability and access to technology innovation). In relation to Criterion 4.1 refactoring of the system is not limited to a specific part of the architecture. In their response tenderer should describe their approach for the refactoring. |
| 14 2 | 17/06/2020 08:59 | 22/06/2020 09:40 | Question 2.3.i, meaning of "development team" | We understand that the "development team" in question 2.3, bullet "i" refers to the whole "Contractor team", and not only at operational level for development activities. Could you please confirm our understanding? | 22/06/2020 In Criterion 2, question 2.3. – Management, tenderer is requested to provide details of a delivery approach. Development team in question 2.3.i refers to the whole team, including but not limited to the operational level development activities. |

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| 14 3 | 22/06/2020 12:27 | 23/06/2020 15:50 | Bidding Entity | <p>Our understanding from the previous clarification is that the Companies based in third countries (i.e. USA) are eligible to participate in this tender. We have an office in the United Kingdom and in the Netherlands.</p> <p>Since the Netherlands office is opened recently it does not qualify the financial criteria. In this case, could you please advice, if we can bid from the Netherlands entity and show the financial strength of the group to fulfill this criterion. Alternatively, are we allowed to bid from our UK entity?</p> | <p>23/06/2020</p> <p>Tenderer to note the following: Participation in procurement procedures is open on equal terms to all natural and legal persons falling within the scope of the Treaties. This includes all legal entities registered in the EU and all natural persons having their domicile in the EU. Participation is also open to all natural and legal persons registered or having their domicile in a non-EU country which has an agreement with the European Union in the field of public procurement on the conditions laid down in that agreement. The rules of access to the market do not apply to subcontractors. The procurement procedures of the Agency are not however open to tenderers from countries which have ratified the Multilateral Agreement on Government Procurement ("GPA"). In the view of the scenario of the question raised by the tenderer: a.) Cooperation between the EU and the U.S. in public procurement is governed under the GPA. The Agency is not part of the GPA, therefore a U.S. entity does not have access to procurement procedure of the Agency. b.) Netherland or UK based entities indeed have access to procurement procedures of the Agency. c.) Tenderer may rely on</p> |

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| | | | | | Agency. c.) Tenderer may rely on another entity's capacity in order to demonstrate meeting selection criteria. This other entity – if not related to the tenderer shall be either a partner within joint tender (consortium) or a subcontractor (with all consequences thereof). If the said entity is related to the tenderer (e.g. being the tenderer's parent company or sister company), the letter of intent provided by this entity shall be deemed sufficient. |
| 14 4 | 23/06/2020 17:24 | 24/06/2020 09:46 | Meaning of "Resourcing" in question 4.1 | We understand that the meaning of "resourcing" in question 4.1 refers to defining the roles and profiles considered by the team. Can you please confirm our understanding? Should we also provide sizing foreseen for the team? | 24/06/2020 Your understanding is correct. Resourcing refers to roles and profiles required for the tenderer's refactoring approach. Tenderer should provide the foreseen sizing of the team as well as their estimation approach. |
| 14 5 | 24/06/2020 17:02 | 25/06/2020 09:38 | Pricing | For extra muros work, we intend to complete it in multiple locations. Each working location will have difference price. Could we add more sheets to show up pricing at each location? | 25/06/2020 Tenderer may NOT propose different daily rates for each extra-muros location. Proposed daily rates for extra-muros services are applicable to all extra-muros locations, irrespective of their geographical position. |

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| 14 6 | 24/06/2020 17:03 | 25/06/2020 21:05 | The proportion of onsite/offsite | For extra muros work, we intend to complete it in multiple locations. In criterion 2 & 3, we have to provide proportion of onsite/offsite for profiles/resources. Should we have to provide proportion of locations for offsite work? | 25/06/2020 The Tenderer is NOT requested to provide a breakdown of the proportion of off-site work for each location proposed. |

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