



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Questions and Answers relating to Tender – EMA-2012-09-IF

External Service Providers for Enterprise Infrastructure Support: provision of resources for Oracle database and middleware product management

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Questions and answers

No.	Question	Answer
1	When the contract has been awarded will there be a facility to raise invoices in either Euros or GBP?	No, invoices must be raised in Euro.
2	For the tender, do we have to fill CVs with EMA template or is it a free anonymous format? If it is EMA template, could you please publish the template.	We refer you to Annex 2 to the Technical Specifications document, entitled "Response Questionnaire". On the worksheet labelled "Instructions", section 4, point 5, you will find the details of the format to be used for CVs and a link to the relevant website, from which the template can be downloaded.
3	As referred in EMA's Guide Book for Tenders pag. 16 question 6.3.5.3, the maximum length per answer for each question should not exceed of two pages A4. As in the tender specifications of procurement procedure EMA/2012/09/IF, does not mention anything related to the extent of each answers per question, could you please confirm us which will be the number of pages permitted to answer each question within the question 04 Tech. and Prof. capacity and 05 Award from the Annex 2 of the tender?	The Agency prefers that tenderers should answer the questions keeping their replies concise and relevant to the Agency's requirements as expressed in the documentation, the key word here being "relevant". We have not stipulated in the technical specifications a minimum or maximum length for documents. We would prefer that tenderers do not include general brochures on their company or services unless they are directly relevant to the subject of the tender.
4	I was wondering if you would be able to supply me with some technical information in order that we provide you with a relevant and intelligent response that is specifically tailored to EMA, particularly for the following question in the ITT: 16.1.2.5. Quality of the technological proposal <i>Taking into account the description of the services and the profiles described in section 4.1.3. , the Tenderer will provide in its response to this ITT:</i> ☐ <i>Its global analysis of the perspectives and evolutions during</i>	Technical information relevant to this ITT is provided in section 3.3 ICT Standards of the Technical Specifications, in Annex 4: Required Skills per Profile, and in Annex 6: EMA ICT Standards.

No.	Question	Answer
	<i>the next 4 years on the following points:</i> <i>~ Oracle high-availability OLTP and Data Warehouse database solutions</i> <i>~ the role of Oracle middleware in multi-tier applications</i> <i>~ technologies and tools used (See Annex 6, EMA ICT Standards)</i> <i>~ the technical skills of the profiles with required expertise for this lot</i> ☐ <i>In order of priority, what the Tenderer considers to be the 10 most important technological points that will influence these services in the next 4 years and an explanation of how each of those points is taken into account in its offer of services for this tender</i> In the context of the present ITT could you provide me with information on the following; - Dependencies with other agencies, organizations, software as a services providers ... in terms of: - Consume/Provide services through any means such as web services, any message exchange pattern, data integration - Security. (shared sso infrastructure , domain federation ..?) - What are the current and foreseeable needs in terms of data storage, database throughput, for your OLTP and DW ? Rough estimate would be fine. - Are there any applications undergoing refactoring, upgrading? if so what is the nature of the work being carried out?	The European Medicines Agency hosts a number of systems and Oracle databases that are accessible to external stakeholders and European regulatory authorities. Please see the EU Telematics section on the Agency's website (www.ema.europa.eu). The European Medicines Agency is alone responsible for managing its security domain. Currently our production databases require approximately 4 TB of storage for OLTP applications and 1.5 TB for data warehouses. Test and development database sizes are similar. Growth estimates vary but 10% per annum may be assumed. Applications are currently migrating from Oracle Application Server 10g to Oracle WebLogic Server 11g. Databases are currently migrating from Oracle RAC 10gR2 on OCFS 2 to Oracle RAC 11gR2 on ASM.

No.	Question	Answer
5	Paragraph 15 of the technical specifications, point 4, p. 53/61, <i>"Provision of evidence that the Tenderer has in the recent past provided resources of the type (see section 4.1.3) and in the quantities (see section 9) requested in this ITT"</i> It is our understanding that the evidence requested in the above point refers to the presentation/ description of the 3 reference contracts, which shall cumulatively (in combination) cover the type and quantities (i.e. around 1200 person days per year) of resources requested in the technical specifications. Please confirm for both the nature of evidences and the size of the quantity requirement.	Any evidence that can be independently verified will be accepted. Examples of evidence which could be provided include a contract award notice (although that would normally indicate only the overall value of the contract awarded and not the number of person days undertaken), a copy of the contract itself, a contact person at the customer (which we have asked tenderers to provide as part of their response) in which case we would intend to use the contact details in respect of a contract reference to verify the facts as we deem necessary, a publication in the press (press release) and so on. The tenderer is requested to provide evidence that they have in the recent past provided resources in the quantities requested in this ITT. The quantities requested are clearly stated as the volume of the tender which therefore serves as a benchmark against which reference contracts can be measured. The contracting authority is seeking reasonable assurance that quantities of this order of magnitude have been contracted in the past and therefore, tenderers should consider volumes of 4,000 person-days per contract on average as being the minimum acceptable level.
6	Award criteria pages 55-57 of the technical specifications, <i>"16.1.2.1 Resource Selection Methodology <u>Evidence of active application of this in recent contracts</u>", "16.1.2.2 Personnel Management..... <u>Evidence of effective application of this in recent contracts....</u>" etc</i> The technical specifications require from Tenderers to provide evidence of the application of their proposed methodologies in previous (recent) contracts. We understand that the evidence requested refers to the presentation/description of the contracts in which the Tenderer has applied these methodologies. Please confirm.	Any evidence that can be independently verified will be accepted as long as it proves that the tenderer has actively and effectively applied the methodology that it has described.

No.	Question	Answer
7	Paragraph 15 of the technical specifications, point 3, page 53/61, <i>"Two CVs per profile described in section 4.1.3 Detailed specifications of the profiles required"</i> a. It is our understanding that the proposed CVs must at least cover the requirements marked as "mandatory" in order to be accepted. Please confirm. b. Could you please elaborate further on the requirement of section 4.1.3.1.7? We understand that it is not necessary the proposed CVs to demonstrate ability to use all the products and tools of Annex 4, but proven experience in some of them is sufficient. Is our understanding correct?	a. Your understanding is correct. b. The required skills per profile as listed in Annex 04 would ideally be the minimum (i.e. "mandatory") requirements that every consultant should master. In practice, it is understood that consultants tend to specialise in a few technologies. Therefore, the required skills per profile are those that every tenderer has to be able to cover collectively across all consultants of the tenderer who are available to work under this contract.
8	Paragraph 16.1.2.5 of the technical specifications, page 57/61, <i>"Its global analysis of the perspectives and evolutions during the next 4 years on the following points: -Oracle high availability OLTP and Data Warehouse database solutions -the role of Oracle middleware in multi-tier applications -the technologies and tools used (See Annex 6, EMA ICT Standards) -the technical skills of the profiles with required expertise for this lot"</i> With regards to the above requirement, could you please elaborate further on the exact points that Tenderers should focus at in the presentation of their "global analysis" for <u>the technologies and tools used (See Annex 6, EMA ICT Standards)</u>, and <u>the technical skills of the profiles with required expertise for this lot</u>. Our perception is that, given the scope of the call for tenders (i.e. the provision of expertise in the domain of Oracle	With regard to technologies and tools, the Agency does not expect tenderers to provide a detailed description of every single tool or technology listed in Annex 06. Rather, tenderers should provide a general overview of how they see these areas evolving and how the tools that are currently used at the Agency fit within those perspectives and evolutions. Specifically, we would like your views on the evolution of the areas of database, middleware and business intelligence and on technologies that might impact these areas. With regard to the technical skills of the profiles with required expertise for this tender, the Agency does not expect tenderers to provide a detailed description of

No.	Question	Answer
	databases and middleware products), the Tenderers should provide their global analysis of the perspectives and evolutions in the domains described in the first two bullets (i.e. in the domains of <i>Oracle high availability OLTP and Data Warehouse database solutions and Oracle middleware's role in multi-tier applications</i>) and should then present how the anticipated evolutions and trends in the above domains will influence the technological environment used in EMA (replying thus to the third bullet of the question) and the technical skills of the profiles requested by EMA for this contract (replying thus to the last bullet of the question). Please confirm that our perception of this question is correct. In case that our above assumption is not correct, please elaborate further on the exact points that Tenderers should focus at with regards to the third bullet of the above requirement, given that providing an analysis for all the tools and technologies presented in Annex 6 would require hundreds of pages which seems to us irrelevant to what EMA would like to assess under this criterion.	every single skill but rather to provide a general overview of how they see the skill-sets of the profiles evolving and how the skills that are currently used at the Agency fit within those perspectives and evolutions.
9	Invitation Letter, page 2, numbered item 5 It is mentioned that tender must be signed by an authorised representative. Could you please specify if the whole offer should be signed on each page separately or only where necessary (i.e. a signed cover letter and only specific declarations, forms, annexes which require a signature, etc)? In case the whole offer should be signed on each page could you please specify whether a full name signature is required or just the initials of our legal representatives, and if	The whole offer does not need to be signed on each page separately. The covering letter needs to be signed, together with those declarations, forms and so on where a signature is specifically requested. The full name of the signatory should be used. Electronic signatures and initials are not permitted.

No.	Question	Answer
	electronic initials are allowed?	
10	Invitation Letter, page 3, numbered item 6 & Technical Specifications, section 10.5 At the invitation letter is stated that all tenders must be valid for 6 months from the submission deadline date. At the technical specifications document is stated that the tenderers must enclose a confirmation that the prices, conditions and stipulations are valid for 12 months from the submission date. Could you please which is the applied validity period for the tender in subject?	This is an error. The correct validity for prices, conditions and stipulations is 12 months from the date of submission, as stated in the technical specifications document. The letter of invitation will be corrected and an updated version will be published on our website.
11	Paragraph 16.1.2.1 of the technical specifications, page 55/61, <i>"...- what database(s) or other mechanism does the Tenderer use to keep track of the skills of its potential candidates <u>and find the candidate that best matches the Agency's requirements</u></i> <i>- <u>How does the Tenderer select the best suited candidate?</u>"</i> Could you please indicate what the difference between the above two requirements is, given that both requirements ask Tenderers to explain the tools and methodology to be used for selecting the candidate <u>that best suits the Agency needs</u>. Is it correct to assume that there is no need to present anything more with regards to the second bullet as long as the Tenderer's approach is described under the first bullet of the above requirement?	The first bullet point refers to the systems and databases that the tenderer has in place to track skills and match candidates to the Agency's needs from the skills point of view. The second bullet point relates to the overall process of selection, of which the databases and systems are only one part.

No.	Question	Answer
12	What would be a typical engagement size in terms of Man days for a Work Packet	A work packet is a defined subset of a project allocated to a particular resource. This is not applicable to the operational support and maintenance of our applications and environments, which is by nature not a project with a beginning and an end but a continuous activity of service provision. Work packets are not referred to in the tender documentation.
13	Once the contractor agrees to the work package as per the request forms and the discussions are scheduled with our consultants and the consultant selected, what would be the maximum lead time we would get in order to get the work initiated.	The Agency will request the provision of services to be performed by a resource with a specific profile as illustrated in Annex 10: Standard Profile Specification and Request Form. This contract will not operate on the basis of work packages but rather the provision of services.
14	Should expertise in Oracle as regards selection criteria be extended to include equivalent products?	No. Since all of our enterprise applications are based on Oracle products (database, middleware, Business Intelligence), we specifically require Oracle expertise in all domains as a selection criterion for this tender. Equivalent experience in the products of another vendor would not be suitable for this tender. Without deep Oracle experience, the personnel provided would be unable to perform the services required to maintain and manage our environment. We therefore see no grounds for adapting the Technical Specifications document to add "or equivalent".
15	Are project references of both "time and means" and "fixed price" type considered as valid?	We have no objection to tenderers submitting both "time and means" and "fixed price" contracts as references, as long as the references demonstrate the tenderer's expertise in the areas of the tender.
16	Who is the incumbent contractor?	The incumbent contractor currently providing services in the areas of the tender is Oracle Belgium BVBA.

No.	Question	Answer
17	Technical specifications for open invitation to tender, Section 15. Selection criteria: technical and professional capacity, page 53/61, "4. Details of 3 major contracts awarded to the tenderer: <i>Relevant to the contract required by the Agency</i> <i>In respect of which professional IT staff were supplied</i> <i>Each contract must have been undertaken for a different client (departments, divisions, directorates etc. are regarded as the same client)</i> <i>Contracts must have been undertaken over the last three years</i> <i>Provision of evidence that the Tenderer has in the recent past provided resources of the type (See section 4.1.3) and in the quantities (See section 9.) requested in this ITT."</i> ... <i>"Total number of person-months delivered across all profiles (e.g. Project Manager: xyz person months; Software Architect: xyz person-months; ...) during the complete duration of the contract."</i> Questions: a) Could you please explain in detail what are the minimum requirements that should be covered by the contract reference in order for Tenderers to successfully pass this selection criterion? What are the exact requirements that a reference should cover (as well as all the references cumulatively), e.g. number of person days, number of profiles, etc. Please provide us with the exact and accurate criteria/thresholds that	a) The minimum requirements are listed in Section 15, paragraph 4. See also the answers to your detailed questions below.

No.	Question	Answer
	will apply. Here are some more specific questions b) <i>"Relevant to the contract required by the Agency"</i>. We understand that relevance to the contract is demonstrated by similar technologies used in the reference. Please confirm. c) <i>"In respect to which professional IT staff were supplied"</i>. Our understanding is that this requirement does not exclude as valid project references contracts where services are not provided under Time & Means basis (but on a fixed Price or Quoted Time & Means basis). Please confirm or else clarify. d) Our understanding is that ongoing projects that cover the characteristics specified in Technical specifications are valid project references. Please confirm. e) We understand that a signed declaration of the Tenderer stating that all information provided in the description of the contract reference (including the financial figures provided etc.) is actual and correct along with the provision of the appropriate contact details of the Client, that EMA could contact in order to verify the information provided will be considered as acceptable and "verifiable" evidence of the implementation of the reference-contracts. Please confirm. f) Please elaborate on the type of resources (profiles) that the Tenderer should have provided in a project in order to be considered as a valid reference. As the profiles requested under this tender are very specific. We understand that profiles that delivered similar tasks are acceptable as similar type of resources. g) Is there a minimum number of man-days in order for a	b) The contract referenced must be relevant to the services requested by the Agency in this ITT i.e. the provision of resources for Oracle database and middleware product management. c) Your understanding is correct. See also the answer to Q15. d) Ongoing projects are acceptable, provided that the tenderer can demonstrate that the services relevant to this ITT have already been provided or are being provided. e) Your understanding is correct. f) There are situations where reference contracts describe and allocate the necessary skill sets in a manner different from that within this ITT. Provided that the tenderer demonstrates that all the responsibilities required in the profiles in section 4.2 of the Technical Specifications document are covered by the profiles as described in the reference contracts, this is acceptable.

No.	Question	Answer
	project to be valid as a reference? Please also specify if this number concerns the total number of man-days or the man-days delivered by specific profiles. h) Moreover, please clarify whether in case of an ongoing project, estimated man-days until the end of the contract should be provided.	g) See the answer to Q5. h) An estimate of man-days to the end of the project is acceptable. See also the answer to c) above.
18	Technical specifications for open invitation to tender, section 2. Executive summary, page 6/61 – “The Agency estimates, without this being binding, that the total annual resource requirement for time and materials services is expected to represent approximately 1000 person-days per annum.” and Technical specifications for open invitation to tender, Section 15. Selection criteria: technical and professional capacity, page 53/61, “Provision of evidence that the Tenderer has in the recent past provided resources of the type (See section 4.1.3.) and in the quantities (See section 9.) requested in this ITT. ... Total number of person-months delivered across all profiles (e.g. Project Manager: xyz person months; Software Architect: xyz person-months; ...) during the complete duration of the contract.” Question: Our understanding is that in order for each reference contract	See the answer to Q5.

No.	Question	Answer
	to be considered similar in quantities with this contract it is sufficient to have approximately 1.000 person-days per annum, all profiles included. Please confirm.	
19	Annex 04 Required Skills per Profile Question: Our understanding is that it is not required for an individual CV to cover all the skills of his/her profile. We understand also that the skills as indicated in Annex 04 are those that every tenderer has to be able to cover collectively across all experts of the tenderer who are available to work under the contract. The CVs to be provided in response to this ITT should not cover even cumulatively all the required skills per profile as indicated in this Annex. Please confirm.	The required skills per profile as listed in Annex 04 would ideally be the minimum (i.e. "mandatory") requirements that every consultant should master. In practice, it is understood that consultants, particularly for more technical profiles, tend to specialise. Therefore, the required skills per profile are those that every tenderer has to be able to cover collectively across all consultants of the tenderer who are available to work under this contract.
20	Tender specifications for open invitation to tender, Section 4.1.3. Detailed specifications of the profiles required at entry level. Questions: a) Our understanding is that it would be sufficient for the CVs to cover only the mandatory requirements of the profile descriptions in order to successfully cover the selection criterion that relates to the evaluation of the Tenderer's personnel. Please confirm. b) Our understanding is that a CV covering only the mandatory requirements of a profile will be considered as	a) Your understanding is correct. We assume, however, that any tenderer would wish to present its organisation in the best possible light and would therefore strive to fulfil as many of the requirements, mandatory or otherwise, as possible. b) Your understanding is correct.

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	valid and will not be rejected. Please confirm. c) "Ability to use the relevant products and tools as specified in Annex 4: Requires Skills per Profile". Our understanding is that this is not a mandatory requirement. Please confirm or else clarify.	c) Only those requirements that are qualified as such in the documentation are mandatory.
21	Technical specifications for open invitation to tender, section 2. Executive summary, page 6/61 – "Tenderers will be given a minimum of 4 working days' notice if they are required to attend such a meeting. Tenderers should note that this meeting is a mandatory part of the evaluation process and that refusal of an invitation shall result in the exclusion of the Tenderer from any further part in the procurement procedure." and Technical specifications for open invitation to tender, section 16.1.2.7. Presentation at the Agency, page 58/61 – "Tenderers should be prepared to complement the written response with a visit to the Agency in order to present their expertise, to provide answers to additional questions that the Agency's Evaluation Committee may have as part of the evaluation process. " Questions: a) What is the purpose of the presentation meeting? Could you please provide the agenda? Are Tenderers allowed to "complement" the submitted tender after the closing date when all the tenders have been opened?	a) As clearly stated in the technical specifications document of the invitation to tender, the purpose of the presentation is so that tenderers may further present their expertise as described in their written response and/or provide answers to additional questions that the Agency's Evaluation Committee may have as a

No.	Question	Answer
	The “expertise” of Tenderers is evaluated during the selection phase. What should be demonstrated in addition during the meeting? Will Tenderers be evaluated only on the basis of submitted tenders? Will any new elements presented during the presentation be taken into account? Does the meeting require a physical presence? Could the meeting take place through video-conference?	result of the evaluation of the written tender response. The presentation will be based on the written tender responses and no new elements are to be presented. The Agency prefers that these presentations are held face-to-face but is willing to consider the use of video-conferencing upon request. If presentations are required, notice will be given to those tenderers required to make a presentation and the notice will be accompanied by an agenda and any necessary accompanying documentation. Tenderers are required to respond to the requirements of the agenda, which are set by the Evaluation Committee. The scoring mechanism for the tender and for the presentations is laid out clearly in the technical specifications document. The initial evaluation is against the technical award criteria and the price criterion as laid out in the document. If presentations are required, an additional 10 points is available for the presentation and the total score for the tender will be out of 110, instead of 100.
22	Invitation Letter – “Either by registered post or by courier service, dispatched no later than Monday 2nd April 2012, the postmark or the date of the deposit slip with the courier services serving as proof of posting date/ time.” and Guidebook for Tenderers, section 7.2 Through a recognised postal or courier service, page 19/29 – “If using a postal service, Tenderers must use a registered or recorded mail service and their tender must be posted in time for a postmark to be added referring to the final date for the submission of tenders or earlier.” Question: Our understanding is that if tenders are submitted by registered post or by courier service, dispatched no later than Monday 2nd April, the postmark or the date of the deposit slip	As stated in the letter of invitation published on our website, for tenders submitted either by registered post or by courier service, dispatched no later than Monday 2nd April, the postmark or the date of the deposit slip with the

No.	Question	Answer
	with the courier service will serve as proof of the posting date. Please confirm.	courier service will serve as proof of posting date/time. See also the answer to Q49.
23	Technical specifications for open invitation to tender, section 15. Selection criteria: technical and professional capacity, page 53/61 – “2. Details of staff turnover during the last financial year: total staff turnover and percentage of staff that have worked within the relevant business area for over 3 years.” Question: Our understanding is that “relevant business areas” are support of information systems (including Oracle products), medicines information systems, pharmacovigilance, regulation. Please confirm and complete the list if necessary.	The “relevant business areas” refers to those areas which are the subject of the tender, in this case the provision of resources for the management of Oracle products.
24	Contract Notice, Section IV 3.7, page 4/5 - “Minimum time frame during which the tenderer must maintain the tender – Duration in months: 6 (from the date stated for receipt of tender)” and Invitation to tender, page 3/6 - “All tenders submitted must be valid for a period of six months from the closing date for receipt of tenders during which the tenderer may not modify the terms of the tender in any respect” and	

No.	Question	Answer
	Technical specifications for open invitation to tender, section 10.5. Period of validity of the tender, page 48/61 – “Tenderers must enclose a confirmation that the prices, condition and stipulations contained within the response to the Invitation to Tender (ITT) are valid for twelve months for the date of submission of the tender.” Question: Is the period of validity of the tender 6 or 12 months?	The period of validity is 12 months. See the answer to Q10.
25	Technical specifications for open invitation to tender, section 4.1.3. Detailed specifications of the profiles required at entry level, page 21/61 – “Relevant third level qualifications are desirable ... Relevant professional qualifications are very desirable. ... Experience in multicultural organisations is desirable. Etc.” Questions: a) Could you please clarify what is meant by “third level qualifications”? b) Taken into account that the CV’s are selection criteria could you please clarify how the “desirable” and “very desirable” characteristics will be taken into account for evaluation of pass/fail?	a) Third level qualifications refer to any qualifications obtained after the end of secondary school education. Therefore, an example of a third level qualification would be a university degree. b) See the answer to Q20a.

No.	Question	Answer
26	Technical specifications for open invitation to tender, section 4.1.5.5 Replacement of Contractor personnel not initiated by the Agency, Figure 3: Diagrammatic presentation of the process for replacement page 37/61 – “2. Follow the process in section 2.2.5.4 (from 6.)” Question: There is no section 2.2.5.4 in the Technical Specifications document. Please clarify the correct reference.	This is an error. The correct reference is 4.1.5.4, which is the section entitled "Process for ordering services".
27	Technical specifications for open invitation to tender, section 16.1.2.1 Resource Selection Methodology, page 55/61 – “The description should address, inter alia, elements as” Question: Our understanding is that the coverage of the elements listed in the paragraph will be sufficient for obtaining the maximum points per award criterion. Please confirm our understanding or else please clarify (eventually complement the list). Same question for section 16.1.2.2 Personnel Management and 16.1.2.3 Account Management.	The lists in question provide a number of elements that the Agency would expect to see as part of the resource selection methodology. However, as resource selection methodologies differ from one organisation to another, it is possible that tenderers may wish to include elements not in our list.
28	Technical specifications for open invitation to tender, section 16.1.2.5 Quality of the technological proposal, page 57/61 – “Taking into account the description of the services and the profiles described in section 4.1.3., ...”	

No.	Question	Answer
	Question: Section 4.1.3 describes the profiles. Where should we refer in the technical specifications for the “description of the services”?	You should refer to section 4.1 entitled “Description of the Services” for the description of the services.
29	Technical specifications for open invitation to tender, section 4.1.5.11.1. On the Contractor’s side, page 42/61 – “ The Contractor nominates a contract manager in charge of the Framework Contract... The Contractor must designate a single main contact person, and at least one back-up person in case of absence, who will take care of all requests addressed to it by the Agency. The Contractor shall provide a single contact office with telephone number, postal address, e-mail address. The Contractor must provide a list of all persons responsible for the management of the customer’s relationship with the Agency, with a list of their roles and responsibilities.” and Technical Specifications for open invitation to tender, section 15. Selection criteria: technical and professional capacity, page 53/61- “3.2 The CVs of the individuals proposed to manage the account evidencing their expertise in this area.” Questions: Our understanding is that we do not have to provide detailed CVs of all the members to be included in the governance structure that the Tenderer will put in place to manage this	We have not stipulated a number of CVs for account management personnel. The requirement states that “the CVs of the individuals proposed to manage the

No.	Question	Answer
	contract and that only CVs of the Contract Manager profile and the contact person for all requests addressed to the Contractor by the Agency would suffice. Please confirm or clarify. With respect to the point "The Contractor must provide a list of all persons responsible for the management of the customer's relationship with the Agency, with a list of their roles and responsibilities", could you please clarify what information is exactly required?	account evidencing their expertise in this area". It is up to the tenderer to decide how many persons and in what roles should be involved in the management of the account from the tenderer's side. We have not included specific profiles for such roles as we would expect account management roles to differ among tendering organisations. The roles and responsibilities regarding interfaces between the Agency and the successful contractor are laid out on page 72 of the technical specifications.
30	Technical specifications for open invitation to tender, section 16.1.2.1 Resource Selection Methodology, page 55/61- "Evidence of active application of this in recent contracts." Questions: a) What exactly will be considered as acceptable evidence? What information do you expect in order to award maximum points in this criterion? The same questions apply also to all the similar requirements under section 16.1.2.2. Personnel Management, section 16.1.2.3. Account Management and section 16.1.2.4. Skills Assurance. b) In particular, would it suffice to provide extracts of the contract, where it is demonstrated that the Tenderer had to apply a similar methodology during the implementation of the contract?	a) Any evidence that can be independently verified will be accepted as long as it proves that the tenderer has actively and effectively applied the methodology that it has described. b) Yes, assuming that the Agency would be able, if it deems this necessary, to independently verify that the contract referenced has been executed successfully in that respect.

No.	Question	Answer
31	Technical specifications for open invitation to tender, section 16.1.2.2 Personnel Management, page 56/61 – “What is the Tenderer’s policy for internal promotion (in terms of responsibility and financial) of its personnel (full-time staff and freelancers)?” Question: Does EMA has a preference for a specific policy? What elements should be addressed in order to get maximum points under this criterion?	No. This covers, <i>inter alia</i>, how tenderers ensure that their full-time and freelance staff remain motivated and on top of their business and how their experience and expertise is put to best use and allowed to grow.
32	Technical specifications for open invitation to tender, section 16.1.2.5 Quality of the technological proposal, page 57/61 – “Taking into account the description of the services and the profiles described in section 4.1.3. , the Tenderer will provide in its response to this ITT: Its global analysis of the perspectives and evolutions during the next 4 years on the following points: Oracle high-availability OLTP and Data Warehouse database solutions The role of Oracle middleware in multi-tier applications technologies and tools used (See Annex 6, EMA Standards) the technical skills of the profiles with required expertise for this lot.” Questions:	Section 16.1.2.5 Quality of the technological proposal does not refer to the development plans for future releases of a particular vendor’s product, in this case Oracle. That knowledge is the province of the vendor alone. Rather it concerns the trends and evolutions in the industry’s use of that vendor’s products, which is an area of open discussion in the industry and one to which independent service providers and product vendors alike must adapt since neither controls market evolution. One such example might be the drive towards Cloud computing. In terms of the industry’s trends in the use of Oracle products, and the need to adapt to them, an independent service provider is not necessarily disadvantaged compared with the vendor itself.

No.	Question	Answer
	a) Could you please confirm that the “services” subject to this procurement procedure are the provision of human resources for the support of Oracle products listed in section 3.3.2 (page 18/61) or other products that may be acquired in the future? b) Could you please describe the methodology that will be used by EMA to evaluate the “analysis of the perspectives and evolutions”? In particular, what are the specific criteria that will be used by EMA to award the score under this (sub)criterion for everyone of the four points listed above? c) To our understanding, the criterion does not address suggestions by Tenderers to make use of any product or forecasted market evolutions in order to add value to the contract services, but evaluates the Tenderers’ current knowledge concerning the four points quoted above. Is this correct? d) Please explain whether EMA expects Tenderers to guess the future plans of vendors of the products concerned. If this is the case, please confirm that this is a valid evaluation criterion. e) Please specify how EMA ensures equal terms of competition between independent service providers and vendors of products listed in the first three points (or Tenderers having privileged relations with them), given that they influence directly such evolutions and are in the possession of non-public information whose knowledge is evaluated in this criterion. f) Please clarify the meaning of the term “global” in relation to the question. For example, in the case of “Data Warehouse database solutions” does it restrict only to Oracle or the entire	a) -The services to be provided under this tender are for human resources for the support of Oracle products which are listed in the tender and any new Oracle products that may be acquired by the Agency in the future. b) The Agency will assess the tenderer’s understanding of the market evolutions in the fields of interest. c) It is incorrect. This requirement will allow the Agency to assess how the tenderer will provide the service requested based on its knowledge of the fields of interest and its ability to make use of the market’s evolutions to add value to the service requested. d) The Agency expects the tenderer to use its knowledge of the fields of interest of the tender in order to give a reasoned analysis of the perspectives and evolution of the areas in question. e) The Agency is conscious that an incumbent supplier which is also a vendor may have access to knowledge which is not available to other suppliers and makes every effort to ensure that other suppliers are not disadvantaged by this. In this particular case, however, we are concerned with the evolution of industry trends rather than that of particular products and therefore an independent service provider in the area of interest of this tender should not be disadvantaged. f) Referring to your example, it does refer to the global market insofar as it is applicable or can reasonably be made applicable to the Agency’s environment.

No.	Question	Answer
	international market of data warehouse solutions (including academic research that might evolve to a commercial product)?	
33	Technical specifications for open invitation to tender, section 16.1.2.5 Quality of the technological proposal, page 57/61 – “Its global analysis of the perspective and evolutions during the next 4 years on the following points: Oracle high-availability OLTP and Data Warehouse database solutions The role of Oracle middleware in multi-tier applications technologies and tools used (See Annex 6, EMA Standards)” Questions: a) As regards the technologies and tools listed in Annex 6, we understand that only those directly relevant to this contract are meant. Please confirm or else indicate which of the methodologies, techniques, tools, architecture and products listed in Annex 6 should be addressed in the response to this criterion. b) Taking into account the large number of the technologies and tools of Annex 6, could you please provide us with a detailed example (indicating the structure and extent of the information to be provided), in order to get a maximum score?	a) The Agency does not expect tenderers to provide a detailed description for every single tool or technology listed in Annex 6. Rather, tenderers should provide a general overview of how they see these areas evolving and how the tools that are currently used at the Agency fit within those perspectives and evolutions. Specifically we would like your views on the evolution of the areas listed. b) A concise paragraph for each technological area with a general description of how this information has been gathered and the relevant references, when appropriate. The Agency would expect to see an analysis of perspectives taking into account the evolution of individual products and technologies, but also competing products, technologies and architectures.

No.	Question	Answer
34	Technical specifications for open invitation to tender, section 16.1.2.5 Quality of the technological proposal in the domain of the lot, page 57/61 – “Its global analysis of the perspectives and evolutions during the next 4 years on the following points: ... the technical skills of the profiles with required expertise for this lot.” Questions: a) Does the above point refer to the technical skills of the profiles of Database Administrators, Middleware Administrators and Business Intelligence Administrators only or other profiles as well? b) Our understanding is that the Tenderer will have to describe the perspective and evolutions of technical skills that should be possessed by each of the profiles in order to be able to exploit the perspectives and evolutions during the next 4 years on the: a) Oracle high-availability OLTP and Data Warehouse database solutions; and b) the role of Oracle middleware in multi-tier applications. We understand that we do not have to address the methodologies, technologies, tools, products, etc. of Annex 6, EMA ICT Standards, unless they refer to (a) and (b) as above. Please confirm or else please clarify.	a) It refers to the profiles described in the technical specifications document. b) The Agency does not expect tenderers to provide a detailed description of every single skill but rather, to provide a general overview of how they see these skill-sets evolving and how the skills that are currently used at the Agency fit within those perspectives and evolutions.
35	Technical specifications for open invitation to tender, section 4.1.3. Detailed specifications of the profiles required at entry level, page 21/61 – “English is mandatory at level 3 (fluent)” Questions: Could you please specify the required level of English knowledge according to the Common European Framework of	The required level of English in terms of the CEFR would be C1/C2.

No.	Question	Answer
	Reference (CEF) level, used in the Europass format?	
36	Technical specifications for open invitation to tender, section 4.1.5.11. Interfaces, roles and responsibilities, page 42/61 – “ The Contractor nominates a contract manager in charge of the Framework Contract. He will be responsible for all contractual relations with the Agency. The Contract Manager must be reachable by the Agency during Agency working hours. In case of absence, a back-up person must be designated. The Contractor must designate a single main contact person, and at least one back-up person in case of absence, who will take care of all requests addressed to it by the Agency.” Questions: a) We understand that the single main contact person and its backup will take care of all requests for services. Please confirm. b) It is our understanding that the Single Point of Contact principle is not violated by the fact that the Contract Manager is also reachable by the Agency in addition to the main contact person. Therefore it will not have a negative bearing on the evaluation. Please confirm our understanding or else clarify.	a) The single main contact person and their back up will take care not only of all requests for services but any other administrative matters which may be addressed to them by the Agency, escalating them where necessary to the Contract Manager for action. b)Your understanding is correct.
37	Technical specifications for open invitation to tender, section	

No.	Question	Answer
	14. Selection criteria: financial and economic capacity, page 51/61- "For joint tenderers, including subcontractors, the same documentation must be provided for each company individually.....The documentation supplied in response to this section will be reviewed to assess the general financial health of the tenderer (or all tenderers in the case of joint applications) and parent companies where the parent company is providing a guarantee." Questions: Our understanding is that if a single Tenderer (or any member of the group for joint tenders) is not going to rely on the capacities of its parent company for the provision of services in the contract, it does not have to provide any evidence for the parent company regarding the financial and economic capacity as well as the technical and professional capacity requirements. Please confirm.	Where parent companies are not providing a guarantee, the accounts for the parent company are not taken into account for the assessment of financial and economic capacity and tenderers are not required to supply them..
38	Technical specifications for open invitation to tender, section 15. Selection criteria: technical and professional capacity, page 52/61- "The Tenderer's professional and technical capacity will be evaluated on the basis of: 5. A statement of the Tenderer's policy on the use of subcontractors, and of the means of ensuring quality when subcontractors are used." Questions: Our understanding is that in case of joint tender only the	The tenderer should supply a policy on the use of subcontractors on behalf of the

No.	Question	Answer
	leader of the consortium needs to supply its policy on the use of subcontractors. Please confirm.	consortium. If this is the policy of the consortium leader, this is acceptable.
39	Annex 2 - Response Questionnaire, 03b Selection Financial Questions: We understand that if audited accounts are not available for year 2011 yet, data for the year 2010 are to be provided. Please confirm.	Confirmed.
40	Annex 02 – Response Questionnaire – Instructions for completing this workbook – “1. Tenderers must complete this workbook. Each workbook should be identified with a file name as follows: Name of Tenderer or Consortium/ Response Questionnaire. If a Tenderer is applying for both lots, both Lot numbers should be identified in the file name” Questions: Our understanding is that reference to two lots as quoted above does not apply. Please confirm.	This is a clerical error. There are no lots in this procurement procedure.
41	Technical specifications for open invitation to tender, section 4.1.5.8.2. Quality of the work delivered by time and materials resources, page 39/61- “Progress monitoring: all resources will report on a weekly basis via timesheets showing the number of hours spent per agreed task and progress on the	

No.	Question	Answer
	task.” and Technical specifications for open invitation to tender, section 4.1.5.10. Reporting requirements, page 41/61- “The Contractor must provide the following reports to the Agency in English: Timesheets signed by individual contractors: Using the standard Agency tool Monthly” and Technical specification, Annex 8 Standard timesheet. Questions: a) Will timesheets be submitted both monthly and weekly? b) If the answer to question a) is yes, is the required information identical for monthly and weekly timesheets, i.e. the information on Annex 8? c) The use of the “standard Agency tool” implies electronic submission of timesheets. However, the fact that timesheets are “signed” by individual contractors and the Standard timesheet of Annex 8 indicate paper-based timesheets. Could you clarify, indicating whether there is a difference for the monthly and weekly timesheets? d) Will the individual contractors submit timesheets directly to EMA or will the Tenderer have to collect them and submit	a) Yes. b) The monthly timesheet will contain the details from the weekly timesheets for that month. c) Annex 8 is a print out of the timesheet which is completed electronically. Timesheets are printed off and signed manually. The same template is used for monthly and weekly timesheets. d) Each individual contractor should present timesheets to the responsible person

No.	Question	Answer
	them to EMA's Project Office?	within EMA, normally the Programme Manager, for signature as required and should then submit the signed timesheets to the tenderer. The tenderer then submits signed timesheets as supporting documents to the invoice for that individual.
42	Annex 3 Response Questionnaire – Financial, 01 Price, "Maximum mark up per profile" Questions: Could you please explain what is the "maximum mark-up per profile requested"? Moreover, it is indicated that this information will be used for information purposes only. Could you please explain in detail why you are asking tenderers to provide such information? Will it in any way affect the Tenderer's evaluation as regards prices (per person/day) for the different profiles as indicated in the same worksheet?	Please refer to the glossary (section 1.1 of the Technical Specifications document) for an explanation of "Mark up" and "Total mark up". The "maximum total mark-up per profile" is the maximum value of "Total mark up" that the tenderer would apply to every profile. The Agency confirms that this is for information purposes only.
43	Annex 2 –Response Questionnaire – sheet 04.05 List of Subcontractors Question: Our understanding is that in case no subcontracting is envisaged, tenderers should leave the sheet "04.05 List of Subcontractors" empty. Please confirm.	Your understanding is correct.
44	Technical Specifications for Open invitation to tender, Section 15 Selection criteria: technical and professional capacity, page 53/61 "Provision of evidence that the Tenderer has in the	

No.	Question	Answer
	<i>recent past provided resources of the type (See section 4.1.3.) and in the quantities (See section 9.) requested in this ITT."</i> Question: a) Could you please clarify to what type of evidence you refer? For example will a "Contract Award Notice" (published in TED) be accepted as evidence? b) Our understanding is that the "type of resources" is related to the profiles requested in the ITT as well as similar profiles based on the profile descriptions of section 4.1.3. Furthermore, our understanding is that it is not mandatory that each reference covers all three requested profiles. For example, if a project reference covers the Database Administrator profile or similar and does not concern Oracle Business Intelligence, it will be eligible to pass the selection phase (considering that it covers all the other requirements as stated in section 15. of the Specifications). Please confirm or else please clarify. c) Based on the quoted part above, tenderers need to present evidence to confirm their experience in certain fields, demonstrating the use of resources of the type requested in this CFT (i.e. Database Administrators, Middleware Administrators and Business Intelligence Administrators) while indicating the tools of a specific vendor (Oracle). According to EU law on public procurement, any reference to a vendor or a brand should be accompanied with the term "or equivalent". It is clear that a tenderer with experience in one thematic area, using products of a certain vendor, can be considered eligible to offer services in the same technical field, even if it has to	a) See the answer to Q5. b) The Agency has not indicated a mandatory requirement that each reference should cover all three profiles. However, the Agency would expect to see all the profiles represented in the three reference contracts requested and would expect the references to cover all the other requirements, including the volume mentioned in the answer to Q5. c) See the answer to Q14.

No.	Question	Answer
	use the tools of a different vendor. Could you please confirm that the term "or equivalent" can be considered valid in relation to the specific vendor as included in the profile descriptions of section 4.1.3?	
45	Annex 3 Response Questionnaire – Financial, Instructions <i>"1. Tenderers should complete worksheet "01 Price" only. Sheet "02 Price Scenario" will complete automatically when figures are entered into sheet "01 Price". Tenderers should not attempt to change Sheet 02 which is protected.</i> <i>2. In worksheet "01 Price", tenderers should complete Column D (prices for weekend working) and Column E (prices for work done on UK public holidays which coincide with Agency holidays) only if there is a difference in their rates for these services. It is anticipated in 2012 that there will only be 3 Agency holidays which coincide with UK public holidays (6 and 9 April and 27 August). It is unlikely that work would be required on 25/26 December and 2 January, which are the only other Agency holidays which coincide with UK holidays. UK public holidays which are normal working days for the Agency in 2012 are 7 May, 4 and 5 June and it is expected that tenderers will provide service on these days at the standard rate. A full calendar of Agency holidays for 2012-2014 can be found in Annex 1 to the draft Service Level Agreement in Annex 05 to the Technical Specifications."</i> Questions: Since the prices in Sheet 2 will be automatically filled by the prices in Sheet1, we understand that the Tenderer must fill	Your understanding is correct.

No.	Question	Answer
	the prices in Columns D and E even if there is no difference in the rates for these services. Please confirm.	
46	Annex 3 Response Questionnaire – Financial – Sheet 02 Price Scenario Questions: Since the sheet Price 02 Price Scenario is protected and is automatically calculated based on values in sheet 01 Price, there should be an indication in the titles of the columns in sheet 02 of the prices that will be entered there. In other words, columns D, F and H of sheet 02 have the same title "Price on Agency's premises €". We believe that there should be a different naming in each column as indicated below: <u>Title in column D:</u> € - Price per person/day on the Agency's premises (normal working hours 09.00-17.30 Mon-Fri and UK public holidays which are normal Agency working days) <u>Title in column F:</u> € - Price per person/day on the Agency's premises (weekends - Saturday and Sunday) <u>Price in column H:</u> € - Price per person/day on the Agency's premises (UK public holidays coinciding with Agency holidays) Please provide us with an updated version of the excel "Annex 3 – Response Questionnaire – Financial.	Services are all required on the Agency's premises. As the columns D, F and H are all linked by formula to the relevant columns in sheet 01 and sheet 02 is protected to ensure that these formulae do not change, we see no need to amend the sheet nor to issue an updated version of the Response Questionnaire – Financial.
47	Technical Specifications for open invitation to tender, Section 16.1.2.3 Account Management, page 56/61 "This criterion will be used to evaluate the efficacy and efficiency of the	

No.	Question	Answer
	methodology used to manage the contract that would be put in place at the conclusion of this procurement procedure.” Question: Our understanding is that in case of a joint offer, the Account Management methodology that will be put in place may apply to the consortium as a single entity regardless of the distribution of roles among consortium members (this may imply that all the management positions may be vested by only one consortium member). Please confirm our understanding.	Your understanding is correct.
48	How does EMA ensure fair competition in view of the fact that the incumbent contractor is the vendor of the products concerned in this tender?	The Agency has ensured fair competition by running on open procurement procedure for these services, under which all tender responses will be evaluated against the set of criteria clearly laid out in the documentation.
49	Would EMA consider a one week extension to the requested submission date due to the complexity of the response required?	Yes. The tender submission date/time will now be 12.00 on Monday 16th April 2012. The tender opening will now take place at 16.00 on Wednesday 18th April 2012.
50	a) The answer to question no 29 (from the “Questions and Answers relating to Tender – EMA-2012-09-IF” document) refers to page 72 of the Technical Specifications which does not exist. It is noted that the specifications document has only 61 pages. Could you please provide reference to the correct page number of the Technical Specifications?	The correct page number in question is page 42.

No.	Question	Answer
	b) With respect to the point "The Contractor must provide a list of all persons responsible for the management of the customer's relationship with the Agency, with a list of their roles and responsibilities", could you please clarify what information is exactly required?	The tenderer should list the job profiles that it would envisage to be involved in the management of the customer relationship with the Agency with a brief description of each profile explaining its role and responsibilities.
51	The answer to question no 17 (from the "Questions and Answers relating to Tender – EMA-2012-09-IF" document) refers to section 4.2 of the Technical Specifications which does not exist. Could you please provide reference to the correct section of the Technical Specifications?	The correct section is 4.1.2.
52	Questions and Answers relating to Tender - EMA-2012-09-IF, A5, states the following: "The contracting authority is seeking reasonable assurance that quantities of this order of magnitude have been contracted in the past and therefore, tenderers should consider volumes of 4000 person-days per contract on average as being the minimum acceptable level". In addition, Questions and Answers relating to Tender- EMA-2012-09-IF, Q17 states: "Please also specify if this number concerns the total number of man-days or the man-days delivered by specific profiles". Moreover, in the Technical Specifications for open invitation to tender, section 15, under Selection criteria: "technical and professional capacity", page 53/61 states: "Total number of person-months delivered across all profiles (e.g. Project Manager: xyz person-months; Software Architect: xyz person-months; ...) during the complete duration of the contract.".	

No.	Question	Answer
	Questions: We understand that the threshold set for the volume of person-days concerns the total number of person-days of the referenced contract (all profiles involved), and that the number of person-days concerning work delivered by profiles with responsibilities required in this ITT is a subset of these person-days. This would be in line with the Financial Regulation. Please confirm. Our understanding is that the threshold of 4000 person-days applies to the mean value of person-days over the three reference contracts. Please confirm our understanding or otherwise clarify the exact meaning of the term "4000 person-days per contract on average". To what exactly does 'average' refer?	Your understanding is incorrect. The total volume of person days should comprise profiles relevant to and requested by this ITT only. Person days for profiles neither relevant to nor requested by this ITT should not be counted towards the total volume for a reference contract. Section 15.4 of the Technical Specifications document states that the 3 reference contracts must, among other characteristics, be "relevant to the contract required by the Agency" and prove that "resources of the type... and in the quantities... requested by this ITT" have been provided . 'Average' refers to a usual or a typical contract.

Document History

Version	Who	When	What
1.0	AZA	24/2/12	First draft
2.0	SEA	14/3/12	First version for publication.
3.0	SEA	27/3/12	Second version for publication.
4.0	SEA	02/04/12	Third version for publication.
5.0	AZA	12/04/12	Fourth version for publication.