



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Questions and Answers relating to Tender – EMA-2012-13-ICT

External Service Providers for software applications: provision of resources for online analytical processing systems

Contents

Contents.....	1
Questions and answers	2
Document History	26

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom

Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union



Questions and answers

No.	Question	Answer		
1	Herewith we would like to ask for the clarification of the tender specifications: Reference: Section 16. Selection criteria: professional and technical capacity, Requirements: Lot 2, requirement #4 (page 86 of the Technical Specifications) “Tenderers must have experience in the domain of the lot with references to three similar contracts for the required services, each of which must have the following characteristics: - Relevant to the contract required by the Agency” Question: Please explain the meaning of the term domain in the requirement - Is it to be understood as provisioning of QTM and FP services, as described in Section 5.3.1? - If not, is it to be understood as services related to “online analytical processing systems”?	In regard to the definition of the term ‘domain’ in the requirement, the Agency would draw your attention to the Executive Summary on Page 6. of the Technical Specifications, and in particular the entry under Purpose: <table><tr><td>Purpose</td><td>This tender aims to put into place contractual arrangements with one or more economic operators for the provision of services, on a time and materials basis (Lot 1) and quoted time and materials or fixed price basis (Lot 2), that will enable the Agency to acquire resources not employed directly by the Agency in the domain of the development and maintenance of on-line analytical processing information systems. These resources will contribute expertise directly to the design, construction, implementation and maintenance of mainly internally developed applications.</td></tr></table> Therefore it is expected that that your experience will be in the provisioning of QTM and FP services specifically related to the development and maintenance of on-line analytical processing systems.	Purpose	This tender aims to put into place contractual arrangements with one or more economic operators for the provision of services, on a time and materials basis (Lot 1) and quoted time and materials or fixed price basis (Lot 2), that will enable the Agency to acquire resources not employed directly by the Agency in the domain of the development and maintenance of on-line analytical processing information systems. These resources will contribute expertise directly to the design, construction, implementation and maintenance of mainly internally developed applications.
Purpose	This tender aims to put into place contractual arrangements with one or more economic operators for the provision of services, on a time and materials basis (Lot 1) and quoted time and materials or fixed price basis (Lot 2), that will enable the Agency to acquire resources not employed directly by the Agency in the domain of the development and maintenance of on-line analytical processing information systems. These resources will contribute expertise directly to the design, construction, implementation and maintenance of mainly internally developed applications.			
2	There appears to be a mistake in the Annex 02 Response Questionnaire Instructions Sheet: 04a Professional and Technical Capacity Lot 1 4 Information in question 04.02 should be provided for the three most recent years available. If you wish to change the years shown in the headings, select the most recent year from the drop down list in Cell E11. Cells F11 and G11 will change automatically.	This is an error, this should read: The answer to question 04.02.01 should be either 'Yes' or 'No' in column F		

No.	Question	Answer
3	There appears to be a mistake in the Annex 02 Response Questionnaire Instructions Sheet: 04b Professional and Technical Capacity Lot 2 4 Information in question 04.02 should be provided for the three most recent years available. If you wish to change the years shown in the headings, select the most recent year from the drop down list in Cell E11. Cells F11 and G11 will change automatically.	This is an error, this should read: The answer to question 04.02.01 should be either 'Yes' or 'No' in column F
4	There appears to be a mistake in the Annex 02 Response Questionnaire Instructions Sheet: 04d Tenderer's Skills List 2 This sheet relates to Q 4.08 on worksheet 04 Professional and Technical Capacity.	This is an error, this should read: This sheet relates to Q 4.07 on worksheet 04 Professional and Technical Capacity.
5	<u>Question</u> <u>Reference in the tender documentation: Annex 4 Required Skills per Profile.</u> Annex 4 states that "the worksheet entitled Skills per Profile lists the tools, techniques and methodologies used in the Agency and indicates which <u>skills are required</u> for each of the profiles listed in the Technical Specifications document". Could you please clarify if <u>all</u> the required skills marked with YES must be covered in the CVs, or if the tenderer should specify in the CVs which of those skills are covered (not necessarily all skills marked with YES)?	On Page Answer in page 84 of the Technical Specification it states: "Tenderers must be able to ensure the quality of service and thus must have the required skills available in the tenderer's organisation. Tenderers are expected to be able to provide, as a minimum, the skills requested by the Agency in Annex 04. The Tenderer's Skills List to be completed by the Tenderer" The complete list of required skills per profile shows the skills that every tenderer has to be able to cover collectively across all consultants of the tenderer who are available to work under this contract. Furthermore as it is understood that consultants, particularly for the more technical profiles such as Software Data Architect, System Analyst, Developer, Senior Developer, Testing Manager, Testing Engineer and Technical Consultant , tend to specialise in a few technologies it is clearly not possible for ever CV to include every skill indicated. Therefore the tenderer should specify in the CVs they submit which of those mandatory skills are covered.

No.	Question	Answer
6	In page 55 of the document "Technical specifications for open invitation to tender..." (WC500136726) for Lot 1, it is mentioned "...the subject of Lot 1 currently employ ten resources at the Agency's premises, this number includes six of the supplier's employees, the rest being consultants (who are either freelance or contracted via agencies), all of who are carrying out exclusive functions on a full-time basis". It also says: "The legal and financial implications of TUPE are a matter for discussion and consultation between the prospective tenderer, the incumbent supplier and the affected personnel at the appropriate time." However, is it possible to have any detail of the economic implications of this situation?	Thank you for your question. More information on the Transfer of Undertakings can be found in Section 13. of the Guidebook for Tenderers, this is located at: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/01/WC500057107.pdf
7	In technical specifications, section 15, p.83 EMA writes "For Lot 2: Euro 500,000 per annum for each of the last three financial years." (a) Is the minimum financial turnover requirement for tenderers for Lot 2 Euro 500,000 per annum or Euro 5,000,000 per annum? Please clarify (b) If the referred number is correct, please explain the big difference of the required minimum financial turnover for tenderers between the two Lots, when the sizes of both contracts are of the same order.	a. The minimum financial turnover requirement is Euro 500,000 per annum for each of the last three years. b. Under Lot 2, multiple framework contracts with reopened competition will be awarded with no declared or effective priority or ranking amongst the parties. The aim is to have a pool of up to 5 framework contracts. Specifications for each Specific Contract will be sent to all successful parties which are awarded a framework contract. All parties will be eligible to respond if they wish to do so and a tender procedure will be conducted for each specific contract. Bids received will be evaluated according to the methodology described in the tender specifications document. As the type and volume of the work required is likely to vary in specific contract specifications put out to tender under the Lot 2 framework contract, the minimum financial turnover threshold has been lowered in order to take into account the variance in value of these specific contracts.
8	In technical specifications, section 5.2.4.4, p.56, point 7 EMA writes "The Europass CV template must be used as per the Agency's instructions as set out in the annexes to the draft Framework Contract." Please confirm that this is also applicable to the tendering procedure, thus all Tenderers need to provide the requested CVs in the Europass format.	Yes, the Europass CV template should be used for CVs presented as part of the tenderer's response to the bid and all tenderers are required to present CVs in this format. We refer you to point 04a.5 in the Instructions worksheet of Annex 02 Response Questionnaire which sets out this requirement
9	In technical specifications, section 16, point 4, p.84 EMA writes "Contracts must have been undertaken over the last three years" Please	a. The statement includes contracts which have been signed within the last three years and which have either been completed within that period or are still on-going.

No.	Question	Answer
	clarify whether this statement includes contracts that (a) have been signed by the Tenderer within the last three years, i.e. January 2010 onwards (b) have time and means services that have been requested and executed within the last three years, although the contract might have been signed before that date (c) have been signed before January 2010 but the actual requests for services and work have started after January 2010, thus within the last three years	b. The statement includes contracts on which work has been requested and executed within the last three years, although the contract might have been signed earlier. c. The statement includes contracts signed before January 2010 but on which work started after January 2010 and which was completed within the last three years or is on-going.
10	Lot 2, Scenario 1. Considering the following information provided to Tenderers by EMA - Annex 13 - Scenarios for Lot 2, p.3/6 "Tenderers should note that they are not required to provide copies of the artefacts themselves, but to provide total price for the scenario." - Annex 2 - Response questionnaire, 06a Award Criteria Lot 2 - Annex 3 - Response questionnaire - Financial - Lot 2 (a) Please confirm that the Tenderers are NOT requested to provide any kind of deliverable referred to in scenario 1, as part of the actual Inception and Elaboration phase of the system (b) Clarify exactly what type of documents EMA expects the Tenderers to provide in order to be evaluated in the criteria written in the "Response questionnaire" and in particular 06a.01 "The quality of the technological proposal" and 06a.02 "The quality of the methodological proposal" (c) Please clarify whether a document that will explain HOW these	a. Tenderers are not required to provide the deliverables from Scenario 1 for the inception and elaboration phases of the system. b. In paragraph 17.2.1.1. of the technical specifications document, it states that "Tenderers should provide a detailed description of the approach and project methodology that they would use when undertaking the projects described in Scenario 1 and Scenario 2 contained in Annexes 12a & 12b. In addition, tenderers should provide examples of any templates that they use to implement their project methodology." As the Agency is not aware of the types of templates used by individual tenderers, it is up to tenderers to decide what templates they wish to present, in addition to the detailed descriptions of the approach and project methodology, in order to comply with the requirement. c. It is up to tenderers to decide what to include in their detailed descriptions of the approach and project methodology for scenario 1.

No.	Question	Answer
	2 deliverables will be produced, WHAT will be their content (according also to the 06b "Project Methodology") and HOW the effort and pricing for producing these deliverables are calculated covers EMA's request for Scenario 1	
11	Lot 2, Scenario 2 (d) Please clarify and confirm the same as in previous questions for Scenario 2	d. The same comments in answers a, b and c above also apply in relation to Scenario 2.
12	Clarification 1 Technical Specifications, Section 5.2.3.1 Project Manager, page 24: "5.2.3.1.2 Education - Bachelor's Degree in Computer Science, Information Systems, Business Administration or other related field or equivalent work experience." Questions a) Could you please specify how many years is the "equivalent work experience"? b) In which situation as below should the CV demonstrate "equivalent work experience" (situation a, situation b or both)? a. A candidate does not have a Bachelor at all and he has X years of experience; b. The candidate has a Bachelor in other than the aforementioned domains (e.g. in Engineering) and has X years of experience in the position. c) The same questions as above apply also to the following profiles: - 5.2.3.2. Business analyst, page 26; - 5.2.3.3. Software Data architect, page 29; - 5.2.3.4. System analyst, page 32; - 5.2.3.5. Senior System Analyst, page 34; - 5.2.3.6. Developer, page 36; - 5.2.3.7. Senior Developer, page 38; - 5.2.3.8. Testing Manager, page 41; - 5.2.3.9. Testing engineer, page 43; - 5.2.3.12. Lead consultant, page 49; - 5.2.3.13. Technical consultant, page 51.	a) To obtain a Bachelor's Degree or similar qualification generally requires 3-5 years of study depending on the location and course subject. The "equivalent work experience" would therefore be a minimum of 3 years. b) The work experience requirement would apply in both situations a) and b). c) The answers in a) and b) above apply to all the other profiles where a requirement for equivalent work experience is required.

No.	Question	Answer
13	Clarification 2 Technical Specifications, Section 5.2.3.1. Project Manager, page 24: "Relevant professional qualifications (e.g. PMI PMP; Prince 2 Practitioner) are very desirable" Question a) Our understanding is that it is not mandatory for a candidate to possess "Relevant professional qualifications" in order to be considered eligible. Please confirm our understanding. b) The same question applies to all the remaining profiles.	a) Your understanding is correct. The requirement for relevant professional qualifications is designated as very desirable or desirable, depending on the profile. b) See 13a) above.
14	Clarification 3 Technical Specifications, Section 5.2.3.1.6 General Characteristics, page 24: "Competencies in the role – Demonstrable competences in the role are very desirable. ...Communication abilities are very desirable. ...Time management capabilities are very desirable. ... Supervisory and leadership capabilities are very desirable" Questions a) Our understanding is that it is not mandatory for a candidate to possess all general characteristics in order to be considered eligible. Please confirm our understanding. b) Could you please clarify if the candidates proposed for each profile should cover cumulatively all desirable (and very desirable) characteristics? c) Taken into account that CV's are selection criteria (of a pass/fail nature) could you please clarify how the desirable (and very desirable) characteristics will be evaluated?	a) The general characteristics in each profile are designated as very desirable or desirable and therefore are not mandatory. b) We would like to see as many as possible of the desirable and very desirable characteristics listed in the profiles covered by the candidates proposed for each profile. c) It is sufficient that the CVs cover all the mandatory requirements of the profile descriptions in order to cover the selection criterion relating to evaluation of the tenderer's personnel. However, we would assume 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.
15	Clarification 4 Tender Specifications, Section 5.2.3.9 Testing Engineer, page 43, "Experience – A minimum 3 years of relevant IT experience, focusing on the application domain of on-line analytical processing systems. 2 years' experience in the selected business domains would be an advantage." Questions a) Could you please specify the "selected business domains"?	a) We refer you to paragraph 5.2.2. on Page 22 of the technical specifications document where the relevant business domains are listed.

No.	Question	Answer
	b) Our understanding is that a candidate with no experience in any of the “selected business domains” will be eligible. Please confirm our understanding. c) If our understanding on the above is correct could you please clarify how “advantageous” experience will be evaluated?	b) The requirement for experience in the selected business domains is not mandatory but would be an advantage. As it is not mandatory, candidates without such experience would be eligible. c) See the answer to 14c) above.
16	Clarification 5 Technical Specifications, Section 5.2.3.2. Business Analyst, page 26, “5.2.3.2.3 Relevant professional qualifications – • Relevant professional qualifications are very desirable. • Relevant qualifications in the area of business analysis and/or business process analysis and modelling (e.g. OMG Certified Expert in BPM, Six Sigma Black Belt or higher, BABoK) are very desirable.” Question a) We understand that if the candidate possesses any of the certifications mentioned in the second bullet, the requirements of the first bullet are automatically fulfilled. Please conform. b) If the candidate does not possess any of the certifications mentioned in the second bullet, what kind of “relevant professional qualifications” would be “very desirable”?	a) Your understanding is correct. b) The certifications in the second bullet are examples of the type of qualifications relevant to the area in question and the list is not exhaustive. It is up to the tenderer to decide which certifications not mentioned among the examples it considers to be relevant to this profile.
17	Clarification 6 Technical Specifications, Annex 4 Required Skills per Profile, worksheet “Skills per Profile” Question In this sheet there are several technologies that are not required by any profile. Is the Tenderer required to cover them? If yes, in which part of the Tender (e.g. in CV's, PRFs, simple declaration would be enough)?	As stated in Section 16 of the technical specifications document, tenderers are expected to be able to provide, <u>as a minimum</u>, the skills listed for each profile in Annex 4 Required Skills per Profile. In CVs presented by the tenderer, the candidates described are required to have the ability to use the tools and methodologies listed under that profile in Annex 04 Required Skills per profile. If, in addition, candidates have skills which are listed in Annex 04 but not designated for that particular profile, then the tenderer is at liberty to highlight this and a simple statement would be sufficient.
18	Clarification 7 Tender Specifications, Annex 14 Indicative minimum resources per skill, worksheet “Skills per Profile”	

No.	Question	Answer
	Question In the above Annex there are several technologies for which no minimum number of resources is required (e.g. Eclipse, FileMaker, etc.). Will these technologies be considered during the selection phase and how? What would be the impact on selection if entries are left blank?	As stated in point 7, under the heading Requirements: Lot 2 in section 16 of the technical specifications document, the tenderer is expected to be able to provide, as a minimum, the skills required by the Agency as listed in Annex 04, Required Skills per profile. If the tenderer wishes to give information in its response in worksheet 4d in Annex 02 Response Questionnaire on the number of resources with skills for which no minimum number of resources is required in Annex 14, Indicative minimum resources per skill, the tenderer is at liberty to do so. If, however, these entries are left blank, there will be no impact on the selection provided that the tenderer meets the minimum requirements.
19	Clarification 8 Tender Specifications, Section 16. Selection Criteria: professional and technical capacity, page 87, "Evidence Required: Lot 2 - ...3. The Tenderer will provide the CVs of the individuals proposed to manage the account evidencing their expertise in this area. Evidence of expertise in the area of account management and of either one similar assignment covering a minimum four year period or of two previous similar assignments each covering two years is required." Questions a) We understand that for Lot 2 the Tenderer does not need to include CV's for its technical staff. Please confirm our understanding. b) Is it acceptable for account management personnel to be the same for both Lot 1 and Lot 2?	a) Your understanding is correct. b) Yes, provided that they meet both sets of criteria as stated under the headings Evidence required Lot 1 and Evidence required Lot 2 in section 16 of the technical specifications.
20	Clarification 9 TED notice, Information about Lots, page 3/5, "Lot No:2, ..., Framework agreement with maximum of 5 participants with re-opening of competition" and Technical Specifications, Section 17.2.1. Description of the award criteria for Lot 2 for the Framework Contract, page 91, "For Lot 2, a Multiple Framework Contract (MFC) with reopened competition will be concluded. Framework Contracts will be awarded to a maximum of five Tenderers (a minimum of three are required for the successful operation of the MFC) with the highest overall scores after the conclusion of the evaluation detailed below."	There is a clerical error in paragraph 17.2.1.2 in the technical specifications document. The correct figure for the maximum number of framework contracts to be awarded under Lot 2 is five (5).

No.	Question	Answer
	and Technical Specifications, Section 17.2.1. Description of the award criteria for Lot 2 for the Framework Contract, page 92 “17.2.1.2 Price ... It is anticipated that framework contracts will be awarded to a maximum of four (4) parties for this Lot (a minimum of three are required for the successful operation of the MFC).” Questions Is the maximum number of Lot 2 contractors 4 or 5?	
21	Clarification 10 Technical Specifications, Annex 13 Scenarios for Lot 2, Section 2. Scenario 1: Inception and elaboration phase of on-line analytical processing information systems, page 2/6, “ 2.2 Objective The scope of this scenario is limited to the inception and elaboration phases of this project. The expected deliverables for the two phases that are the subject of this scenario (i.e. inception and elaboration) are, compliance with RUP@EMA v2.0: • Vision document • System architecture document • High-level system use cases describing the complete system to be built. • Business view of data via: - o UML class data models or, - o Entity relationship diagrams (ERDs) • Descriptions of the reports to be built in the construction phase. • Detailed plan to perform the construction and transition phases • Risk register” And Technical Specifications, Annex 2 response questionnaire, Sheet “06b Project Methodology”, “ The quality of the technological proposal - Scenario 1 Project Vision Project Software Development Plan Risk Register The quality of the methodological proposal - Scenario 1 Project Methodology	

No.	Question	Answer
	Project management methodology Project reporting structure” Question Our understanding is that the Tenderer does not need to provide (drafts of) the aforementioned deliverables. The description of the technological and methodological approach that the Tenderer will use for the production of those deliverables is sufficient. Please confirm	See the answer to Q10 above.
22	Clarification 11 Technical Specifications, Annex 13 Scenarios for Lot 2, Section 3. Scenario 2: Construction phase of on-line analytical processing information systems, page 4/6, “The expected deliverables are: • Technical analysis and design documentation as support of the delivered solution such as: - o Architecture document; - o Physical data model; - o ETL design documents; - o Reporting design documents; - o Testing strategy; - o Administration procedures and scripts. • Deployment guide and scripts for the deployment of the solution. • Code and scripts for all objects developed during the projects. • Required predefined reports and ad-hoc reporting access for the business. • Training for end-users and IT using train-the-trainer approach.” And And Technical Specifications, Annex 2 response questionnaire, Sheet “06b Project Methodology”, “ The quality of the technological proposal - Scenario 2 Architecture Test Strategy Deployment guide The quality of the methodological proposal - Scenario 2 Project management methodology Project reporting structure	

No.	Question	Answer
	Question Our understanding is that the Tenderer does not need to provide (drafts of) the aforementioned deliverables. The description of the technological and methodological approach that the Tenderer will use for the production of those deliverables is sufficient. Please confirm.	See the answer to Q10 above.
23	Clarification 12 Tender Specifications, Section 5.2.3 Detailed specifications of the profiles required at entry level, pages 34 and 38, "5.2.3.5 Senior System Analyst, ... , 5.2.3.7 Senior Developer" and Tender Specifications, Annex 4 Required skills per profile and Tender Specifications, Annex 14 Indicative minimum resources per skill Question a) In Annex 4 the required skills for the profiles "senior system analyst" and "senior developer" are missing. Could you please let us know if there are minimum required skills for those two profiles? b) In Annex 14 there are not minimum resources for the profiles "senior system analyst" and "senior developer". Could you please let us know if there are minimum resources required for those two profiles?	a) The required skills shown in the column headed System Analyst apply to both the System Analyst and Senior System Analyst roles. Those shown in the column headed Developer apply to both the Developer and Senior Developer roles. b) The minimum resource requirements shown in the column headed System Analysts are inclusive of System Analysts and Senior System Analysts. Those in the column headed Developers are inclusive of Developers and Senior Developers.
24	Clarification 13 Tender Specifications, Section 17.1.2.5 Relationship with extra-muros sites, page 90, "This criterion will be used to evaluate the appropriateness of the arrangements the Tenderer proposes to put in place to execute projects extra muros" Question What kind of arrangements should the Tenderer describe? Could you give examples?	Tenderers should provide information on how they will organise themselves to ensure smooth operation of any extra-muros services that the Agency may request. This might include <i>inter alia</i> how tenderers would ensure a seamless integration of the deliverables into the Agency's environment, what communication model the tenderer would propose, how the tenderer would enable the Agency to monitor the extra-muros activities and so on.
25	Clarification 14 Tender Specifications, Section 16. Selection Criteria: professional and technical capacity, page 85: "Evidence Required: Lot 1 ...3.2 The CVs of the individuals proposed to	

No.	Question	Answer
	manage the account evidencing their expertise in this area" and Tender Specifications, Section 16. Selection Criteria: professional and technical capacity, page 87: "Evidence Required: Lot 2 ... The Tenderer will provide the CVs of the individuals proposed to manage the account evidencing their expertise in this area. Evidence of expertise in the area of account management and of either one similar assignment covering a minimum four year period or of two previous similar assignments each covering two years is required." Question Are the requirements for the management team of Lot 2 applicable also to Lot 1?	The evidence required for Lot 1 requires evidence that the individuals proposed have expertise in their area i.e. the management of accounts under which time and materials services have been supplied. As Lot 2 covers fixed price and quoted time and means services, the additional requirement for evidence of one or two similar assignments is specific to this Lot.
26	Clarification 15 Could you please provide us with a document or URL describing RUP@EMA?	There are no significant differences between RUP and RUP@EMA.
27	Reference in the tender documentation: Technical Specifications for open invitation to tender In section "5.2.3.7 Senior Developer" it is required that each proposed expert should have "Two years of programming experience in the programming technologies currently used at the Agency". Could you please clarify whether there is a specific set of programming technologies that each candidate should have the required experience or it is adequate to have two years of programming experience in at least one programming technology?	While the Agency would like to see candidates put forward with a range of experience in programming technologies, we are aware that some candidates will specialise in one particular type and therefore it is adequate to have two years of programming experience in at least one programming technology.
28	Question: Reference in the tender documentation: Technical Specifications for open invitation to tender, Section 7.2. subcontracting • Could you please clarify whether a letter of intent is required for freelancers whose CVs are submitted in relation to the Selection Criteria: Technical and Professional Capacity in Lot 1? • Additionally, should the Tenderers include the names and addresses of these freelancers in sheet 04.05 List of Subcontractors in Annex 2, Response Questionnaire? • Could you please confirm that the documents required	We refer you to worksheet 04.05 List of Subcontractors in Annex 02 Response Questionnaire. If the sub-contractor is a one-person company, the information in columns F, G & H is not required. Column H refers specifically to the letter of intent. This instruction is intended to refer to freelancers who have established themselves as a one-person company. Referring to worksheet 04.05, tenderers are required to include the names and addresses of freelancers who constitute a one-person company in this sheet. All that is required for one-person companies is completion of names and

No.	Question	Answer
	under points (i), (ii) and (iii) of the referenced section (i.e. document signed by the tenderer stating clearly the identity, roles, activities and responsibilities of subcontractor(s) and specifying the volume/ proportion of work to be undertaken by each subcontractor; a letter of intent; and all documents regarding the exclusion and/ or selection criteria) should not be provided for one-person companies?	addresses in worksheet 04.05.
29	Could you please indicate where we can find the financial ID form to be filled out as requested in your tender (Question 03a-08)?	This is an error and can be ignored; this form is now only provided to successful tenderers, due to the time critical nature of the required supporting documents (bank statements).
30	In relation to section 5.2.4.2 of the technical specification and the observation of the potential applicability of TUPE regulations, would you be able to provide answers to the following questions? 1. Is the incumbent a single supplier providing resources against a specific contract, or is the current arrangement similar to the proposed multi-supplier cascading framework agreement? 2. Could you share the contact details for a relevant person at the incumbent supplier, to enable us to discuss with them the implications of the TUPE regulations (as per section 13.1 of the Guidebook for Tenderers)?	1. The current supplier is the sole supplier for these resources under a framework contract. 2. Matters and information sharing pertaining to TUPE are shared between the outgoing and incoming suppliers after contracts have been awarded and the Agency will take no part in this process. The references to TUPE in the technical specifications document were intended to bring this legislation to the attention of tenderers. We advise you to seek the opinion of your legal advisers in the first instance with regard to applicability of TUPE. However, should you decide you require any specific information from the incumbent supplier at this stage please indicate exactly what information is required and we shall contact the incumbent supplier. Any information provided would have to be given to all tenderers by the Agency at the same time in order to ensure equal treatment.
31	Reference in the tender documentation: Technical Specifications for open invitation to tender, Section 7.2. subcontracting and Questions and Answers relating to the tender procedure (Question and answer No.28) 1) In case a freelancer has not established himself/ herself as a one-person company, could you please clarify whether a letter of intent is required? 2) Moreover, should the Tenderers include the names and addresses of freelancers who do not constitute a one-person company in sheet 04.05 List of Subcontractors in	1. A letter of intent is not required for freelancers who have not established themselves as a one-person company. 2. No.

No.	Question	Answer
	Annex 2, Response Questionnaire?	
32	Reference in the tender documentation: Technical Specifications for open invitation to tender, Section 5.2.2. Overview of the Profiles Required In relation to the education requirements for all profiles requested, please confirm that a Bachelor's Degree in Mathematics is considered as a degree in a related field and consequently is sufficient to cover the requirement.	A Bachelor's Degree in Mathematics can be considered a degree in a related field and therefore is sufficient to cover the requirement. Please note that the candidate must still possess the minimum years of professional experience required under each profile.
33	In the technical specifications, section 5.2.2, page 22, EMA writes concerning the profiles required " Full description of each profile can be found later in this document". We haven't seen in the profile description of the technical consultant. Can you clarify ?	The profile description for the Technical Consultant is in section 5.2.3.13 on page 51/96 of the Technical Specifications document.
34	In the technical specifications, section 5.2.2, page 22, EMA writes concerning the profiles required " Full description of each profile can be found later in this document". We haven't seen the skills required for the "Technical Consultant" and "Lead Consultant" in the annex 4 "required skills per profile". Can you clarify ?	The Technical and Lead Consultant profiles would typically be used for very specific short-term requirements. We refer you to sections 5.2.3.12.6. (Lead Consultant) and 5.2.3.12.7 (Technical Consultant) where you will see that the precise requirements for these profiles, which would include skills, would be specified at the time of conclusion of the relevant specific contract. As the skills required may vary widely depending on the particular requirements at the time, it was not possible to specify these in Annex 4 Required Skills per Profile.
35	In the Excel document "Annex 14 - Indicative minimum resource per skill" provided to Tenderers, it seems that the profile of Senior Developer is missing. Could you please provide the minimum skills required for this profile?	We refer you to the answer to Q23 (b) above.
36	Could you please provide indicative data volumes of the ICT systems mentioned in the technical specifications? i.e. of the Agency's administrative and business projects and systems and the EU Telematics Systems and Projects.	Section 4 of the Technical Specifications document gives a high level overview of the Agency's current systems. In order to respond to the Lots in this tender, tenderers do not need the detailed technical information requested, as the purpose of the tender is to provide resources to work on the Agency's systems. In the case of Lot 2, for fixed price and quoted time and means services, detailed technical information will be provided to tenderers when specific contracts are to be placed in the form of specifications which will be issued to the successful tenderers to which framework contracts have been awarded. See page 92, section 17.2.2., for further details of this process.

No.	Question	Answer
37	Could you please provide indicative bug rates of the mentioned Agency's ICT systems?	See the answer to Q36.
38	Please clarify whether any of the mentioned ICT systems are integrated and in these cases, what is the common integration point of these systems/modules.	See the answer to Q36.
39	It is not possible to edit the "company x – Name" in the tab - 03b Section Financial - for security reasons, although you ask to mention the name of the partner in that box. What should we do?	This is an error, the document has been corrected and may be re-downloaded again from our website using the following link: Technical Specifications-Annex 2- Response questionnaire
40	In the "instructions" sheet of the excel file the following has been written: 01b Joint applicants 1 All members of a joint application, including sub-contractors that are not one-man companies, must complete this form. Additional copies of this worksheet may be added as required. Does it mean that also the leader applicant of a group of companies should fill out this form? Further if a company replies alone to the tender, does it have to fill out the form 01b?	No, the lead applicant completes only sheet 01a Identification. No, only form 01a Identification needs to be completed by a single bidder without joint applicants.
41	We refer to Annex 02 – Response Questionnaire, tab 05 Award Criteria Lot 1. We understand that cells L4, L17, L31, L41, L49 and L53 must be left blank given that Tenderer's responses are given in the subsequent questions. Is this correct? If not, please indicate what hyperlinks should be entered there.	If the tenderer has a single document covering all the subsequent questions in a section, then the hyperlink to that document should be entered in L4 and all subsequent boxes relating to that question e.g. hyperlink should be put in cell L4 and also in cells L6, L8, L10, L12 and L14. If there are a number of separate documents covering the subsequent questions, then the individual hyperlinks should be entered in the box against the relevant sub-question and the top cell can be left blank e.g. L4 blank, L6 – individual document hyperlink, L8 – individual document hyperlink and so on through the section.
42	On the same tab, our understanding is that the 2 A4 page limit of the Guidebook for Tenderers (cf. section 6.3.5.5) applies to each sub-question, eg. 05.01.a, 05.05.b etc. Could you please confirm that this is indeed the case?	Your understanding is correct.
43	In order to be able to define our staffing strategy for the contract, we would like to know the profiles of the personnel	The profiles working under the current OLAP contract are as follows:

No.	Question	Answer
	of the incumbent contractor currently working on the OLAP contract (eg. 1 Project Manager, 2 Testing Engineers etc.).	1 Business Analyst 3 Developers 1 Testing Manager 1 Technical Consultant (from March onwards) The above work on a full-time basis. The following profiles are also working under this framework contract but on a part-time basis: 1 Project Manager 2 Technical Consultants
44	Could you please provide clarification regarding the below question? A company X founded in 2010, and therefore not having balance sheets and profit and loss accounts for the past three years, will rely on the capacities of a company Y of the same group. This company Y owns the majority of shares of company X and signs an endorsement letter providing company Y with the necessary resources and capacities for performance of the contract. Company X will reply in its own name, as part of a consortium, to this call for tenders and will provide the necessary documentation related to Company X for the exclusion criteria and related to the combined resources for Companies X and Y for the selection criteria. • Could you please confirm that this is fully compliant with this call for tenders and will therefore be accepted? • Could you please confirm that it is fully compliant to present project references for projects performed by Company Y as part of the selection criteria?	• The financial and economic information required in Section 15 would be required for both Company X and for Company Y as the parent company. A letter of guarantee, including a guarantee of financial as well as human and other resources, would be required from Company Y in support of Company X. Company X may then utilise the combined resources of both companies in its response to the professional and technical capacity part of the ITT. • It is compliant for Company X to present project references performed by Company Y as part of the selection criteria.

No.	Question	Answer
45	In relation to the call for tenders “EMA/2012/13/ICT External Service Providers for Software Applications”, could you please provide clarification regarding the below question? Regarding the evidence to be provided for the professional and technical capacity for lot 2, in particular the contract references requested, we intend to take the following approach. For a long-term project started in 2006 and still on-going provided to a customer by a stable team and organisation involving a mix of fixed-price and time & means activities, but split into several contracts of limited duration without gaps in between, we intend to provide one combined contract reference as proof of our technical capacity covering all those specific contracts and the whole project duration. Could you please confirm that this is acceptable in the scope of this call for tenders? The contract reference described in the question is intended to be one of the three references requested.	This is acceptable.
46	In worksheet 04d of the questionnaire, Tenderer’s skills list, there is no column for the Consultant profiles. Could you please confirm? In addition, the number of tools differs from the number of tools in the file “Technical Specification – Annex 4 - Required Skills per profile”. Could you please confirm?	This is an error, the documents have been corrected and may be re-downloaded again from our website using the following links: Technical Specifications-Annex 2- Response questionnaire Technical specification - Annex 4 - Required skills per profile
47	Paragraph 15 of the technical specifications, point 4, p. 85-86/96, “Evidence that the Tenderer has in the recent past provided resources of the type (See section 5.2.3.) and in the quantities (See section 10.) requested in this ITT. Any evidence that can be independently verified will be accepted. This includes e.g. a Contract Award Notice if this information is clearly mentioned.” a) It is our understanding that the evidence requested	

No.	Question	Answer
	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 16000 person days in total) of resources requested in the technical specifications. Please confirm that our understanding is correct. b) According to the clarifications already provided by EMA, ongoing project references will be accepted as valid references for the selection criteria. Also, projects which have started before 02/2010 but a part of them has been or is being delivered after 02/2010 will also be considered as valid. It is our understanding that in order to demonstrate the compliance of the project references with the requirements of the tender specifications, the total volume of the projects should be taken into account and in the case of an ongoing project, the estimated man-days until the end of the contract should be provided. Please confirm that our understanding is correct. 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 professional IT staff were not supplied under Time & Means basis (but on a fixed Price or Quoted Time & Means basis). Please confirm that our understanding is correct or else clarify. d) 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	a) Your understanding is not entirely correct. The requirement for evidence allows the Agency to verify independently that the contract has been fulfilled. Acceptable forms of evidence include a contract award notice (provided that it includes details of the total number of person-days delivered across all profiles during the contract), a copy of the contract itself, a contact person at the customer, 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, or a press release. b) Your understanding is correct. c) For Lot 1, we would expect to see contract references for which time and materials resources were supplied. For Lot 2, we would expect to see contract references for which resources had been supplied on a fixed price or quoted time and means basis.

No.	Question	Answer
	to verify the information provided will be considered as acceptable and “verifiable” evidence of the implementation of the reference-contracts. Please confirm that our understanding is correct.	
48	It seems that there are some inconsistencies between the sheet “04d Tenderer's Skills List” of the Response Questionnaire and the “Annex 4 – Required Skills per Profile.xsl”. For example the following mandatory skills which are included in Annex 4 are not included in “04d Tenderer's Skills List” which must be filled by Tenderers: ☐ 3 - Object-oriented Analysis and design (OOA&D) ☐ 130 - "Oracle 10g, 11g Data Warehouse Features (Partitioning, Analytical Functions, Indexing, SQL Tuning, Compression, Partition Pruning, materialized Views, Query Rewrite)" ☐ 131 - Data Model Design (Star Schema Design, FN3 Design) ☐ 132 - Oracle Data integrator Could you please provide us with a corrected version of “04d Tenderer's Skills List”?	See the answer to Q46.
49	The technical specifications dictate that the successful tenderer may be required to become a potential transferee for the purposes of TUPE with regards to the ten resources currently employed by the incumbent supplier at the premises of the Agency. Given this fact and in order to be possible for Tenderers to estimate and appropriately take into account the financial implications of such a transfer for the preparation of their financial offers, we would like to receive the following information with regards to the human resources that could be subject of a potential transfer	The profiles are listed under Q43. As indicated in the technical specifications there are six full-time employees. For the remaining information requested, whilst incumbent contractors may provide requisite information earlier than the statutory minimum of 14 days before transfer under the TUPE Regulations, there is no obligation to do so. Although the Agency has contacted the incumbent and requested such information the incumbent contractor has not provided it.

No.	Question	Answer
	under the TUPE: ☐ profile; ☐ length of service; ☐ salary (either stakeholder or final salary), benefits and type of pension; ☐ type of contract (permanent employee, freelance contract) Alternatively, could you please provide us with any relevant information that could make all Tenderers capable to assess the financial expectations of the ten resources in subject and to form their financial offers accordingly?	
50	Invitation Letter, page 2, numbered item 5 It is mentioned that the 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)?	The covering letter must be signed by an authorised representative, together with those documents where a signature is specifically requested. It is not necessary to sign every single page of the offer.
51	Regarding CVs, does experience in SQL server count towards the required experience in the application domain (OLAP)?	The Agency has an Oracle based environment and as SQL Server differs in functionality, syntax, organisation and features from Oracle, this experience would not count towards the required experience in the application domain (OLAP).
51	Could you please explain what has been modified in the updated versions of Annex 2 and Annex 4? Further in relation to the updated annex 4, should not annex 14 also be updated?	Lines 129 to 138, which relate to Oracle Skills, have been aligned. Annex 14 has also been corrected and may be re-downloaded again from our website using the following link: Technical specification - Annex 14 - Indicative minimum resources per skill
52	In your reply to question 42 you have confirmed that the two-page limit defined in the Guidebook applies to this call for tenders. The Guidebook in section 6.3.5.3 states: "which should not exceed two pages of A4 paper per question" (bold is ours)	

No.	Question	Answer
	It is our understanding that this two-page limit is not a strict limit, but a general guidance, which should be applied where possible. This understanding is supported by the fact that there are several questions for which it is impossible to provide an answer within the strict two-page limit. Examples of such questions are: • 06b Project Management Methodology • 06b Vision Template • 06b Software Development Plan Template • 06b Architecture Template • 06b Test Strategy Template • 06b Deployment Guide Template Regarding the 06b Project Management Methodology, you have clarified in your answer to question 10b, that the tenderer is requested to provide a description of the approach, the project methodology and the templates they use. Such a description is not possible to be provided within two pages. Additionally, the enforcement of a strict two-page limit on these questions would not allow the production of high quality replies due to extreme shortening of texts. Consequently, this would result in replies which would not allow a comparable evaluation. Therefore, (a) could you please confirm our understanding that the two pages is not a strictly imposed limitation applicable to all calls for tenders? (b) If not, could you please consider on lifting this constraint for the current invitation to tender due to the special characteristics of the requirements, the specific questions included in the questionnaire and the information provided in the Q&As?	(a) Your understanding is correct; this limit is not a strict limit, but a general guidance, which should be applied where possible. (b) Please see the answer above
53	Technical Specifications, Section 5.2.3.6.6. General characteristics, page 36-37: "For ETL Developer Only:... For BI developer only" Questions	

No.	Question	Answer
	a) We understand that two (2) CVs for the Developer profile, one (1) CV for the “ETL Developer” profile and one (1) CV for the “BI developer” profile should be provided. Please confirm. b) The general characteristics specific to the BI developer are unclear, could you please clarify?	a) Please refer to page 24, where it clearly states that you must submit two CVs per profile described in section 5.2.3. b) With the exception of one ‘typo’ (for underline read underlying), we believe the general characteristics are clear.
54	Technical Specifications, Section 5.2.3.3.4 Software Data architect, page 29: “Five years of programming experience in the programming technologies currently used in the Agency” Questions a) Our understanding is that the programming technologies currently used in the Agency are the technologies specified in Annex 4 - Required skills per profile, for every profile. Please confirm our understanding. b) The same question as above apply also to the following profiles: - 5.2.3.6. Developer, page 36; - 5.2.3.7 Senior Developer, page 38; - 5.2.3.8. Testing Manager, page 41; - 5.2.3.9. Testing engineer, page 43; - 5.2.3.10. Trainer, page 45; - 5.2.3.14. Project Officer, page 52;	a) Your understanding is correct, each profile need only have the skills indicated by 'Yes' in in Annex 4 - Required skills per profile, if they have some of the others then that is good but not essential. b) Your understanding is correct, each profile need only have the skills indicated by 'Yes' in in Annex 4 - Required skills per profile, if they have some of the others then that is good but not essential.
55	Question In the updated Excel we see that the “<i>Oracle Business Intelligence Enterprise Edition</i>” has been included twice in the worksheet, and each time is required in different profiles. Could you please let us know which of the two lines should we keep?	This is an error, we will amend, and republish Annexes 4 & 14, along with the Response Questionnaire, all will have the entry currently in line 48 removed and the entry currently in line 133 corrected.

No.	Question	Answer																																
	Technical specification - Annex 4 - Required skills per profile-updated, “ <table><tr><td>Business Analysts</td><td>Software Data Architects</td><td>System Analysts</td><td>Developers ?</td><td>Testing Managers</td><td>Testing Engineers</td><td>Trainees ?</td></tr><tr><td>Ref.</td><td>Description</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>48</td><td>Oracle Business Intelligence Enterprise Edition</td><td>Yes</td><td>Yes</td><td>Yes</td><td>Yes</td><td>Yes</td></tr><tr><td>133</td><td>Oracle Business Intelligence Enterprise Edition</td><td>Yes</td><td>Yes</td><td>Yes</td><td></td><td></td></tr></table>”	Business Analysts	Software Data Architects	System Analysts	Developers ?	Testing Managers	Testing Engineers	Trainees ?	Ref.	Description						48	Oracle Business Intelligence Enterprise Edition	Yes	Yes	Yes	Yes	Yes	133	Oracle Business Intelligence Enterprise Edition	Yes	Yes	Yes							
Business Analysts	Software Data Architects	System Analysts	Developers ?	Testing Managers	Testing Engineers	Trainees ?																												
Ref.	Description																																	
48	Oracle Business Intelligence Enterprise Edition	Yes	Yes	Yes	Yes	Yes																												
133	Oracle Business Intelligence Enterprise Edition	Yes	Yes	Yes																														
56	In relation to the Q&A, regarding question 46 about the missing Consultant profiles in the Skills List, the new questionnaire and Annex 14 do not include these 2 profiles (Technical and Lead Consultants). Could you please confirm?	The revised questionnaire and Annex 14 do not contain columns for the Technical and Lead Consultants. The reason is explained in the answer to Q34 above.																																
57	We want to present the CVs of our account management team, composed of more than two members. Please advise how to use the Annex 02 excel file to insert additional hyperlinks under the tab “04a Prof & Tech Lot 1”.	We indicated in cell F33 that you should add additional lines to the Excel sheet. However, this is not possible in the currently published version. We suggest therefore that the additional information is put into a separate sheet, clearly headed with the worksheet title (e.g. 04a Prof and Tech Lot 1), and the question number (e.g. 04.03.02) to which the information relates.																																
58	Technical specification - Annex 14 - Indicative minimum resources per skill, “ <table><tr><th colspan="8">Skills Per Profile</th></tr><tr><th>Description</th><th>PM</th><th>BA</th><th>DA</th><th>SA</th><th>Dev</th><th>TM</th><th>TE</th></tr><tr><td>Oracle Business Intelligence Enterprise Edition</td><td>2</td><td>6</td><td>10</td><td>10</td><td>40</td><td>9</td><td>10</td></tr><tr><td>Oracle Business Intelligence Enterprise Edition</td><td></td><td></td><td>10</td><td></td><td>40</td><td></td><td></td></tr></table> Question In the updated Excel we see that the “Oracle Business Intelligence Enterprise Edition” has been included twice in the worksheet, and each time there are different requirements per	Skills Per Profile								Description	PM	BA	DA	SA	Dev	TM	TE	Oracle Business Intelligence Enterprise Edition	2	6	10	10	40	9	10	Oracle Business Intelligence Enterprise Edition			10		40			This was corrected in the version published on 15/02/2012. The corrected Skill is now on Line 131.
Skills Per Profile																																		
Description	PM	BA	DA	SA	Dev	TM	TE																											
Oracle Business Intelligence Enterprise Edition	2	6	10	10	40	9	10																											
Oracle Business Intelligence Enterprise Edition			10		40																													

No.	Question	Answer
	profile. Which of the two lines is the correct one?	
59	Technical specification – 1.1 Glossary: “Tenderers should be aware that the incumbent suppliers of the services which are the subject of Lot 1 currently employ ten resources in situ at the Agency's premises which includes six of the supplier's employees, the rest being consultants (who are either freelance or contracted via agencies), all of who are carrying out exclusive functions for the Agency, all on a fulltime basis. Any change of service provider may, therefore, be subject to the Transfer of Undertakings (Protection of Employment) Regulations 2006 (sometimes known as "TUPE") which apply in the UK. The attention of tenderers is therefore specifically drawn to these Regulations, as a successful tender may result in them becoming a potential transferee for the purposes of TUPE, and they are recommended to seek legal advice as to the extent to which TUPE will apply to the proposed contract and to reflect the legal and financial implications of such a transfer in their tender if they so wish.” Questions a) Please confirm that TUPE applies only to the six supplier's employees only. b) Please provide details of their current remuneration (on a daily or yearly basis). c) Please provide details of fringe benefits (pension, health insurance, etc.) that they enjoy under their current contracts and related costs. d) Please provide details of the nature of the said employment contracts; specifically whether they are employment contracts of indefinite periods and/or employment contracts of fixed terms and/or other. In the case of possible employment contracts of fixed terms, please indicate the duration of these current contracts and the possible obligation of renewal upon expiration and any consequences of non-renewal.	a) This is our understanding. b) See the answer to Q49. c) See the answer to Q49. d) See the answer to Q49.
60	Technical specifications – 14. Exclusion criteria, 15. Selection criteria: financial and economic capacity: Question If bidding for both lots and for the sake of minimising paper	Yes, this is acceptable.

No.	Question	Answer
	copies, could we submit the evidence required in the above two sections only once?	
61	Could you please provide us with the following document: OWB Naming Convention EMA/253293/2009 documentum\Docbases\EDMS\Information Technology\Development\Standards, which is mentioned in Appendix 6, page 11 of the tender specifications?	In order to respond to the Lots in this tender, tenderers do not need the document requested, as the purpose of the tender is to provide resources to work on the Agency's systems. In the case of Lot 2, for fixed price and quoted time and means services, detailed technical information will be provided to tenderers when specific contracts are to be placed in the form of specifications which will be issued to the successful tenderers to which framework contracts have been awarded and any relevant documentation will be annexed to those specifications. See page 92, section 17.2.2., for further details of this process.

Document History

Version	Who	When	What
2.0.1.56	RC	19/02/2013	Sent for Publication