EMA/158242/2014

Questions and answers relating to open tender procedure – EMA/2014/01/PH Monitoring of Scientific and Medical Literature and the Entry of Relevant Information into EudraVigilance

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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

Questions and answers

No.	Question	Answer
1	Please send us the documentation you wish to have completed in WORD format so that we can enter the data.	The documents that need to be completed are PDF forms and can be completed on the computer.
2	Do we need to complete the Draft Contract and the Service Level Agreement or is it just for information?	The Draft Contract and Service Level Agreement are for information.
3	We were wondering whether government agencies such as EMA are not subject to the usual copyright rules where they have an obligation mandated in law to provide a service for the public good. In this case, publishers may have to provide the EMA with copies of articles free of charge. Do you happen to know if such an arrangement exists?	EMA is not exempt from the provisions of copyright and as described in the technical specifications it is the responsibility of the contractor to ensure that “terms and conditions asserted by copyright holder“ with regard to their work is fully satisfied. (see also: Section 11 of the technical specifications, page 25).
4	Annex IX: Point B-C summary and Point D summary, column A is labeled as “Substance”. Please clarify that you expect to see the different substances searched under one substance Group. e.g Paracetamol, Acetylcysteine, Ascorbic acid, Caffeine e.t.c for the Group of Paracetamol.	EMA expects to see the results for each substance variant/substance combination listed for a specific substance group as per Annex VII-A reflected in column A of Annex IX. With reference to the example of the substance group “Paracetamol” the results for the literature search should also contain the substance combination “Paracetamol, Acetylcysteine, Ascorbic acid, Caffeine”.
5	Annex VII- A: Should the Tendered perform a quality check of the info provided in the list? E.G on page 5 of 69 it is reported HYDROCHLOROTHIAZIDE, RISEDRONATE MONOSODIUM HEMI-PENTAHYDRATE.	EMA does not expect potential tenderers to perform a quality check of the provided list of substance groups. The substance variants/substance combinations for each substance group have been selected based on the submissions of information on medicinal products by marketing authorisation holders in accordance with Article 57(2), second subparagraph of Regulation (EC) 726/2004.
6	If we license an ESTRI-compliant gateway do we need to bear the licensing costs and pass these on to the EMA?	EMA expects the contractor to provide the technical infrastructure to comply with the requirements set out in the

No.	Question	Answer
		technical specifications. Alternatively, EVWEB can be used by the contractor.
7	Does the EMA have a preferred of existing supplier of an ESTRI-compliant gateway?	EMA does not have a preferred gateway provider. However, the gateway needs to be compliant with the ESTRI standards and tested as regards full interoperability with the EudraVigilance Gateway.
8	If we choose to use EVWeb instead of an ESTRI-compliant gateway, are there any costs associated with being registered to use EVWeb?	EMA allows the use of EVWEB free of charge by the contractor.
9	Would the EMA consider it acceptable if a 3rd-party intermediary was used to deliver the data via an ESTRI-compliant gateway? For example a company that has a licensed gateway and provides this as a service.	The use of a third party service provider in support of the technical gateway infrastructure is acceptable to EMA. If a third party service provider is used, the details of that provider must be disclosed in the tender as a subcontractor (see section 4.2 of the technical specifications).
10	If we deliver full-text articles – for example as PDFs – do these need to be delivered via the gateway also?	The tender specifications refer to a stepwise implementation approach i.e. using the current ICH E2B(R2) ICSR format requires the copies of the literature articles to be submitted separately to the EudraVigilance literature repository, a process which is not based on a gateway submission. However, following implementation of the new ICH E2B(R3) format, copies of literature articles are to be submitted as attachment jointly with the ICSR via the gateway.
11	Does daily screening imply daily searches of the databases for each product?	EMA expects daily searches of the proposed literature reference databases for each substance group (including all substance variants and substance combinations) that will be subject to the specific contract.
12	If duplicates are detected in EudraVigilance whilst entering ICSRs, how should these be handled? Do they need to be flagged, still entered or not entered?	The ICSRs should be entered in EudraVigilance with a cross reference to the world-wide unique case identifiers of the

No.	Question	Answer
		duplicated reports identified in EudraVigilance. The information should be provided in the ICSR data field “Other case identifiers in previous transmissions”. This will allow EMA to create master reports associated with the duplicate reports as part of the EudraVigilance data quality management process.
13	Does the tracking/reporting component need to be on-demand and interactive from the outset? Or is an initial phase where static daily reports are provided acceptable? If static daily reports are acceptable in the initial phase, how long can this phase be?	EMA expects the provision of daily reports in line with the requirements set out in the technical specifications. Static but complete and daily updated tracking reports are acceptable.
14	The Technical Specification determines that no variants are permitted. Does this explicitly apply also for the specified intellectual property rights? May we participate in the tender with an alternative proposal for dealing with copyrights?	No variants are permitted for any part of the tender including intellectual property rights. Alternative proposals for dealing with copyrights would need to be analysed in-depth and that could cause severe delays to the conclusion of the tender. Given the need to match with legal deadlines, the Agency is not in a position to accept alternative proposals for dealing with copyrights.
15	What are the volumes of re-use-re-sharing individual articles? i.e. across other MAH, EC, NCA?	This aspect is outlined in chapter 3.1., table point II.c of the Tender Specifications and relates to the need to support the pharmacovigilance obligations of the various stakeholders as set out in Directive 2001/83/EC and Regulation (EC) 726/2004. The actual volume will depend on the number of substance groups for which the literature monitoring services are going to be provided.
16	Where and who are the locations that could be using the literature?	This aspect is outlined in chapter 3.1., table point II.c. There are the persons and entities working for the European Medicines Agency or cooperating with it, including contractors,

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		subcontractors whether legal or natural persons, the European Commission and currently 32 National Competent Authorities in EEA Member States. The European Medicines Agency is located in Canary Wharf, London E14, UK. The location of the 32 National Competent Authorities can be found as follows: http://www.hma.eu/66.html. Further information on the location of the European Commission's offices can be found as follows: http://ec.europa.eu/about/ds_en.htm.
17	We wish to seek clarification on a Selection Criteria around Financial and Economic Capacity. Wherein "the annual turnover of the tenderer must be of a minimum value of EUR 4 million for each of the last three financial years". Is this mandatory and can a company in business for little over a year now with decent organisational experience backed by a team of highly experienced individuals in the required domain, strong financial turnover and financial backing participate in this tender?	It is required that "the annual turnover of the tenderer must be of a minimum value of EUR 4 million for each of the last three financial years" as described in Section 13 of the Technical Specifications, page 25. Please note however that an entity is permitted to rely on the capacities of other entities for both economic and financial capacity and for technical and professional capacity, regardless of the legal nature of the links which it has with them, but in that case it must prove to the contracting authority that it will have the resources necessary for performance of the contract, for example by producing an undertaking on the part of those entities to place those resources at its disposal.
18	We wanted to confirm scope of EU languages and non EU languages for the purposes of translations for the literature tender – would this be possible?	The scope of languages for which a translation of literature articles into English might be required will depend on the journal/reference database(s) and the journals covered for the purpose and scope of the supply of daily, accurate and exhaustive scientific and medical literature as outlined under

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		chapter 3, table item no. II.
19	Does EMA hold any copyright licences, for example CLA (UK) or CCC (US)?	The Agency is licensed with CLA, for more information about our current Public Administration license please see: https://www.cla.co.uk/licences/licences_available/public_administration or the explanatory leaflet for license coordinators https://www.cla.co.uk/data/pdfs/public_admin/pa_explanatory_leaflet.pdf
20	Translations of literature articles are required from source language to English, for which we would plan on using a third party translation service. Would this service provider to us need to be represented as a subcontractor in the proposal, or can they be referenced as a service provider?	Such third party would need to be represented as a subcontractor.
21	For the pilot phase, please can the EMA advise the expected volume of substances to be covered? Will this be dependent on the size of the award, or it will be similar regardless of size? For example, if the award is for 100 drugs will the pilot also be for 100 drugs or for 10 drugs? This will have a significant impact on determining the cost involved in running the pilot.	The pilot has to be seen in preparation of the launch of the fully operational literature monitoring services to be provided by the European Medicines Agency in line with the requirements set out in the tender specifications. The scope of the pilot should cover the substance groups 1 to 20 (including related substances) as outlined in the Technical Specifications - Annex VII-A Substances and related substance groups and the herbal substance groups 1 to 50 (including related substances) as outlined in the Technical Specifications – Annex VII-B Herbal substances.
22	I am having difficulty entering data into the grey (mandatory) section of the form “Technical Specifications – Annex II”.	Information should be entered in the blue boxes (grey areas are for clarification only). If unable to see the blue boxes, please click on “Highlight Existing Fields”, top right corner on the form.
23	Regarding Section 13, Evidence required, No 3, our company has an overall turnover statement which covers all activities including the works, supplies and	Section 13, point 3 states the following: “a statement of overall turnover and turnover concerning the works, supplies or

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	services specified in this particular contract/tender, in the last three years. Is there any additional statement required?	services covered by the contract during the last three financial years". It is the responsibility of the tenderer to ensure that the statement sufficiently addresses the requested information and to provide any additional documentation if deemed necessary to comply with the requirements of point 3.
24	How many ad hoc searches do the EMA anticipate requiring each year?	The number of ad-hoc screenings as outlined in chapter "3.1. Description of Services - Tasks, Deliverables, Timelines and Audit", table item number III.d of the Technical Specifications, will depend on the need for further information in support of signal evaluations and/or benefit risk assessments of medicinal products or a class of medicinal products that need to be carried out by the EMA and the Pharmacovigilance Risk Assessment Committee. For further information please refer to the "PRAC: Agendas, minutes and highlights" as published at the EMA website http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000353.jsp&mid=WC0b01ac05805a21cf. Note: not all signal evaluations or benefit risk assessments may require ad-hoc screening of the scientific and medical literature and this will be decided on a case by case basis.
25	Without knowing how many results an ad hoc search may find, we feel in fairness to both the EMA and as a potential contractor to provide an hourly rate for the literature searching, and a unit cost per record for any full text and translations required. Would the EMA be satisfied with this pricing approach? Any ad hoc searches would then be priced based on these unit costs, rather than trying to predict an overall cost based on unknown quantities of full	In accordance with the Technical Specifications - Annex I Costing sheet, point C.3, tenderers are expected to provide a unit price for the ad hoc screening of scientific and medical literature in the context of a signal evaluation and/or benefit risk assessment of a medicinal product or class of medicinal products. The scenario for the evaluation of the price of Annex I

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	text or translations required.	Costing sheet provides ad-hoc screening examples for years 1 to 6 to assist in the determination of the expected workload and the calculation of a unit price. In accordance with the Technical Specifications - Annex I Costing sheet, points C.1 and C.2, the unit price for translations of literature articles refers to the cost per word.
26	For the ad hoc screening requests, is the expectation that there would be no date parameters applied to the databases being searched? E.g. if one was to search Medline, would the search be conducted across the entire database or for a pre-specified date range? Please could you answer this in the context of the general requirement for ad hoc screenings as outlined in the Technical Specifications (Chapter 3.1 table item III.d) and also for the scenario ad hoc screenings as outlined in Annex I.	The ad-hoc screenings as referred to in table item number III.d of the Technical Specifications as well as the scenario for the evaluation of the price of Annex I Costing sheet, ad-hoc screening years 1 to 6 are not restricted to a specific time frame and should be exhaustive in support of the signal evaluation or the overall benefit risk assessment to be performed.
27	Under Chapter 4, Participation in the tender (page 21 of the Technical Specifications), section 4.2 (ii) the EMA asks for a letter of intent from each subcontractor. In Chapter 13, Selection criteria (starting on page 25 of the Technical Specifications), the section under Evidence Required, point 4 (on page 26) the EMA asks that if the tenderer relies on other entities, a written undertaking on the part of those entities is required. Is this a different requirement from the letter of intent requested in section 4.2 (ii)? If so, can the EMA please stipulate what different or additional information is required?	In accordance with chapter “4.2. Subcontracting” of the Technical Specifications the following needs to be provided with the tender submission if the tenderer envisages subcontracting any part of the contract: (i) A document signed by the tenderer stating clearly the identity, roles, activities and responsibilities of subcontractor(s) and specifying the volume/proportion for each subcontractor. (ii) A letter of intent by each subcontractor stating its unambiguous undertaking to collaborate with the tenderer if it wins the contract and the extent of the resources that it will put at the tenderer’s disposal for the performance of the contract. (iii) If requested under points 12, 13 and 14 any documents regarding the exclusion and/or selection criteria for any

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		subcontractors. If such documents are not provided, the Agency shall assume that the tenderer does not intend subcontracting. Chapter 13 of the Tender Specifications refers to the selection criteria in relation to the financial and economic capacity of the tenderer. The evidence required is to be based on the documents or information listed below as evidence of compliance with the economic and financial capacity. If subcontracting is envisaged, documentation must be provided in relation to any subcontractors. If the tenderer is a company and is otherwise required under the law of the State in which it is established to publish its accounts, the following information is requested: 1. appropriate statements from banks or, where appropriate, evidence of relevant professional risk indemnity insurance; 2. financial statement for the last three years for which accounts have been closed; 3. a statement of overall turnover and turnover concerning the works, supplies or services covered by the contract during the last three financial years; 4. if the tenderer relies on the capacities of other entities (e.g. a parent company), a written undertaking on the part of those entities confirming that they will place the resources necessary for performance of the contract at the disposal of the tenderer for the period of the contract. In such case the Agency may require that the successful tenderer(s) and such entities are

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		jointly liable for the execution of the contract. The Agency may waive the obligation of a tenderer to submit the documentary evidence referred to above in points 1, 2 and 3 if such evidence has been submitted to it for the purposes of another procurement procedure and if it still complies with the requirements of the Agency. If, for some exceptional reason which the contracting authority considers justified, the tenderer is unable to provide the documentation mentioned in points 1, 2 and 3, it may prove its economic and financial capacity by any other means which the contracting authority considers appropriate.
28	In the “Scenario” table of the “Technical Specifications - Annex I Costing Sheet “(ref. page 4-6), the fields for total cost of yearly activities (e.g. A, B, C, D, E and F) are non-editable (i.e. without blue box). Please confirm how to fill these sections.	The “evaluation of price” table for the scenario of the “Technical Specifications - Annex I Costing Sheet “(ref. page 4-6) is for EMA use only for the purpose of comparing the tenderers’ prices. The tenderers should complete the blue boxes on page 2 of the costing sheet (see also question 22 of the Questions and Answer document).
29	Regarding Section13, point 3, I would appreciate if you may elaborate on the following: we may provide the last three years Group Financial Statements under IFRS, full notes or selective data (Balance sheet & Income statement). Is this financial info adequate for your requests or do you need additional data?	Point 3 of the evidence required under Section 13 “Selection criteria: financial and economic capacity” of the Technical Specifications, states the following: “a statement of overall turnover and turnover concerning the works, supplies or services covered by the contract during the last three financial years”. It is the responsibility of the tenderer to ensure that the statement sufficiently addresses the requested information and to provide any additional documentation if deemed necessary

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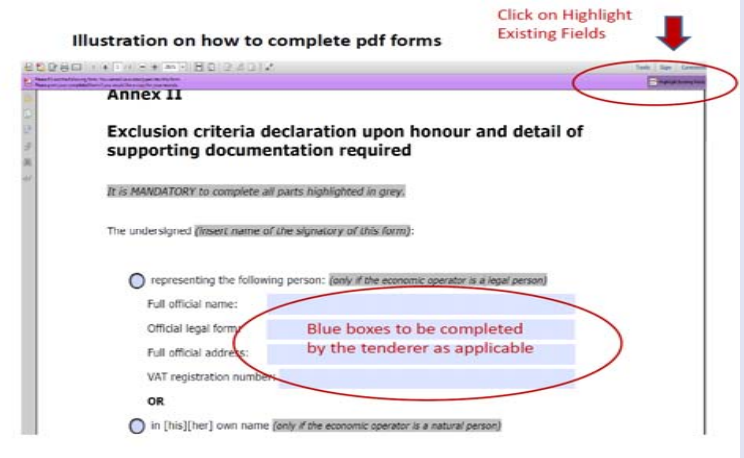
		to comply with the requirements of point 3.
30	In Chapter 3, III.d (page 11 of the Technical Specifications) the EMA has outlined the need for ad hoc literature searches. Does the EMA expect the results of these ad hoc searches to be de-duplicated across the various databases the contractor will use?	The results of the ad hoc screening of scientific and medical literature in the context of a signal evaluation and/or benefit risk assessment of a medicinal product or a class of medicinal products as referred to under table item number III.d of chapter 3 of the Technical Specifications should be de-duplicated across the various databases the contractor will use.
31	It says on the Annex II form that "It is mandatory to complete all parts in grey…." Could you further instruct please?	Please refer to the illustration below for further instructions as to how to complete the relevant sections of Annex II of the Technical Specifications. This is for illustration purposes only and it is the responsibility of the tenderer to complete the required forms correctly. 
32	When I have completed this form (Annex II), I will print it out and sign it.	Tenderers should submit the scanned version of the completed

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	Should the version enclosed on the CD ROM that we will submit with the tender be: a) A scan of the original signed version, or, b) An unsigned original PDF?	and signed form in separate binders or folders which must be clearly labeled. It should also be submitted on a separate CD from the rest of the tender.
33	In the table on Tasks/Deliverables in section 3.1, under part IV.d, it is stated that the Agency requires a daily user-friendly listing of all ICSRs that have been generated as a result of the literature screening activities. Information required in this list includes worldwide unique case identification number, as well as other information. A clarification is required as to the time lag between the ICSRs having been generated from the literature screening activities and the sharing of the daily listing with the Agency. For example, for any ICSRs identified on a Monday, does the Agency expect these ICSRs to be included in the line listing shared with them on the same day or any time after that? If this is not to be shared on the same day, can this timeline be specified so that this can be implemented in the processes to be put in place?	Chapter 3, table item no. IV.a of the Technical Specifications defines the timelines for the processing of individual cases related to suspected adverse reactions identified as a result of the scientific and medical literature screening activities. Table item IV.d further defines the requirements for the daily, user-friendly listing in electronic format of all ICSRs that have been generated as a result of the literature screening activities for publication at the EudraVigilance restricted website. The exact point of time of publication of the list each day will be defined by EMA once the services will be initiated. The first daily list to be published should include all new ICSRs (or ICSRs with follow-up information) that were entered in EudraVigilance within 24 hours from that point of time onwards. Subsequently the published lists should then include all new ICSRs (or ICSRs with follow-up information) entered within 24 hours from the time of last publication of the previous list.
34	Regarding Section 14 it is required to provide a list of the principal services provided in the last three years, with the sums, dates….. Does the word 'sums' refer to financial sums or something else. Please clarify.	The sum referred to in the second bullet point under "Evidence required" as outlined in Chapter 14. "Selection criteria: technical and professional capacity" refers to the contract value of the principal services provided in the past three years.
35	What might be a typical inquiry to the "service desk" (3.1.VIIb.ii) from marketing authorisation holders and national Competent Authorities in EEA Member States? Would questions come in languages other than English?	A question from a marketing authorisation holder to the service desk could be the following: "An article regarding a serious adverse reaction for a substance

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		which is subject to the literature monitoring services operated by the EMA has been published in an international scientific journal. However, this article is not listed as part of the electronic literature screening outputs published by EMA (as referred to in chapter 3 of the Technical Specifications, table item no III.c). Please can you explain why this article was not included?" The official working language for the service desk is English. If in exceptional cases a question is received in another official EU language, the tenderer should have the facility to provide headline answers in the language of the question (technical background documents can remain in English).
36	For the follow-up with authors (3.V.a) in the case of serious adverse events, can this due diligence be performed via written communication?	The follow-up of individual cases related to suspected adverse reactions identified as a result of the scientific and medical literature screening can be performed via written procedure as part of the process that needs to be established in line with the requirements outlined in table item no. V of chapter 3 of the Technical Specifications.
37	How many entries presently exist in the "defined list of active substances used in medicinal products" (2)? How frequently will this list be updated?	As outlined in table item number I.a of chapter 3, the Agency has defined a range of substances including herbal substances, which may be subject to the services described in the tender. A list of substance groups with a ranking in descending order by number of marketing authorisation holders in the EEA is provided in Annex VII-A "Substances" of the Technical Specifications with a total of 300 substance groups. Annex VII-B "Herbal Substances" of the Technical Specifications contains 100 herbal substance groups. Updates to the list are

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		planned annually, i.e. once a year.
38	Do all submitting partners need an existing European presence in order to participate?	Please refer to chapter "4.1. Agreements on public procurement" of the Technical Specifications where the following is stated: "Participation in the Agency's tendering procedures is open on equal terms to all natural and legal persons coming within the scope of the Treaties and to all natural and legal persons in a third country which has a special agreement with Union in the field of public procurement under the conditions laid down in that agreement. The Agency can therefore accept offers from and sign contracts with tenderers from the EU Member States, EEA countries and any other country, which has an international agreement with the Union in the field of public procurement. The tender procedures of the Agency are not, however, open to tenderers from countries which have ratified the Multilateral Agreement on Government Procurement ("GPA"). If the tenderer envisages subcontracting any part of this contract, those requirements do not apply to the subcontracting partners. However, the requirements as outlined in chapter 4.2. "Subcontracting" must be fully adhered with.
39	Are the specific conditions listed for securing the contractor's computers (3.1.VIIIa.iii) requirements or recommendations?	The conditions as stated under table item VIIIa.iii. of chapter 3 of the Technical Specifications are requirements that need to be adhered to as follows: "Any required connection to the EMA network shall be made available by means of a virtual private network or a site to site secure connection, to be defined by the EMA. The costs of this connection on the contractor's site are to

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		be supported by the contractor".
40	What languages are expected, at a minimum, to ensure qualified staff possesses 'multi-language skills' (14) for analysis of non-English content?	As stated in chapter 14. "Selection criteria: technical and professional capacity" of the Technical Specifications the criteria relating to language skills for the contract are: "Experience in dealing with clients of similar scale providing high quality service and expertise in the field of scientific and medical literature monitoring, individual case processing in English and thereby the ability to deal with information from journals in languages other than English, copyright law, digital rights management and enterprise rights management". "Each expert individually must have an excellent level of spoken and written standard UK English and multi-lingual skills to enable processing of information from non-English articles. For non-native speakers, this should be demonstrated by a self-certification in the CV of English proving a level of B2 or at least 3 years of work-experience in an English speaking environment". In addition, please refer also to question 35 regarding language requirements for the service desk.
41	What circumstances would necessitate establishment of an ESTRI gateway (3.1.VIII.a.iv)	As outlined under table item number IV.d of chapter 3 of the Technical Specifications, the following options are acceptable to allow for the entry of individual cases into EudraVigilance and transmission to EEA Member States: - Using the Agency's EVWEB solution - Using a fully tested and validated software solution, which allows for the electronic transmission of ICSRs via the EVPOST function or a local gateway solution that can be connected to

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		the EudraVigilance Gateway. The necessity to establish an ESTRI gateway is therefore based on the decision of the tenderer as to which software solution they want to operate to process the individual cases related to suspected adverse reactions identified as a result of the scientific and medical literature screening activities in line with the requirements set out under table item number IV of chapter 3 of the Technical Specifications. The tenderer may wish to use the EVWEB or EVPOST functions which are integrated with the EudraVigilance Gateway.
42	Does EMA require direct access to the PV production system (3.1.III.c.ii), or would system-generated reports and live demos of the system, via WebEx, suffice?	Access to the PV product system must be provided in the context of the two yearly independent audits as referred to under table item number X. “Independent Audit”. Furthermore the Technical Specifications require the following level of access in line with table item number III.c.ii of chapter 3: Access to a scalable and tested, quality assured system that facilitates record keeping and full audit trail of the activities outlined under table item number III.c.i.
43	Would the ad-hoc screenings (3.1.III.d) include retrospective searches, covering broad timespans?	The ad-hoc screenings as referred to in table item number III.d of chapter 3 of the Technical Specifications are not restricted to a specific time frame and should be exhaustive in support of the signal evaluation or the overall benefit risk assessment to be performed.
44	What experience and background is assumed for entry of ICSRs into EudraVigilance (3.1.IV.c.i)?	In accordance with chapter 14. “Selection criteria: technical and professional capacity” of the Technical Specifications the required experience is: • “Experience in dealing with clients of similar scale

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		providing high quality service and expertise in the field of scientific and medical literature monitoring, individual case processing in English and thereby the ability to deal with information from journals in languages other than English, copyright law, digital rights management and enterprise rights management". • "Each expert individually must have an excellent level of spoken and written standard UK English and multi-lingual skills to enable processing of information from non-English articles. For non-native speakers, this should be demonstrated by a self-certification in the CV of English proving a level of B2 or at least 3 years of work-experience in an English speaking environment". • "Expertise in the medical and pharmaceutical domain". Tenderer must provide detailed CVs of team members (maximum 5) proposed for the assignment, taking into account the minimum expertise requirements as outlined above.
45	Would the independent audit (3.1.X.a) require direct access to internal systems?	Access to the internal system used in support of the requirements outlined in the Tender Specifications must be provided in the context of the two yearly independent audits as referred to under table item number X. "Independent Audit".
46	What is the average turnaround time (3.1.II.e) anticipated for translation of Non-English articles to English?	In accordance with table item II.e of chapter 3 of the Technical Specifications the timelines for the provision of the translation of the literature article will be defined by the Agency at the time of the request.
47	Does EMA subscribe to Mobile Library for document delivery (3.1.II.c)? Does EMA anticipate including content from its own holdings in the PV literature	As regards the supply of scientific and medical literature for the purpose of monitoring of the safety and benefit-risk profile for

No.	Question	Answer
	monitoring stream?	the defined substances, the requirements referred to in chapter 3 of the Technical Specifications must be adhered to. This includes the requirements as outlined under table item II.c as follows: i. Full-text access. ii. Capability to print and to store literature in EudraVigilance and the dedicated literature article repository in one of the following formats: doc; htm; pdf; docx; html. iii. Provision of perpetual access to the saved and stored literature in EudraVigilance and related literature repository in accordance with point vi. table item IIc. EudraVigilance and the related literature repository includes also content from other sources than those related to the literature monitoring services outlined in the Technical Specifications.
48	What is the anticipated volume of drugs/products for literature monitoring, and subsequent ICSRs that would result from the literature review?	The tenderer is expected to determine the anticipated workload and volume based on an all-inclusive total monthly price for tasks and deliverables as per service description items 3.1.II to VIII of the Technical Specifications and in accordance with the substance groups referred to under point B.1 to B.17 of the costing sheet (Technical Specifications – Annex I). This also needs to take into account the journal/reference database(s) to be proposed by the tenderer.
49	Should we understand that rationale for categorising the substance groups (ref. Tech specs – Annex I Costing Sheet; pg. 2) into B.1 (1-10), B.2 (1-20) and so on, is driven by an expectation that the pricing is volume-related?	The categorisation of substance groups as outlined under point B of the costing sheet (Technical Specifications – Annex I) refers to the all-inclusive total monthly price for tasks and deliverables as per service description items 3.1.II to VIII of

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		the Technical Specifications and is volume related according to the number of substance groups referred to under point B.1 to B.17.
50	Is the ramp-up expected to be rapid (i.e. building from substance groups 1-10 and going on to 1-20 and so on)? Or relatively gradual (i.e. 1-50, 1-300 etc.)? Operational resourcing would hinge on this.	The exact number of substance groups to be included in the literature monitoring services will be defined at the time of the signature of each specific contract under the framework contract. In accordance with table item number IX.c of chapter 3 of the Technical Specifications, a two month pilot in preparation of the operational phase is required. The expected volume of substances to be covered as part of this pilot is further clarified in the Q&A document, question number 21. Following successful completion of the pilot, the literature monitoring services have to be delivered for all substance groups as decided and defined in the specific contract in question. No ramp-up or stepwise approach will be acceptable. The Agency cannot say at this stage how many substance groups will be decided to be monitored for the first specific contract.
51	Please confirm how to add on-going costs for systems licensing etc. (ref. Tech specs – section IIIC of 3.1 Description of Services - Tasks, Deliverables, Timelines and Audit; pg.11) in the Costing Sheet?	For tasks and deliverables as per service description items 3.1.II to VIII an all-inclusive total monthly price should be provided as outlined under point B of the costing sheet (Technical Specifications – Annex I). The total set-up cost (including initial set up AND pilot phase as per service description item 3.1.IX) should be provided as outlined under point A of the costing sheet. Unit prices have to be specified for the services as outlined under point C of the costing sheet.

Document history

Version	Who	When	What
0.1	Camelia Manta	04/04/2014	Questions 1-2
0.2	D. Vogl	09/04/2014	Q3
0.3	D. Vogl	10/04/2014	Q4-Q5
0.4	S. Brosch	16/04/2014	Q6-Q13
0.5	S. Brosch	16/04/2014	Q14
0.6	C. Manta	24/04/2014	Q15-Q19
0.7	C. Manta	28/04/2014	Q20
0.8	C. Manta	29/04/2014	Q20 amended
0.9	C. Manta	02/05/2014	Q21
1.0	C. Manta	02/05/2014	Q22-Q23
1.1	C. Manta	05/05/2014	Q24-Q28
1.2	C. Manta	06/05/2014	Q29-Q31
1.3	C. Manta	08/05/2014	Q32-Q51