EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Technical specifications for open invitation to tender

Procurement Procedure "Monitoring of Scientific and Medical Literature and the Entry of Relevant Information into EudraVigilance", reference no. EMA/2014/01/PH

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Annexes

Technical specifications for open invitation to tender

EMA/2014/01/PH
"Monitoring of Scientific and Medical Literature and the Entry of Relevant Information into EudraVigilance"

1. Title of the invitation to tender

This document contains the Technical Specifications for the Open Invitation to tender no. EMA/2014/01/PH, "Monitoring of Scientific and Medical Literature and the Entry of Relevant Information into EudraVigilance".

The contract notice for this open tender has been published in the Official Journal of the European Union S60 on 26 March 2014.

1.1. Executive summary & indicative timetable

Item	Summary
Contracting authority	European Medicines Agency hereinafter referred to as "EMA" or "the Agency".
Purpose	This call for tenders aims to put into place contractual arrangements with a maximum of three economic operators in priority order for the provision of services for the monitoring of scientific and medical literature and the entry of relevant information into EudraVigilance required by Article 27 of Regulation (EC) 726/2004.
Contracts	A maximum of three framework contracts in order of priority is expected to be signed. The framework contracts lay down the legal, financial, technical and administrative provisions governing the relations between the Agency and the contractors during their period of validity. Framework contracts do not constitute orders. Orders are placed through specific contracts. The framework contract will define the types of services and their corresponding price. Based on these costs, specific contracts may be concluded according to the terms and conditions of the framework contract and of the corresponding financial and technical tender of the contractor.
Duration of framework contracts	Four years with two possible extensions of one year each (4 + 1 + 1). Maximum possible duration: six years.
Place of delivery	Services are to be performed at the contractor's premises. Results of the services are to be delivered electronically to EMA at Canary Wharf, London E14, United Kingdom.
Particulars of delivery	Delivery of services must be in conformity with the placed orders. The results of the services are to be stored electronically on the system hosted at the Agency and made available by EMA. Tracking information in relation to the tasks

Item	Summary
	is to be maintained by the contractor and made available to EMA electronically. Written reports are to be made available to EMA electronically. The results of the work are to be presented to EMA on a weekly basis. Contractor staff are expected to attend quarterly project management meetings either at EMA's premises in London or through the organisation of virtual meetings. In addition, contractor staff are expected to attend training sessions at EMA's premises in London where such training cannot be organised online.
Volume (indicative)	The estimated contract volume is for the monitoring of scientific and medical Literature and the entry of relevant information into EudraVigilance for up to a maximum of 300 substance groups and 100 herbal substance groups.
Joint Offers	Permitted.
Variants	Not permitted.
Subcontracting	Information on all subcontractors must be included in the tenderer's response.
Launch of tender in OJEU	26/03/2014 Documents available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000261.jsp&mid=WC0b01ac0580029488
Deadline for request of clarifications from EMA	06/05/2014 Requests to be sent in writing to: litmonitoring@ema.europa.eu
Closing date for receipt of tenders	13/05/2014 Please see the *Invitation to Tender* for detailed delivery instructions.
Opening of tenders	Tuesday, 20/05/2014 14:00 BST at EMA premises in London One person representing the tenderer may attend the opening. Tenderers wishing to send a representative to this meeting should submit a request in writing by e-mail (litmonitoring@ema.europa.eu) no later than 14:00 BST on Monday, 19/05/2014.
Completion of evaluation of tenders	August 2014 (estimated)
Signature of contract	Q4 2014 (estimated)

1.2. Background information

The European Medicines Agency's (EMA) main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

The Agency is responsible for the scientific evaluation of applications for European Union (EU) marketing authorisations for human and veterinary medicines in the centralised procedure.

Most of the EMA's scientific evaluation work is carried out by its scientific committees, which are made up of members from EEA countries, as well as representatives of patient, consumer and healthcare-professional organisations. These committees have various tasks related to the development, assessment and supervision of medicines in the EU.

In total, the Agency works with a network of over 4,500 European experts, which includes the members of the Agency's scientific committees, as well as its working parties and other groups. These experts are made available to the EMA by the medicines regulatory authorities in EEA countries.

Most relevant to the call for tender, the EMA is responsible for coordinating the EU's safety-monitoring or 'pharmacovigilance' system for medicines. It constantly monitors the safety of medicines through the EU network and can take action if information indicates that the benefit-risk balance of a medicine has changed since it was authorised.

The EMA has a Pharmacovigilance Risk Assessment Committee (PRAC), which provides recommendations on the safety of human medicines.

The Agency works through:

- developing guidelines and setting standards;
- providing specific support to pharmacovigilance planning through risk-management plans;
- collecting data and information on the benefits and risks of marketing medicines;
- assessing the data and information collecting and, through the EMA committees giving opinions on marketing authorisations that might include new warning or restrictions to optimise safe and effective use;
- coordinating the monitoring of pharmaceutical companies' compliance with their pharmacovigilance obligations;
- informing the public on the safety of medicines and cooperating with all external parties, in particular through the Agency's interaction with representatives of patients and healthcare professionals;
- contributing to international cooperation activities with authorities outside the EU.

It also supports methodological research, managing the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). This network aims to strengthen the monitoring of authorised medicines in Europe by facilitating the conduct of multicentre, independent, post-authorisation studies focusing on safety and on the balance of benefits and risks.

In the area of data collection, the Agency operates EudraVigilance, the European data-processing network and management system that supports the electronic reporting of Individual Case Safety Reports (ICSRs) related to all medicinal products authorised in the European Economic Area (EEA). EudraVigilance is the database into which ICSRs, identified as part of literature monitoring activities, are entered, alongside ICSRs arising from spontaneous or solicited sources. It provides the Pharmacovigilance Risk Assessment Committee (PRAC), which is responsible for assessing and monitoring safety issues for human medicines, the EMA and medicines regulatory authorities in Member States with a unique tool to continuously monitor the safety profile of medicines and to rapidly initiate actions where necessary to protect public health. The Agency also coordinates the EU rapid-alert and incident-management systems for responses to new safety data.

2. Objectives and context of the invitation to tender

Scientific and medical literature is an important source of information on suspected adverse reaction case reports (also referred to as Individual Case Safety Reports). Currently, for active substances included in more than one medicinal product for human use, literature cases are reported in adverse reaction case reports in a duplicative way by marketing authorisation holders in the EU, based on their obligation to monitor scientific and medical literature as outlined in the Good Pharmacovigilance Practices (GVP) guideline, Module VI "Management and reporting of adverse reactions to medicinal products".

To enhance the efficiency of reporting and to provide a simplification for the industry, the Agency is required by legislation to monitor a defined list of literature for a defined list of active substances used in medicinal products for which there are several marketing authorisations.

The objective of this procurement procedure is to conclude a contract that allows the Agency to implement the provisions set out in Article 27 of Regulation (EC) 726/2004[1] as follows:

1. The Agency shall monitor selected medical literature for reports of suspected adverse reactions to medicinal products containing certain active substances. It shall publish a list of active substances being monitored and the medical literature subject to this monitoring.
2. The Agency shall enter into the EudraVigilance database relevant information from the selected medical literature.
3. The Agency shall, in consultation with the Commission, Member States and interested parties, draw up a detailed guide regarding the monitoring of medical literature and the entry of relevant information into the EudraVigilance database.

More specifically, through this procurement procedure, the Agency aims to outsource the monitoring of scientific and medical literature and the entry of relevant information into EudraVigilance required by Article 27 of Regulation (EC) 726/2004 taking into account that there are highly specialised organisations established that already have the necessary experience and background to support these activities.

3. Subject of the tender

Scientific and medical literature is a significant source of information for the monitoring of the safety profile and of the risk-benefit balance of medicinal products, particularly in relation to the detection of new safety signals or emerging safety issues.

Requirements for the monitoring of scientific and medical literature and the reporting of individual cases of suspected adverse reactions related to medicines are described in detail in the Good Pharmacovigilance Practices (GVP) guideline, Module VI "Management and reporting of adverse reactions to medicinal products", chapter VI.B.1.1.2 "Literature reports" and VI. Appendix 2 "Detailed guidance on the monitoring of medical and scientific literature".

In support of the provisions set out in Article 27 of Regulation (EC) 726/2004, the Agency requires the services as outlined below.

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Consolidated version: 05/06/2013).

3.1. Description of Services - Tasks, Deliverables, Timelines and Audit

The services are to be performed at the contractor's premises. Results of the services are to be delivered electronically to the European Medicines Agency, which is based in Canary Wharf in the Docklands area of London (E14), United Kingdom.

No	Tasks/Deliverables	Timelines
I	**Definition of number of active substances**	
I.a	The Agency has defined a range of substances including herbal substances, which may be subject to the services described in this tender. These substances have been selected on the basis of being active ingredients for medicinal products with high numbers of marketing authorisation holders in the EEA and are presented as follows: i. The substances are grouped by active moiety including e.g. salts, esters as well as combinations, which hereafter are referred to as substance groups. A list of those substance groups with a ranking in descending order by number of marketing authorisation holders in the EEA, starting from number one, is provided in Annex VII-A "Substances". ii. The herbal substances are grouped by genus. A list of those herbal substance groups with a ranking in descending order starting from number one is provided in Annex VII-B "Herbal Substances". The definition of the number of substance groups may be subject to annual updates and changes by the Agency.	The Agency will define at the time of conclusion of each specific contract the number of substances to be included in the services for the time period covered by the specific contract
No	Tasks/Deliverables	Timelines
II	**Supply[2] of scientific and medical literature for the purpose of monitoring of the safety and benefit-risk profile for the defined substances**	
II.a	For the purpose and scope of the supply of daily, accurate and exhaustive scientific and medical literature as outlined under table item no. II.b, the Agency requires: i. The name, type, reference and short description of the journal/reference database(s) as well as the number and the names of the journals covered. **NOTE 1**: For further information refer to GVP module VI App 2.2 "Where to look".	At the time of the offer
II.b	The Agency requires the daily supply of accurate and exhaustive scientific and medical literature as referred to in GVP Module VI (such as articles from periodicals, journals, reviews, reports, conference proceedings, media releases or similar products) for the substances as referred to under table item no. I.a.: i. For the purpose of the identification and retrieval of any new	This must be carried out throughout the duration of the specific

[2] 'Supply' refers to the availability of literature to the contractor for the purpose of carrying out the services.

	information on: – suspected adverse reactions in humans in relation to spontaneous reports, – reports of single or multiple cases of suspected adverse reactions from studies including study results (with the exclusion of suspected adverse reactions from interventional clinical trials) – situations of lack of therapeutic efficacy, use of a medicinal product during pregnancy or breastfeeding as well as off-label use, misuse, abuse, overdose, medication errors and occupational exposure with and without association of a suspected adverse reaction. ii. The scope refers to widely used and daily updated scientific and medical literature reference databases in line with those referred to in the GVP guideline, module VI as well as specialised databases, where deemed necessary (e.g. for herbal substances) based on the substance groups referred to in table item no. I.a. iii. The supplied literature needs to be accurate and exhaustive thereby avoiding the necessity for duplicate screening efforts by marketing authorisation holders. **NOTE 1**: Daily shall refer to calendar days with the exception of weekends. **NOTE 2**: Non-indexed local journals are to be excluded.	contract
II.c	With regard to table item no. II.a, the following necessities are required: 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. below. iv. Capability to cross-reference literature using Document Object Identifiers (DOIs) and where not available open URL or other applicable reference identifiers in accordance with point vi. below. v. De-duplication of full-text articles, where applicable. vi. The Contractor acknowledges and undertakes to ensure that the Agency will be allowed, under the copyright licence that it received with regard to the publications and information referred to in the deliverables and services outlined in this tender specifications, to:	This must be carried out throughout the duration of the specific contract

	(a) use them for its own purposes: – making them available to the staff of the Agency, – making them available to the persons and entities working for the Agency or cooperating with it, including contractors, subcontractors whether legal or natural persons, the European Commission, National Competent Authorities in EEA Member States, – installing, uploading, processing them, – arranging, compiling, combining, retrieving them, – copying, reproducing them in whole or in part and in unlimited number of copies, – refer to, re-use them, either partially or in whole, when making them available to marketing authorisation holders, national Competent Authorities in EEA Member States, the European Commission, healthcare professionals and the public. (b) refer to, reproduce and/or re-use them either partially or in whole when making them available to national Competent Authorities in EEA Member States and the European Commission. **NOTE**: There are currently 32 national Competent Authorities in EEA Member States.	
II.d	The Agency requires: i. Associated copyright costs to be all inclusive in the contract. **NOTE**: Further information on intellectual property rights can be found in section 11 of these technical specifications.	This must be carried out throughout the duration of the specific contract
II.e	The Agency may require upon request: i. A full translation of literature article(s) into English in the context of the safety evaluation and benefit risk assessment of a medicine. **NOTE:** The timelines for the provision of the translation of the literature article will be defined by the Agency at the time of the request.	This must be carried out by the contractor upon request by the Agency
No	Tasks/Deliverables	Timelines
III	**Screening of supplied scientific and medical literature and recording of all screening activities**	
III.a	The Agency requires: i. The daily screening of supplied scientific and medical literature as	This must be carried out throughout the duration

	outlined under table item no. II. ii. In accordance with GVP module VI, the daily review and assessment of the screened scientific and medical literature to identify: – suspected adverse reactions in humans in relation to spontaneous reports, – reports of single or multiple cases of suspected adverse reactions from studies including study results (with the exclusion of suspected adverse reactions from interventional clinical trials), – situations of lack of therapeutic efficacy, use of a medicinal product during pregnancy or breastfeeding as well as off-label use, misuse, abuse, overdose, medication errors and occupational exposure with and without association of a suspected adverse reaction. iii. The screening shall include all suspected serious and non-serious adverse reactions. **NOTE**: Daily shall refer to calendar days with the exception of weekends.	of the specific contract
III.b	The Agency requires search constructions customised by substance groups for the screening of the supplied literature taking into account the following: i. The substance groups search should be exhaustive, where necessary additional search by trade name (in all their variants) has also to be taken into account. The most comprehensive search strategy should be applied by substance covering all substance variations as defined by each substance group. ii. The search should be performed at full text level taking into account that it may be appropriate to limit the search to a major mention (substance or medicinal product indexed to title, abstractor main topic of article) to increase search precision. iii. The search constructions are to be listed for each substance group and made available to EMA for publication at the EudraVigilance restricted website accessible to the Agency, the European Commission, the national Competent Authorities in EEA Member States and marketing authorisation holders in the EEA. The search constructions need to be routinely updated and maintained where necessary to improve search precision and to align with any updates to the substance groups as referred to in table item no. I.a. iv. Results must be reproducible and tracked. **NOTE**: For further information, please refer to GVP module VI. App2.3 “Database Searches”.	This must be carried out throughout the duration of the specific contract
III.c	The Agency requires:	This must be carried out

	i. A scalable and tested, quality assured system that facilitates record keeping and full audit trail of at least the following: – the date and time when searches were performed, – the exact search string for each substance and related substance group, – the literature (including title and author(s)) that was retrieved and reviewed with clear and identifiable literature references incl. a Document Object Identifier (DOI) or where not available a uniform resource locator (URL) or alternative identifier and the specification of the primary source country (or where not available the country of the primary author(s)) – the criteria upon which literature was excluded for Individual Case Safety Reports (ICSR) processing, – the criteria upon which literature was included for further case processing and creation of ICSRs in EudraVigilance including a flag, if the literature refers to serious and/or non-serious adverse reactions, – a flag to highlight literature that refers to situations of lack of therapeutic efficacy, use of a medicinal product during pregnancy or breastfeeding as well as off-label use, misuse, abuse, overdose, medication errors and occupational exposure where not associated with a suspected adverse reaction. ii. This system must be accessible to EMA. iii. Daily electronic outputs in tabular and user-friendly format on the search scripts and search results based on a minimum of the criteria set under point i) which are to be published at the EudraVigilance restricted website for access by the Agency, marketing authorisation holders, national Competent Authorities in EEA Member States and the European Commission.	throughout the duration of the specific contract
III.d	The Agency may request: i. An 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. ii. The result of the ad hoc screening should be summarised as follows: • the date and time when searches where performed, • the exact search string based on the parameters provided by the Agency, • the literature that was retrieved (including title and author(s) with clear and identifiable literature references incl. a Document Object Identifier (DOI) or where not available a uniform resource locator (URL) or alternative identifier. iii. Copies of the literature articles resulting from the ad hoc screening to be provided to the Agency. **NOTE 1**: The substances or substance groups related to these medicinal	This must be carried out by the contractor upon request by the Agency

	products or product classes may not necessarily be part of Annex VII-A & B. **NOTE 2:** The Agency will provide details on the medicinal product(s) and/or product classes to be evaluated, other applicable screening parameters and the timelines for completion of the literature screening at the time of the specific request.	
No	Tasks/Deliverables	Timelines
IV	**Processing of individual cases related to suspected adverse reactions identified as a result of the scientific and medical literature screening activities**	
IV.a	The Agency requires that all valid individual cases for the substance groups as outlined under table item no. I.a, which are subject to the screening, review and assessment of supplied scientific and medical literature referred to under table item no. III and which relate to: i. suspected serious adverse reactions, are entered in EudraVigilance immediately and no later than seven calendar days, ii. non-serious adverse reactions, are entered in EudraVigilance within three calendar weeks. **NOTE 1**: The Agency will announce the date from which the entry of individual cases related to non-serious adverse reactions will need to be initiated by the contractor. **NOTE 2**: Individual cases related to purely non-serious adverse reactions, with a primary-source country outside the EEA are to be excluded. **NOTE 3:** The Agency maintains the right to change the required timelines if considered necessary for performance reasons**.** **NOTE 4:** Day zero for the timelines related to the entry in EudraVigilance is the date on which the contractor becomes aware of a publication containing the minimum information for an ICSR to be reportable. For further information refer to GVP module VI, chapter VI. App2.7 “Day zero”.	This must be carried out throughout the duration of the specific contract
IV.b	The Agency requires: i. The creation of valid ICSRs in accordance with the modalities detailed in GVP module VI (chapters VI.B.2. “Validation of reports”, VI.B.7 “Reporting of ICSRs”, VI.B.8 “Reporting modalities”, VI.C “Operation of the EU Network”, VI, Appendix 3 “Modalities for reporting”) and in line with Articles 27, 28 and 29 of the Commission Implementing Regulation (EU) 520/2012 including a reference to the DOI or if not available, the URL or other unique identifier for the literature. ii. The creation of one case for each individual patient identifiable based on the characteristics provided in GVP module VI.	This must be carried out throughout the duration of the specific contract

	iii. The creation of ICSRs in English. iv. Compliance with personal data protection legislation[3].	
IV.c	The Agency requires: i. The ICSRs identified from the scientific and medical literature screening to be entered in EudraVigilance in line with the timelines set out under table item no. IV.a. ii. The ICSRs to be entered in EudraVigilance to be checked against potential duplicates. iii. The ICSRs entered in EudraVigilance to be transmitted electronically within one calendar day to the national Competent Authority in EEA Member States based on the primary source country or where not available to the country of the primary author of the article; this applies to suspected adverse reactions originating from within the EEA in line with the document "Reporting requirements of ICSRs applicable to marketing authorisation holders during the interim period" (Doc. Ref. EMA/321386/2012, in the latest version) and until further notice by the Agency. iv. The entry of related copies of literature article(s) and where applicable, translations thereof, into the EudraVigilance related literature repository (file name of the literature should match the world-wide unique case identifier assigned to the created individual case as outlined in GVP Module VI chapter VI. App2.10 "Electronic submission of copies of articles published in the scientific and medical literature"); this shall apply until further notice by the Agency. From a technical point of view, the Agency requires the use of the EudraVigilance Gateway for the electronic transmission and entry of identified ICSRs in EudraVigilance and the handling of related copies of literature article(s) based on a phased implementation approach as follows: In a first phase: – Use of the current ICH E2B(R2) format and related terminologies (as referred to in Article 25, paragraph 1a) and 1b) as well as Article 26, paragraphs 1a), 1b) and 1c) of the Commission Implementing Regulation (EU) 520/2012 and – Submission and loading of electronic copies of literature articles into the EudraVigilance literature repository so that the articles are accessible to EMA and all national Competent Authorities in EEA Member States responsible for medicines for human use. Accepted file formats are: doc; htm; pdf; docx; html. In a second phase: – Use of the ISO 27953-2:2011 standard "Health Informatics, Individual	This must be carried out throughout the duration of the specific contract

[3] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data

	case safety reports (ICSRs) in pharmacovigilance — Part 2: Human pharmaceutical reporting requirements for ICSR" as referred to in Article 26, paragraph 2.a) and related terminology as outlined in Article 25, paragraph 1.a) to 1.g) of the Commission Implementing Regulation (EU) 520/2012. The ISO ICSR standard will allow attaching copies of literature articles directly to the applicable ICSRs. **NOTE**: Independent of the system used for the ICSR processing, a registration of the contractor and the case processing staff is required with EudraVigilance. To allow for the entry of individual cases into EudraVigilance and transmission to EEA Member States, the following options are acceptable: – Using the Agency's EVWEB solution or – 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 the EudraVigilance Gateway. Full compliance with the formats and standards as referred to in Article 26 of the Commission Implementing Regulation (EU) 520/2012 needs to be adhered to.	
IV.d	The Agency requires: i. A 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 accessible to the Agency, the European Commission, the national Competent Authorities in EEA Member States and marketing authorisation holders: – the list should contain as a minimum the world-wide unique case identification number, all related substance(s) and substance groups, the reference to the relevant literature (including title and author(s) and the DOI or the URL or an alternative unique reference (if the DOI is not available), the primary source country (or the country of the primary author), a seriousness flag, the receive date and receipt date to allow to determine the initial and follow-up status in line with the principles set out in GVP Module VI and – the list should link with the electronic output for the literature screening activities as outlined under table item no. III.c. **NOTE**: Daily refers to calendar days with the exception of weekends.	This must be carried out throughout the duration of the specific contract
No	**Tasks/Deliverables**	**Timelines**
V	**Follow-up of individual cases related to suspected adverse reactions identified as a result of the scientific and medical literature screening activities**	
V.a	The Agency requires: i. A process to be put in place that ensures that individual cases are followed-up with the publication author(s) as necessary to obtain	This must be carried out throughout the duration

	supplementary detailed information significant for the scientific evaluation of the cases in line with the GVP module VI. ii. One attempt to follow-up with the primary author(s) shall be made for serious adverse reactions. This refers to individual cases, where the outcome is not known, where pre-defined clinical information is missing (in small number of important medical events) or for both and for serious cases where not all of the minimum reporting criteria are available. iii. That any attempt to obtain follow-up information shall be documented for tracking purposes. This tracking information is to be made available to the Agency systematically as part of the routine reporting as outlined under table item no VII. iv. A process to be put in place that allows for the processing of any follow-up information received by the Agency independent of the source. This information should be tracked as outlined under point iii. v. That any new information related to ICSRs is processed within the following timelines: – Within seven calendar days following receipt of new information related to suspected serious adverse reactions. **NOTE 1**: The Agency maintains the right to change the required timelines if considered necessary for performance reasons. **NOTE 2**: Important medical events refer to the Important Medical Events list maintained by EMA referenced at the EudraVigilance website. **NOTE 3:** Day zero refers to the date of receipt of any new follow-up information.	of the specific contract
No	Tasks/Deliverables	Timelines
VI	**Quality Management**	
VI.a	The Agency requires: i. Well-defined and regularly audited quality management practices as integral part of the contractor's organisational structure and its business processes to ensure that the contractor operates to consistently high levels of quality, efficiency and cost-effectiveness. ii. Measures to be put in place to facilitate performance monitoring, the assessment whether performance meets the Agency's stakeholders' needs and that allow taking appropriate action such as understanding and extending features of good performance and correcting areas of underperformance (as per the Service Level Agreement in Annex VI). iii. Measures to be put in place to ensure continuous training of staff in line with the required services. iv. Adequate back-up procedures in case of short and long-term staff	This must be carried out throughout the duration of the specific contract

	absence to ensure continuity of the services to be provided.	
VI.b	The Agency requires: i. Business process definitions, Standard Operating Procedures (SOPs) and work instructions (WINs) to be provided to the Agency for approval. These are to be aligned within one month following any updates to GVP module VI and other related guidance[4] and provided to the Agency for approval. The services are to be delivered in line with the applicable updates. ii. Processes to comply with the requirements of ISO 9001:2001. The documented processes shall be open to audit by the EMA, or its nominated auditor, at any time. **NOTE:** This does not mean that the Contractor needs to be ISO 9001:2001 certified; but if not so certified, the Contractor should demonstrate that the principles and standards embodied in that standard are being met through formal internal procedures.	One month after entry into force of the framework contract with regular updates as necessary
No	**Tasks/Deliverables**	**Timelines**
VII	**Service and operations management and periodic reporting**	
VII.a	The Agency requires: i. Service and operations management related to the activity of planning, organising, and controlling resources to achieve the required services as part of this procurement procedure. ii. The appointment of a dedicated service and contract manager as interface with a dedicated project manager appointed by the Agency. iii. The appointed service and contract manager and relevant contractor staff to attend quarterly project management meetings at the Agency's premises in London or via organisation of virtual meetings with the Agency.	This must be carried out throughout the duration of the framework contract
VII.b	The Agency requires: i. Weekly activity reports in electronic format to be made available to the Agency that facilitate performance monitoring, the assessment of whether performance meets the Agency's and stakeholders' needs and that allow taking appropriate action such as understanding and extending features of good performance and correcting areas of underperformance. ii. A service desk to assist enquiries from marketing authorisation holders and national Competent Authorities in EEA Member States. All enquiries and responses are to be logged and any issues reported are to be summarised with a proposal for resolution as part of the weekly activity reports.	This must be carried out throughout the duration of the specific contract

[4] Detailed guide regarding the monitoring of medical literature and the entry of relevant information into the EudraVigilance database currently in draft and expected to be adopted in the 4th quarter of 2014

	iii. Monthly activity reports, which are subject to the approval by the Agency and which serve as the basis for the initiation of payment for the delivered services. iv. Survey at six monthly intervals of a sample of marketing authorisation holders and national Competent Authorities for substance groups subject to this procurement procedure to identify potential areas of improvement. The surveys should serve as a tool to monitor quality and performance and to identify potential areas of improvement. v. Adherence to presentational requirements as follows: – All templates shall have a consistent style; – All reports shall be presented in English, and written such that they may be understood by a fluent English speaker who is competent in the domain without the need for further explanation or clarification; – Tracking systems across the services shall be consistent in presentation and in the manner of access and use; – All outputs will be treated as records in line with the aforementioned presentational requirements. vi. Records to be maintained in accordance with the provisions of ISO 15489. vii. The contractor to have in place procedures to report violations of the requirements of the European Data Protection Supervisor to the Agency, with a system for creating and maintaining records suitable to support the requirement. Details of areas to be included as a minimum in the monthly activity reports that will be monitored include: viii. A summary of the type and number of articles reviewed and number of individual cases entered in EudraVigilance (grouped by serious/non-serious from the time where applicable), type and number of literature added to the EudraVigilance literature repository, type and number of literature translated into English. ix. That services are provided on time, are reliable, accurate and complete to meet the Agency's satisfaction x. Issues encountered with a proposal how those can be resolved. xi. Performance against contract requirements and invoicing and payments.	
No	**Task/s**	**Timelines**
VIII	**Compliance with the Agency's IT requirements**	
VIII.a	The Agency requires the following: i. The contractor shall have in place a network and server capacity, including the hosting and publishing of information as required by this	This must be carried out throughout the duration

	tender. ii. The contractor shall have in place an internet connection capable of supporting the activities that form part of this tender. iii. 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 be supported by the contractor. iv. It might be required for the contractor to put in place an ESTRI gateway compatible with the EudraVigilance gateway. All the costs for this gateway on the contractor's site are to be supported by the contractor. v. The contractor must follow EMA's recommendation regarding web browsers versions. Currently the EudraVigilance system is only supported on Internet Explorer 8. vi. The terms of use of WIFI and cloud solutions as well as the level of security to implement e.g. Ethernet port security, must be agreed with the Agency. vii. It is the contractor's responsibility to ensure that any communication with the Agency systems has been completed successfully. viii. Personal computers used by personnel for these activities shall be secured from viruses or other security threats. To this effect attention should be given, but not limited, to the following: – Users cannot be administrators of the computers. – All the computers need to have an antivirus programme installed. – All computer need to be running the latest security updates available. – All non-used USB ports should be disabled. – Autorun feature should be disabled. – Encryption of Data should be provided if required. – Passwords should be handled according to the best industry practices, e.g. changed regularly, not shared, disable accounts after a few attempts. ix. Access to information held by the contractor for these activities must be subject to logical security controls, e.g. username and password protected access. x. It is the contractor's responsibility to make all the possible efforts to ensure that information sent to the Agency is free of virus or other security threats. xi. The size of the documents submitted to the literature repository should be the least possible assuring readability and acceptable quality of any existing images.	of the framework contract

	xii. Text within submitted Articles must be in a searchable form, not as image. xiii. The contractor is responsible for putting in place all the necessary mechanisms assuring service continuity, as specified by this tender in compliance with the service level agreement (SLA). To this effect business continuity and disaster recovery plans as well as regular backup procedures shall be put in place. xiv. Access to the building and the areas where the activity that are part of this tender will be performed must be controlled and tracked in compliance with the requirements defined by the European Data Protection Supervisor[5]. xv. In case of unavailability of any of the Agency systems, the contractor should store locally copies of all the information, to be submitted to the Agency as soon as the services are established.	
VIII.b	i. The contractor must provide a solution's design document that demonstrates how the requirements stated in VIII.a will be achieved.	At the time of the offer
No	**Tasks/Deliverables**	**Timelines**
IX	**Service set up & business continuity**	
IX.a	The Agency requires the necessary arrangements to set up the required services taking into account the need to: i. Set up the contractor's staff and to train the staff as necessary. ii. Put into operation the necessary business processes and standard operating procedures. iii. Set-up of business continuity arrangements providing the capability to continue the delivery of services necessary to comply with the provisions set out in Article 27 of Regulation (EC) 726/2004 at acceptable predefined levels following any disruptive incident. The services must not be unavailable for more than 48 hours. iv. A summary report, which is subject to the approval by the Agency, to conclude the set up phase and that will serve as a basis to initiate the pilot as outlined under IX.c. **NOTE**: The Agency will provide online training on EudraVigilance to the contractor's staff free of charge.	Within two months after entry into force of the framework contract and regular updates as necessary
IX.b	The Agency requires: i. A Business Continuity plan, with clearly defined processes and back-up tools that will enable the Agency to continue all the required services and to enable to recover quickly and effectively from any type of disruption whatever its size or cause; this plan is subject to the approval by the Agency.	Within one month after entry into force of the framework contract and regular

[5] https://secure.edps.europa.eu/EDPSWEB/edps/EDPS/Dataprotection

	ii. The alignment of the business continuity arrangements with the business continuity processes of the Agency with the main focus on EudraVigilance. The Agency will provide information on the business continuity arrangements with the main focus on EudraVigilance within one week following the entry into force of the contract and for each update.	updates as necessary
IX.c	The Agency requires: i. A two month pilot, which allows obtaining initial feedback from marketing authorisation holders and national Competent Authorities in EEA Member States on the operation of the services with the aim to take corrective actions on performance as necessary. ii. A summary report to conclude the results of the pilot and the corrective measures as necessary, which is subject to the approval by the Agency.	Two months after completion of the set up phase
IX.d	The Agency requires: i. An adjustment of the services and training of the contractor's staff following the implementation of the new ISO ICSR standard as outlined under table item no. IV.c. Full testing of any new or changed IT infrastructure is to be included and provided for. **NOTE**: The Agency will provide online training on EudraVigilance to the contractor's staff free of charge.	At date announced by the Agency
No	Audit	Timelines
X	**Independent Audit**	
X.a	The Agency requires: i. A two yearly, independent audit of the contractor's internal quality management and control systems and of the services provided to assess their effectiveness with a view to bringing about continuous improvement. The outcome of the audit may be made public by EMA. **NOTE:** The audit is to be performed by an independent auditor appointed by the Agency.	Two yearly
No	Payments	Timelines
XI.	**Payments**	
XI.a	First payment will be initiated: i. Following successful completion of the set up phase as outlined under IX.a and the approval of the summary report by the Agency to conclude the set up phase, and ii. following approval of the summary report to conclude the results of the pilot and the corrective measures as necessary.	Following approval of summary report to conclude set-up phase and pilot

XI.b	Monthly payments based on the activity reports outlined under VII.b.ii, which are subject to the approval by the Agency and which serve as the basis for the initiation of payment for the delivered services.	Monthly following XI.a

4. Participation in the tender

4.1. Agreements on public procurement

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").

4.2. Subcontracting

If the tenderer envisages subcontracting any part of this contract, the following documents must be provided with the tender submission:

(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 subcontractors.

If such documents are not provided, the Agency shall assume that the tenderer does not intend subcontracting.

5. Additional documentation available to tenderers

Further information about the work of the Agency can be obtained on its website: http://www.ema.europa.eu.

Additional information related to this tender can be obtained on the following websites:

- EudraVigilance web portal:

  http://eudravigilance.ema.europa.eu/highres.htm

- 2012 annual report on EudraVigilance:

  http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/07/news_detail_001853.jsp&mid=WC0b01ac058004d5c1

- Good pharmacovigilance practices:

  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp&mid=WC0b01ac058058f32c

- Pharmaceutical legislation medicinal products for human use:

  http://ec.europa.eu/health/documents/eudralex/vol-1/index_en.htm

- ISO - International Organization for Standardization:

  http://www.iso.org/iso/home.html

6. Information visit

Not Applicable

7. Variants

Not Applicable

8. Estimated contract volume

For the delivery of the "Monitoring of Scientific and Medical Literature and the Entry of Relevant Information into EudraVigilance" services through a single service, the estimated contract volume is up to a maximum of 300 substance groups and 100 herbal substance groups. The volume of services to be ordered by the Agency shall be made according to budgetary availability at the time of ordering.

The Agency may exercise the option to increase the framework contract value at a later stage via negotiated procedure with the successful tenderer in accordance with Article 134 (1) (f) of the Rules of Application of the general Financial Regulation[6].

9. Price

9.1. Currency of tender

Prices should be submitted in Euro.

The costing sheet attached to these specifications must be used to submit a tender. Please note that any financial costing sheet must be submitted in separate binders or folders, and on a separate CD, which must be clearly labelled.

9.2. All-inclusive prices

Prices submitted in response to this tender must be inclusive of all costs involved in the performance of the contract (e.g. to include travel, subsistence etc.). No expenses incurred in the performance of the services will be reimbursed separately by the Agency.

[6] Part 1, Title V of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union.

9.3. Price revision

The charges shall be fixed and not subject to revision for specific contracts concluded during the first year of performance of the contract.

From the beginning of the second year of performance of the contract, the charges may be revised upwards or downwards each year, where such revision is requested by one of the contracting parties by notice served no later than three months before the anniversary of the date on which the contract became effective. Specific contracts shall be concluded on the basis of the charges in force on the date on which they become effective. Such charges shall not be subject to revision.

This revision shall be determined by the trend in the European Index of Consumer Prices (EICP) published by the Statistical Office of the European Union in its monthly bulletin under the theme of Economy and Finance: Harmonized Indices of Consumer Prices (European Union index) (http://epp.eurostat.ec.europa.eu).

Revision shall be calculated in accordance with the following formula:

$$Ar = Ao * \frac{Ir}{Io}$$

Where

Ar = revised total amount

Ao = total amount in the original tender

Io = index for the month in which the validity of the tender expires

Ir = index for the month corresponding to the date of receipt of the letter requesting revision of prices

9.4. Costs involved in preparing and submitting a tender

The Agency will not reimburse any costs incurred in the preparation and submission of a tender. Any such costs must be paid by the tenderer.

9.5. Period of validity of the tender

Tenderers must enclose a confirmation that the tender (including prices) is valid for eight months from the final date for submission of the tender.

9.6. Protocol on the Privileges and Immunities of the European Union

The Agency is, as a rule, exempt from all taxes and duties, and in certain circumstances is entitled to a refund for indirect tax incurred such as value added tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union. Tenderers must therefore give prices which are exclusive of any taxes and duties and must indicate the amount of VAT separately.

10. Payment arrangements

Payments under the Contract shall be made by the Agency in arrears and only if the Contractor has fulfilled all his contractual obligations by the date on which the invoice is submitted, including specified deliverables. Payments shall be subject to written confirmation by an authorised staff

member of the Agency that the services have been satisfactorily performed and submission of any reports required in line with the service description. Invoices must be submitted no later than four months following completion of the services. For further details of payment modalities, please see Article I.4 of the draft framework contract (Annex IV).

Payment schedule

No.	Payment	Linked to EMA approval of deliverable	Timeline
1	Total set-up costs, as per financial offer and Specific Contract	IX.a-d: Service set up and summary report; pilot phase and summary report	Within four months of entry into force of the specific contract for these services
2	Delivered services, as per Specific Contract (pro rata, based on annual price, as per financial offer)	VII.b.ii: Monthly activity reports	Monthly, following successful completion of pilot phase
3	Payments for translations of literature article(s) (deliverable no. II.e) and/or ad hoc screening activities (deliverable no. III.d) shall be part of the payment for 'delivered services' for the month during which the service request was completed.	VII.b.ii: Monthly activity reports	As requested by the Agency

11. Contractual details

The Agency wishes to conclude a maximum of three framework contracts in priority order to provide Monitoring of Scientific and Medical Literature and the Entry of Relevant Information into EudraVigilance services, as and when required, for an initial period of four years with the possibility of two renewals each of one year (maximum contract duration is six years). A framework contract will establish the terms governing the services to be delivered during a given period, in particular with regard to the price.

The Agency shall also sign a service level agreement (SLA) with contractors (see Annex VI) which shall form an integral annex of the contract. This SLA sets out the performance levels which the contractor must maintain. In the case of underperformance, where services provided are not on time or not in accordance with professional standards in connection with the required quality for the services as specified in the SLA, the Agency may terminate the contract, according to termination provisions in the contract.

A draft framework contract is attached to these Technical specifications as Annex IV. Tenderers must confirm acceptance of the draft framework contract and terms and conditions of the tender as part of their tender response.

Signature of the framework contract imposes no obligation on the Agency to order services. Only the implementation of the framework contract through specific contracts is binding for the Agency. Orders are placed through specific contracts and each specific contract will contain details of deliverables and timelines for particular services to be provided.

It is the Agency's intention to sign multiple cascading framework contracts with a maximum of three contractors ranked in priority order. If the first priority contractor is unable to fulfil the requirements set out in the request for services, the Agency may invoke the cascade. The cascade may also be invoked if a contractor fails to meet the SLA.

Contractors shall be solely responsible and liable for the following:

- To ensure that the terms and conditions asserted by any copyright holder of publications or information referred to in the contract deliverables for the Agency are fully satisfied.
- To make the necessary arrangements enabling the Agency, its staff members, the European Commission and National Competent Authorities in EEA Member States to reproduce and make non-commercial use of publications and information referred to in the deliverables commissioned. As needed, the contractor(s) shall consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing copyright licenses to reproduce any publications provided to the Agency. The contractor remains solely responsible and liable for obtaining all necessary authorisations and rights to use, reproduce and share the publications provided to the Agency.

Tenderers' attention is drawn to Article II.8 of the draft contract (Annex IV of these specifications) regarding the contractual provisions in relation to intellectual property rights.

12. Exclusion criteria

All tenderers and subcontractors shall provide a declaration on their honour (see Annex II), duly signed and dated by an authorised representative, stating that they are not in one of the situations of exclusion listed in this Annex.

The successful tenderer shall provide the documents mentioned as supporting evidence in Annex II before signature of the contract and within a deadline given by the contracting authority. This requirement applies to all members of the consortium in case of joint tender and to subcontractors.

The Agency may waive the obligation of a tenderer to submit the documentary evidence referred to above if such evidence has already been submitted to it for the purposes of another procurement procedure and provided that the issuing date of the documents does not exceed one year and that they are still valid. In such a case the tenderer shall declare on its honour that the documentary evidence has already been provided in a previous procurement procedure and confirm that no changes in its situation have occurred.

13. Selection criteria: financial and economic capacity

Requirements:

Tenderers must be in a stable financial position and have the economic and financial capacity to perform the contract. The annual turnover of the tenderer must be of a minimum value of EUR 4 million for each of the last three financial years. Tenderers must also have professional risk indemnity insurance with a minimum coverage of GBP 5 million or the equivalent in Euro per claim.

The documentation supplied in response to this section will be reviewed to assess the general financial health of the tenderer (or all tenderers in the case of joint tenders whereby a consolidated assessment shall be made) and parent companies where the parent company is providing a guarantee. In addition to verifying that the financial turnover meets the required minimum amounts, as listed above and in the Official Journal notice, the on-going economic capacity will be assessed including financial independence and liquidity.

Evidence required:

The documents or information listed below must be presented 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 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.

14. Selection criteria: technical and professional capacity

The documents or information listed below must be presented as evidence of compliance with these selection criteria. For joint tenders and in case the tenderer is planning on using subcontractor/s, the evidence requested should be included in the offer for all consortium partners and/or subcontractors. The Evaluation Committee will assess the combined capacities of all members, including sub-contractors.

Requirements:

The criteria for this contract are:

- Authorisation of the tenderer to perform the contract under national law. The tenderer must be established as a recognised legal entity and be registered in a relevant professional or trade register.
- 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.

- Availability of qualified staff compliant with these minimum expertise requirements:

    i. 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.

    ii. Expertise in the medical and pharmaceutical domain.

- Measures established to ensure high quality and timely services to customers.
- Sufficient manpower involved in customer services and literature monitoring and individual case management delivery.

Tenderers must meet all of the above requirements.

Evidence required:

The documents or information listed below must be presented as evidence of compliance with these selection criteria. If subcontracting is envisaged, documentation must be provided in relation to any subcontractors.

- Authorisation to perform the contract under national law, as evidenced by inclusion in a trade or professional register, or a sworn declaration or certificate, membership of a specific organisation, express authorisation of entry in the VAT register.
- A list of the principal services provided in the past three years, with the sums, dates and recipients, public or private in the field of scientific and medical literature monitoring, individual case processing, copyright law, digital rights management and enterprise rights management.
- A description of measures employed to ensure quality of services (quality management for customer service; internal quality management standards).
- A statement of the average annual manpower and the number of staff, of the tenderer who are able to fulfil the requirements of this tender in the last three years.
    - Tenderers must provide the Curricula Vitae for its managerial and scientific staff, in particular those of the person or persons responsible for providing the services.
    - Tenderer must provide detailed CVs of team members (maximum 5) proposed for the assignment, taking into account the minimum expertise requirements as outlined above.

      Curricula Vitae submitted should bear **no indication of name or date of birth, only a number**. A separate list should be included showing the association between these numbers.

      Curricula Vitae should be submitted using the Europass template: http://europass.cedefop.europa.eu/en/documents/curriculum-vitae

15. Award criteria

Stage 1 - Qualitative award criteria

Only tenderers which have passed the exclusion and selection criteria stages shall be assessed against the award criteria in order to determine the most economically advantageous tenders. For joint tenders the award criteria shall be evaluated in relation to the tender as a whole.

The qualitative award criteria which will apply to this tender, together with their respective weightings, points available and minimum scores are set out in tabular format below. Any tenderer not achieving the minimum scores indicated below for each subcriterion shall be eliminated and not evaluated for price.

The qualitative award criteria shall account for **70% of the weighting** for this tender.

No	Award Criterion	Weighting %	Maximum points available	Minimum points, which must be achieved
A	**Proposed model (processes, tasks and controls) for the delivery of the services outlined in a concise management summary**	**20**	**200**	
A.1	Description of service set-up and business continuity arrangements (chapter 3, table item IX)		35	21
A.2	Processes, tasks and controls of supplying daily, accurate and exhaustive scientific and medical literature as outlined in chapter 3, table item no. II.		55	33
A.3	Processes, tasks and controls of timely screening of the supplied scientific and medical literature and record keeping as outlined in chapter 3, table item no. III.		55	33
A.4	Processes, tasks and controls of timely handling of individual cases related to suspected adverse reactions as outlined in chapter 3, table items no. IV and no. V.		55	33
B.	**Scope (including results of the test)**	**30**	**300**	
B.1	The name, type, reference and short description of the journal/reference database(s) as well as the number and the names of the journals covered for the purpose and scope of the supply of daily, accurate and exhaustive scientific and medical literature as outlined under chapter 3, table item no. II.		200	120
B.2	The results of the test		100	60
C.	**Service and Quality Management**	**10**	**100**	
C.1	Proposed operations and control activities:		35	21

No	Award Criterion	Weighting %	Maximum points available	Minimum points, which must be achieved
	operational structure, management supervision, document management.			
C.2	Proposed evaluation and audit: continuous evaluation of activities, assessment of IT systems, internal audit capability.		35	21
C.3	Proposed measures to ensure continuous performance monitoring and improvement and evaluation of stakeholder satisfaction.		30	18
D.	**Team assembly and constitution, taking into account the necessary range and depth of expertise required in accordance with the requirements**	**5**	**50**	
D.1	Detailed description of the functional division and individual responsibilities of the proposed members of the team		25	15
D.2	Proposed communication with the team and vis-à-vis the Agency		25	15
E	**Contract management**	**5**	**50**	
E.1	Proposed reporting: activity reporting and communication, accounting and financial reporting		50	30

Throughout its responses the tenderer should demonstrate that it has understood the requirements for the services and is proposing to put into place the necessary organisation, technical infrastructure, resources and expertise to fulfil the quality, efficiency and timely reporting requirements set out in this Invitation to Tender and in full compliance with the regulatory and legal requirements as set out in EU pharmacovigilance legislation and related GVP module VI.

A - Proposed Model for the Delivery of the Services (maximum possible score: 200 points)

The Agency expects a description of how Service Set-up will be achieved (A.1). This should be presented in the form of:

i. An outline of the planned approach (maximum 2 pages) with specific reference to the principle activities and deliverables.

ii. A high level plan reflecting:

- the main activities together and the sequence in which these will be tackled;

- key deliverables with reference to any requiring sign-off by the Agency , areas where reliance will be placed upon Agency resources to support the completion of Service set-up activities, with an indication of the expected effort required (in man days).

Tenderers should also provide a proposal for a business continuity plan as part of the service set-up description.

Tenderers should specify the processes, tasks and controls of supplying scientific and medical literature as detailed in the service description. (A.2)

Tenderers should describe processes, tasks and controls of timely screening - as well as ad-hoc screenings requested by the Agency - of the supplied literature. A description of the proposed recording of all screening activities should be included. (A.3)

Tenderers should describe processes, tasks and controls of processing individual cases related to suspected adverse reactions identified as a result of the scientific and medical literature screening activities. The description should include the proposed follow-up of individual cases related to suspected adverse reactions identified as a result of the scientific and medical literature screening activities. (A.4)

B - Scope (maximum possible score 300 points)

Tenderers should provide the name, type, reference and short description of the literature databases and names of journals[7] to be used to supply daily, accurate and exhaustive scientific and medical literature as outlined under chapter 3, table item no. II. (B.1)

Tenderers must also complete a test (Annex VIII) to demonstrate how they intend to put in place the required services with the aim to achieve maximum performance in terms of outputs as required by EU pharmacovigilance legislation and defined in GVP module VI thereby providing the highest possible benefits to the Agency, national Competent Authorities in EEA Member States as well as marketing authorisation holders concerned. (B.2)

C- Service and quality management (maximum possible score 100 points)

In line with the Service Level Agreement (Annex VI) the tenderer should provide a proposal for the monitoring and follow up of consistent and compliant application of its standard operating procedures, work instructions and quality assurance to support attainment or better of the required service levels, and a proposal for ensuring that its Standard Operating Procedures (SOPs) and Work Instructions (WINs) are maintained in line with current technological advances. (C.1)

The tenderer should describe its proposal for evaluation and audit, including implementing and monitoring security arrangements in the field of data security, communications between the tenderer and the Agency and specific arrangements for disaster recovery, including arrangements with regard to copyright and data protection. (C.2)

The tenderer should describe its proposal to ensure continuous performance monitoring and improvement and evaluation of stakeholder satisfaction. (C.3)

D - Team assembly and constitution (maximum possible score: 50 points)

The tenderer should provide a plan to put in place a suitably qualified and sufficiently sized team of balanced composition and to meet the service levels required (please note that Curricula Vitae should

[7] in the broader sense covering articles from periodicals, journals, reviews, reports, conference proceedings, media releases or similar products

not be provided in response to this question). The tenderer should also describe the process to replace personnel and the relevant time frames, knowledge transfer including training plans and procedures to maintain high levels of competence for the duration of the contract. Any proposed reliance on EMA in this regard must be specified. (D.1)

The tenderer should provide its proposal for communication with the team and vis-à-vis the Agency. (D.2)

E - Contract management (maximum possible score: 50 points)

The tenderer should describe its proposals for managing this contract in particular with regard to reporting, interaction with the Agency and in accordance with the standards specified in the SLA. (E.1)

* * *

Tenderers should provide responses on each of the technical criteria in separate documents (maximum two A4 pages per subcriterion with the possibility of providing annexes in relation to process descriptions) and clearly mark each answer with the appropriate number. Tenderers should not provide brochures or publicity material for replies. The mere repetition of mandatory requirements set out in these technical specifications will result in a lower score.

The sum of all quality award criteria gives a maximum possible of **700 points**.

Each evaluation committee member shall score each tender out of the maximum points available for each subcriterion. The total score to be awarded to each tenderer for each subcriterion shall be the average score of the points of all the members, calculated to two decimal places. A check shall then be made if the tenderer has met the minimum score required for each subcriterion. If this has not been achieved, the tenderer shall be eliminated at this stage.

Where the minimum score has been achieved in each subcriterion, the total points shall then be converted to the weighting percentage for the five criteria mentioned above. The final score out of 70% shall be given to two decimal places.

Stage 2 – Price

Following completion of Stage 1, price shall be evaluated using the following formula:

$$\frac{\text{Lowest price x weighting for price}}{\text{Tenderer's price}}$$

For the purposes of evaluation, "price" in this formula shall be the amount titled 'Overall total cost over six years' arising from the calculation based on the scenario for evaluation of price provided in the costing sheet in Annex I. Price shall account for **30% of the weighting** for this tender. Tenderers should note that this scenario has been established for the purposes of evaluation only and is not binding or indicative of any future purchase of services by the Agency.

Tenderers' attention is drawn to Article 151 of the Rules of Application of Regulation (EU, Euratom) No. 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union concerning abnormally low tenders.

Stage 3 – Final ranking of tenderers

Following evaluation of price, the points for price and the points for the qualitative award criteria shall be added together (Stage 1 and Stage 2) to arrive at a grand total to two decimal places and to determine the ranking of tenderers.

16. Tender to be submitted

In order to assess each tenderer according to the above-mentioned criteria, the following information must be submitted by the tenderer:

- A letter enclosing the tender on the official letter headed paper of the tenderer and signed by an authorised representative of the tenderer.
- An information form on the tenderer (Annex V).
- Completed declaration in Annex II relating to Exclusion Criteria.
- Documentation requested to enable assessment of Selection Criteria (Chapters 13 and 14 above).
- Documentation requested to enable assessment of Award Criteria (Chapter 15 above).
- A statement to confirm that information provided in response to this tender is accurate and complete as at the date of submission and acknowledgement that the provision of false information, either knowingly or negligently, in response to this tender could result in the tenderer being excluded from future tenders for contracts with the Agency.
- A statement to confirm that the tenderer fully complies with all Agency IT requirements as set out in Chapter 3.1.VIII.
- Confirmation of acceptance of the draft contract and terms and conditions of tender including validity of prices.
- An undertaking to inform the Agency promptly following any matter which would alter or add to any of the information given in response to this tender.
- Documents as requested in relation to proposed subcontracting.
- Tenders submitted by consortia or by groups of service providers or suppliers must indicate the role, title and experience of each member or of the group.
- **To be submitted in separate binders or folders, which must be clearly labelled**, a detailed financial tender using the costing sheet attached in Annex I, and exclusive of VAT, signed by an authorised representative of the tenderer.
- Tenderers are requested to make use of the checklist given in Annex III to ensure that no enclosure has been omitted in their tender.