



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/734923/2014

Technical specifications for open invitation to tender Procurement Procedure EMA/2014/68/COM Access to drug pipeline database(s)

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An agency of the European Union



Summary Information sheet

Reference of contract:

- EMA/2014/68/COM – Access to drug pipeline database(s).
- OJEU No S.35, 19.02.2015 – Contract notice published in the Official Journal of the European Union.

Type of procurement procedure:

- Open tender procedure with publication in the Official Journal of European Union.

Timetable	Date	Comments
Launch of tender	19 February 2015	All documents are available at: http://www.ema.europa.eu (Home>About us>Procurement)
Deadline for request of clarifications from EMA	31 March 2015	Requests to be sent in writing to: EMA.2014.68.COM@ema.europa.eu
Last date on which clarifications are issued by EMA	1 April 2015 <i>(Please note: The Agency is closed from 2 to 6 April)</i>	All clarifications will be published at: http://www.ema.europa.eu (Home>About us>Procurement)
Deadline for submission of tenders	9 April 2015	Please see the Invitation to Tender for precise delivery conditions
Opening meeting	13 April 2015	At 13H00 at EMA premises in London
End of evaluation process (award)	Apr-May 2015	Estimated
Signature of contract	Jun-Jul 2015	Estimated

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Technical specifications for open invitation to tender No. EMA/2014/68/COM – Drug Pipeline Database(s)

1. Title of the invitation to tender

This document contains the Technical Specifications for the Open Invitation to Tender No. EMA/2014/68/COM – Access to drug pipeline database(s).

The contract notice for this open tender has been published in the Official Journal of the European Union OJEU No S.35, 19.02.2015.

2. Objectives and context of the invitation to tender

Objectives of the tender

The Agency requires access to current, comprehensive and complete drug pipeline databases to provide scientific, economic and industry-related information of the human medicines and medical devices including use in clinical practice and in research and development worldwide, and of their developers and marketing authorisation holders, to inform the assessment and monitoring of these products by the Agency and to support its work forecast. The Agency is also looking for abstracted adverse reaction reports to find and/or evaluate adverse reactions of medicines for human use licensed in the EEA.

Context of the tender

The Agency is responsible for the scientific evaluation of applications for European marketing authorisation for medicinal products (centralised procedure). Under the centralised procedure, companies submit a single marketing authorisation application to the Agency. Once granted by the European Commission, a centralised marketing authorisation is valid in all European Union and EEA-EFTA states. The safety of medicines is monitored constantly by the Agency through a pharmacovigilance system. In addition, the Agency supports the pharmacovigilance of nationally authorised products in the EEA.

The Agency also gives scientific advice to companies for the development of new medicinal products. It published guidelines on quality, safety and efficacy testing requirements. A dedicated office provides special assistance to small and medium-sized enterprises (SMEs). Seven scientific committees, composed of members of all EU and EEA-EFTA states, some including patients' and doctors' representatives, conduct the main scientific work of the Agency.

The Agency's Information Centre supports all staff and committee members in the execution of their professional tasks by providing access to information resources in both print and electronic formats. The Information Centre is not open to the general public and is mainly used by the Agency's scientific staff. It coordinates the usage of a number of databases (e.g. bibliographic databases, reference databases, journals databases, scientific databases), which includes user administration, reporting and purchase recommendation, budgeting and procurement as well as training coordination and promotion.

About the Agency

The Agency is a decentralised body of the European Union based in Canary Wharf in the Docklands area of London (E14). Its 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

was established in 1995 and operates under European Parliament and Council Regulation No 726/2004 to provide a system for the authorisation of medicinal products. The Agency is an agency of the European Union and has its own legal personality.

Further information about the EMA can be obtained on its website: <http://www.ema.europa.eu>.

3. Subject of the tender

The Agency intends to establish a service contract (please see Section 11 for full contractual details) with one service provider for a subscription to access one or several databases for unlimited users containing lifecycle and adverse reaction report data about medicinal products and medical devices for human use worldwide from pre-clinical to clinical studies phase IV up to and including marketing and discontinued projects; including scientific (therapeutic areas, mechanisms of action, indications in development, (bio-)chemical class, INN and product names, product safety and efficacy, routes of administration, formulations, orphan status, generics and biosimilars, abstracted public adverse reaction reports, etc.), economic (patent expiration, M&A, reimbursement status, etc.) and industry related information (company revenue, company deals, company pipeline, etc.) divided by major regional markets (EU, USA, Japan, BRIC).

The essential requirements which must be fulfilled by the database product(s) during the proposed four-year period of this contract and the desirable features are as follows. In order to confirm that these essential requirements are met, tenderers must complete Annex I: Statement of Fulfilment of Essential Requirements. Tenderers which fail to do so, or cannot confirm fulfilment of these requirements shall be eliminated from the procedure.

Areas	Essential requirements (<i>'Must-Have'</i>)	Desirable features (<i>'Nice-to-Have'</i>)
Technical Prerequisites	- The database(s) must be accessible via a standard web browser. - The database(s) must be compatible with the IT environment at the Agency (Windows 7, MS Office 2010, Adobe Flash Player 11.4, Adobe Shockwave Player 11.6, Java 7, Internet Explorer 9). - Free access to all tendered database(s) for evaluation purposes during the entire validity of the tender and submission of the access information (URL, username/password (if applicable)) with the tender.	No software other than the Agency's (mentioned on the left) or "app" required to access the database(s).
Data	The data is required to be current, comprehensive, complete and	Data presentation and visualisation tools (i.e. graphs,

Areas	Essential requirements (<i>'Must-Have'</i>)	Desirable features (<i>'Nice-to-Have'</i>)
	frequently updated covering: Scientific information and adverse reaction reports on medicinal products and medical devices for humans at all stages of their lifecycle development phase, clinical trials information, safety and efficacy, research, development and marketing data, therapeutic area, ATC code, mechanism(s) of action, indications, formulations, routes of administration, INN and product names, (bio-)chemical class (cell and gene therapy, monoclonal antibody, recombinant DNA, etc), bibliographic references, orphan status, generics and biosimilars, regional location of main studies, abstracted public adverse reaction reports. Business and commercial information (e.g. company pipeline, market shares, company revenue, company deals, potential developments within specific therapeutic areas, revenue and sales, merging and acquisitions, licensing, patents (e.g. countries in which valid, expiration, litigations), CAGR (compound annual growth rate) related to human medicinal and medical device industry divided by major regional markets (EU, USA, Japan, BRIC).	tables). - Financial forecast (i.e. probability of the medicinal product/medical device entry in the market and sales forecast). - Reimbursement status of the product.
Language of the content	English	Other EEA Member States languages.
Searching, exporting, accounts and alerts	Search facilities must include a basic search function (full text search) and a filter or search function to limit results by	Advanced search function (multiple search terms in multiple fields) and expert search function (using Boolean operators).

Areas	Essential requirements (‘Must-Have’)	Desirable features (‘Nice-to-Have’)
	specified parameters as described in the data requirement section above and including language, time period, location, therapeutic areas, ATC code, indication, product identifier (INN, trade name), organisation, mechanism of action, development phase, orphan status, (bio-)chemical entity (e.g. new, generic, biosimilar, fixed combination) and (bio-)chemical class (cell and gene therapy, monoclonal antibody, recombinant DNA, etc.), revenue, market value, medical devices, adverse reaction, formulation, and route of administration. - The search results must be printable and exportable into MS Office applications. - The tendered database(s) must have individual and personalised user accounts with alerts function.	Option to save searches previously done and their search results.
Administration, Support & Training	Tenderers must be able to offer: - A transparent and flexible license model based on IP recognition (preferably), username and password identification or a combined model, for an unlimited number of users and a period of 4 years, with acceptable¹ terms and conditions. - Access to an administrative account for the EMA Information Centre’s team to monitor the usage and to run regular usage reports and statistics. Alternatively this data must be provided by the tenderer as and	- Free provision of the full text of the referenced publications directly or via the EMA Information Centre’s subscriptions (preferably), or at least via a prepopulated e-mail to the Information Centre. - Extended subscription period / grace period. - Marketing and training material for the internal promotion within the Agency (i.e. product leaflets, awareness sessions) and free on-site training. - Option to integrate the database(s) into the EMA

¹ Not conflicting with the contract for supply of goods & services for the EMA Communication Service (Annex V)

Areas	Essential requirements (<i>'Must-Have'</i>)	Desirable features (<i>'Nice-to-Have'</i>)
	when required by the Agency without further costs. • Training solutions at no additional costs (webinars, training material). • Availability of a technical team providing content and technical support within one business day at no extra cost.	Information Centre's library management system which currently is KnowAll by Bailey's Solution. • A dedicated account manager at no further costs.

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 tender 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>.

6. Information visit

Not applicable.

7. Variants

Not applicable.

8. Estimated contract volume

The contract entails a subscription to the database(s) described in this call for tender for a period of 48 months (4 years) and an unlimited number of users. The estimated budget range for this contract is a maximum of EUR 300,000 – EUR 500,000.

The Agency may exercise the option to increase the estimated 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 Regulation².

9. Price

9.1. Currency of tender

Prices must be submitted in € (Euro).

The financial form attached to these specifications must be used to submit a financial tender (see Annex III).

Please note that only one costing sheet must be submitted per tenderer.

Please note that any financial costing sheet must be submitted in separate binders or folders and on a CD-ROM, which must be clearly labelled.

Tenderers should not indicate ranges of rates. Should a tenderer do so, the highest price in the range shall be used for the purposes of evaluation as part of the award criteria.

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. No expenses incurred in the performance of the services will be reimbursed separately by the Agency.

² 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

Prices submitted in response to this tender shall be fixed and not subject to revision for the first year of performance of the contract. Thereafter prices may be revised in accordance with the terms and conditions of the successful Tenderer (see Section 11 for further details regarding the draft contract).

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 six 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

An initial payment for the first year shall be made in advance of the subscription period once the contractor has established access to the database(s).

Subsequent payments shall be made on each renewal date for the following 3 years.

11. Contractual details

A draft short-form contract is attached to these Technical Specifications as Annex V.

The Agency intends to sign the Tenderer's terms and conditions, which will prevail over the Agency's terms and conditions with the exception of Articles 5.1, 5.2, 5.3, 5.4 and 5.5 of the Agency's short-form contract which shall prevail. The Tenderer's terms and conditions (including any licensing agreement) will be included as an integral annex to the short-form contract. Tenderers are therefore required to submit a copy of their Terms and Conditions including all license agreements that are relevant to their tender.

Tenderers must confirm the acceptance of the draft contract, which includes the Tenderer's own terms and conditions, as part of their tender response.

12. Exclusion criteria

Tenderers must submit the following completed and originally signed document:

- **Annex IV: Exclusion Criteria Declaration**

All tenderers and sub-contractors shall provide a declaration on their honour, duly signed and dated by an authorised representative, stating that they are not in one of the situations of exclusion as listed in Annex IV.

The successful tenderer shall provide the documents mentioned as supporting evidence listed in Annex IV 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 sub-contractors.

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

Tenderers should demonstrate in their proposals that they have the technical and organisational capacity as well as the experience necessary to ensure the required contractual services.

Tenderers must provide all documents and information listed under the sections 'Evidence required'.

13.1. Financial and economic capacity

The requirements for this contract are:

Tenderers must be in a stable financial position and have the economic and financial capacity to perform the contract.

The average annual turnover of the tenderer for the last two financial years concerning the type of services covered in this call for tenders must be no less than EUR 250,000.

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 two 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 two 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.

13.2. Technical and professional capacity

The requirements for this contract are:

1. Authorisation of the tenderer to perform the contract under national law.
2. Experience in dealing with clients within field, sector or industry and/or of the scale of the Agency and the availability of a (range of) product(s) and services as described in Section 3 above.
3. Proof that the tenderer works at a high professional and technical standard applying quality management and providing excellent customer service.

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.

For requirement 1:

- 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.

For requirement 2:

- A list of 3 recent or current contracts showing details of the customer and the product(s) purchased/subscribed to by the customer relevant to these specifications.

For requirement 3:

- Description of the measures employed to ensure the quality of the services including service capacity. If providing statistics on system capacity, please indicate exact period reflected by data, preferably not older than 24 months.

Tenderers must provide all of the above evidence.

14. Award criteria

Tenderers must provide all documents and information as indicated under each award criteria and submit the following completed and originally signed document:

- **Annex II: Questionnaire**
- **Annex III: Financial Form (Costing Sheet)**

No other format is admissible.

Only tenderers who have demonstrated the appropriate capacity to perform the contract on the grounds of the selection criteria (as described under Section 13 above), who have provided the completed and originally signed Annex IV of this document and who have provided the completed Annex I confirming fulfilment of essential requirements shall be assessed against the award criteria.

The award criteria serve to identify the most technically and economically advantageous tender. The quality of each offer will be evaluated in accordance with the award criteria and the associated weighting. No other award criteria, sub-criteria or weightings other than those detailed below shall be used to evaluate the offer. For joint tenders the award criteria shall be evaluated in relation to the tender as a whole.

It is underlined that the mere repetition of mandatory requirements set out in technical specifications, without going into details or without giving any added value, will result in a low score. In addition, if certain essential points of these specifications are not expressly covered by the tender, the EMA may decide to give a zero mark for the relevant qualitative award criteria.

Each evaluation committee member shall score each tender out of the maximum points available for each criterion. The total score to be awarded to each tender for each criterion 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 tender has met the minimum score required for each criterion. If this has not been achieved, the tender shall be eliminated at this stage.

Where the minimum score has been achieved in each criterion, the total points shall then be converted to the weighting percentage for the three criteria mentioned below. The final score shall be given to two decimal places.

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

14.1. Qualitative award criteria

To achieve the technical sufficiency level, each tender must score a minimum of 48 points overall of the maximum 78 points available for quality of the tender (for criteria A and B) as well as the minimum scores indicated below per criterion. In addition, the table below sets out the maximum numbers of points that can be obtained for each individual criterion. Any additional features and functionalities (Criteria C) will be considered as an advantage for the evaluation of the proposed subscription and will thus result in additional points being awarded as set out below. Scoring shall be conducted according to the responses of the Tenderers to the questionnaire in Annex II.

Where the minimum score has been achieved for criteria A & B, the total points for all three criteria (A+B+C) shall be converted to a score out of 60%.

Award Criteria	Maximum Points which can be scored	Minimum Points which must be achieved
Qualitative Award Criteria A Data Quantity and Quality, Accessibility, Search Speed, Quality and User Friendliness <i>(48 maximum points can be scored, but the minimum points must be achieved for each criterion)</i> Tenderers must: ➤ Provide free access to any proposed database(s) for evaluation purposes during the entire validity of the tender. ➤ Include all access details, i.e. URL, username/password as applicable. For IP access please use IP 195.144.18.254.		
A.1. Quantity and quality of scientific information and adverse reaction reports	16	10
A.2. Quantity and quality of business and commercial information	16	10
A.3. Accessibility, speed, quality and user friendliness of search, export facilities, alerts and user accounts.	16	10
Qualitative Award Criteria B Training Solutions, Customer Services, Technical Support and License Model <i>(30 maximum points can be scored, but the minimum points must be achieved for each criterion)</i>		
B.1. Training solutions	10	6
B.2. Customer services and technical support	10	6
B.3. License model	10	6
Qualitative Award Criteria C Additional Desirable ('Nice-to-Have') Features <i>(22 maximum points can be scored, but no minimum points need be achieved for each criterion)</i>		
C.1. Advanced search function (multiple search terms in multiple fields) and expert search function (using Boolean operators).	2	n/a

Award Criteria	Maximum Points which can be scored	Minimum Points which must be achieved
C.2. Free provision of the full text of the referenced publications directly or via the EMA Information Centre's subscriptions (preferably), or at least via a prepopulated e-mail to the Information Centre.	2	n/a
C.3. Option to save searches previously done and their search results.	2	n/a
C.4. Data presentation and visualisation tools (i.e. graphs, tables).	2	n/a
C.5. Extended subscription period / grace period.	2	n/a
C.6. Marketing and training material for the internal promotion within the Agency (i.e. product leaflets, awareness sessions) and free on-site training.	2	n/a
C.7. Option to integrate the database(s) into the EMA Information Centre's library management system which currently is KnowAll by Bailey's Solution, and no software other than the Agency's (mentioned on the left) or "app" required to access the database(s).	2	n/a
C.8. Financial forecast (i.e. probability of the medicinal product/medical device entry in the market and sales forecast).	2	n/a
C.9. Data in other EEA language(s) than English.	2	n/a
C.10. A dedicated account manager at no further costs.	2	n/a
C.11. Data on reimbursement status of each product.	2	n/a

14.2. Financial award criteria

Those tenders scoring the minimum points in the qualitative award criteria shall be evaluated for price.

Price shall account for **40 %** of the weighting for this tender.

The award criteria for price shall be evaluated according to the following formula:

$$\frac{\text{Lowest price} \times \text{weighting for price (40)}}{\text{Tenderer's price}}$$

For the purposes of this evaluation, 'price' in this formula shall be the grand total in the Financial Offer form in Annex III calculated to two decimal places.

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.

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

At the conclusion of this evaluation process a service contract will be awarded to the tenderer with the highest overall score.

15. 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:

	Item	Check
1	A letter enclosing the tender on the official letter headed paper of the tenderer and signed by an authorised representative of the tenderer.	
2	Tender in one original paper copy with one copy of all documents on CD-ROM containing the following elements:	
2.1	Information sheet on the tenderer indicating the following details: – the name and registered business address including telephone number, e-mail address and website address; – any other different current or previous trading name in the past three years; – the name and contact details of the person who may be contacted with any queries regarding this tender; – the legal status of the tenderer; – if the tenderer is a company the company registration number, VAT registration number and date of incorporation; – if the tenderer is a member of a group of companies and if so the relationship between the tenderer and the ultimate holding company, the name and address of the holding company and its registration number, whether the ultimate holding company would be prepared to guarantee the liabilities in connection with this contract; – name of the persons authorised to sign contracts on behalf of the tenderer.	
2.2	A statement of fulfilment of essential requirements (Annex I).	
2.3	Completed declaration in Annex IV relating to Exclusion Criteria as described in Section 12.	
2.4	Documentation requested to enable assessment of Selection Criteria as described in Sections 13.	
2.5	Documentation requested to enable assessment of Award Criteria as described in	

	Item	Check
	Section 14 (see also Annex II).	
2.6	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.	
2.7	A statement to confirm that the tender is valid for 6 months.	
2.8	Confirmation of the draft contract, which includes the Tenderers own terms and conditions, as part of the tender response.	
2.9	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.	
2.10	Documents as requested in relation to proposed subcontracting.	
2.11	Tenders submitted by consortia or by groups of service providers must indicate the role, title and experience of each member or of the group.	
2.12	Completed questionnaire in Annex II.	
2.13	To be submitted in separate binders or folders and on a CD-ROM, which must be clearly labelled: A detailed financial tender using the Financial Offer form attached in Annex III, and exclusive of VAT, signed by an authorised representative of the tenderer.	

Annexes to be completed by Tenderers

Annex I	Statement of Fulfilment of Essential Requirements
Annex II	Questionnaire
Annex III	Financial Form (costing sheet)
Annex IV	Exclusion Criteria Declaration
Annex V	Draft Contract including Tenderers terms and conditions (<i>for information only</i>)

Annex I: Statement of Fulfilment of Essential Requirements to be completed by Tenderers

Tenderers must provide a statement that their tender meets all the Essential ('Must-Have') requirements.

Tenders which do not meet all of the essentials will be eliminated from the procedure.

Name of tenderer: _____

Areas	Essential requirements (<i>'Must-Have'</i>)	Confirmation Y / N
Technical Prerequisites	- The database(s) must be accessible via a standard web browser. - The database(s) must be compatible with the IT environment at the Agency (Windows 7, MS Office 2010, Adobe Flash Player 11.4, Adobe Shockwave Player 11.6, Java 7, Internet Explorer 9). - Free access to all tendered database(s) for evaluation purposes during the entire validity of the tender and submission of the access information (URL, username/password (if applicable)) with the tender.	
Data	The data is required to be current, comprehensive, complete and frequently updated covering: Scientific information and adverse reaction reports on medicinal products and medical devices for humans at all stages of their lifecycle development phase, clinical trials information, safety and efficacy, research, development and marketing data, therapeutic area, ATC code, mechanism(s) of action, indications, formulations, routes of administration, INN and product names, (bio-)chemical class (cell and gene therapy, monoclonal antibody, recombinant DNA, etc), bibliographic references, orphan status, generics and biosimilars, regional location of	

Areas	Essential requirements (‘Must-Have’)	Confirmation Y / N
	main studies, abstracted public adverse reaction reports. • Business and commercial information (e.g. company pipeline, market shares, company revenue, company deals, potential developments within specific therapeutic areas, revenue and sales, merging and acquisitions, licensing, patents (e.g. countries in which valid, expiration, litigations), CAGR (compound annual growth rate) related to human medicinal and medical device industry divided by major regional markets (EU, USA, Japan, BRIC).	
Language of the content	English	
Searching, exporting, accounts and alerts	• Search facilities must include a basic search function (full text search) and a filter or search function to limit results by specified parameters as described in the data requirement section above and including language, time period, location, therapeutic areas, ATC code, indication, product identifier (INN, trade name), organisation, mechanism of action, development phase, orphan status, (bio)-chemical entity (e.g. new, generic, biosimilar, fixed combination) and (bio)-chemical class (cell and gene therapy, monoclonal antibody, recombinant DNA, etc.), revenue, market value, medical devices, adverse reaction, formulation, and route of administration. • The search results must be printable and exportable into MS Office applications. • The tendered database(s) must have individual and personalised user accounts with alerts function.	
Administration, Support & Training	Tenderers must be able to offer: • A transparent and flexible license model based on IP recognition (preferably), username and password identification or a combined model, for an unlimited number of	

Areas	Essential requirements (<i>'Must-Have'</i>)	Confirmation Y / N
	users and a period of 4 years. • Access to an administrative account for the EMA Information Centre's team to monitor the usage and to run regular usage reports and statistics. Alternatively this data must be provided by the tenderer as and when required by the Agency without further costs. • Training solutions at no additional costs (webinars, training material). • Availability of a technical team providing content and technical support within one business day at no extra cost.	

Date: _____ Signature of authorised representative: _____

Print name: _____

Position in company: _____

Annex II: Questionnaire to be completed by Tenderers

Tenderers must provide a completed questionnaire which forms part of the award criteria.

Tenderers who fail to do so will be eliminated from the procedure.

Name of tenderer: _____

Question / Request	Tenderer's Response
Name each database that is subject of your response to this tender EMA/2014/68/COM.	
Please provide the URL and any access credentials for the evaluation.	
CRITERIA A	
Data Quantity and Quality, Accessibility, Search Speed, Quality and User Friendliness	
A.1. Please describe: – the database(s) and the data contained within; – the sources used for the provision of data (e.g. journals, other databases).	
A.2. Please describe: – the database(s)' currency and update interval.	
A.3. Please describe: – the basic search, filter, print and export functions of the database(s); – the down-times of the database(s) within the last 12 months; – the technical requirements relevant for the access of the database(s); – the individual and personalised user accounts with alert functions for all tendered databases.	
CRITERIA B	
Training Solutions, Customer Services, Technical Support and License Model	
B.1. Please describe: – the training solutions that will be available to the Agency at no extra cost.	

Question / Request	Tenderer's Response
B.2. Please describe: – the type of support available to the Agency at no extra cost and the usual response time after receiving a customer query or failure notice; – the monitoring and reporting options.	
B.3. Please explain and enclose: – the license model including the way of identification, the period of subscription and the number of users; – a copy of your Terms and Conditions including your licence model or alternatively provide a link to an online version.	Copy enclosed: YES / NO OR Link: http://_____
CRITERIA C Additional Desirable ('Nice-to-Have') Features	
C.1. Please describe the advanced and expert search functions.	
C.2. Please describe the options for free provision of full texts of the referenced publications directly or via the EMA Information Centre's subscriptions, or at least via a prepopulated e-mail to the Information Centre.	
C.3. Please describe the options for users to save searches, results and alerts.	
C.4. Please describe the data presentation and visualisation tools.	
C.5. What are the extended subscription and/or grace periods?	
C.6. Please describe the marketing and training material that will be available for the Agency for internal promotion at no extra cost, as well as any free on-site training.	
C.7. Please explain the options of integrating the database(s) into the EMA Information Centre's library management system (currently KnowAll by Bailey's Solution) and whether any software or App other than Windows 7, MS Office 2010, Adobe Flash Player 11.4, Adobe Shockwave Player 11.6, Java 7, Internet Explorer 9 is	

Question / Request	Tenderer's Response
necessary.	
C.8. Is a financial forecast included in any tendered database? If yes, please describe.	
C.9. Is the data available in other EEA languages than English? If yes, please describe.	
C.10. Is there a dedicated account manager for any contract with the Agency free of charge? If yes, please describe.	
C.11. Is data about reimbursement status of each product included in any tendered database? If yes, please describe.	

Date: _____ Signature of authorised representative: _____

Print name: _____

Position in company: _____

Annex III: Financial Form (costing sheet) to be completed by Tenderers

Tenderers must provide a completed costing sheet which forms part of the award criteria.

Tenderers who fail to do so will be eliminated from the procedure.

Tenderers must use the table below to submit their financial tender. Tenderers should submit this sheet in separate binders or folders which must be clearly labelled.

In addition, it should also be submitted on a separate CD from the rest of the tender.

Prices must be submitted in EUR.

Tenderers should not use ranges of prices. Should it do so, the highest price in the range shall be used for evaluation purposes.

Name of tenderer: _____

Name of Database(s)		Total Price in EUR (per year)
1		
2		
3		
4		
5		
GRAND TOTAL for four years (<i>Total Price in EUR (per year) x 4</i>)		

Date: _____ Signature of authorised representative: _____

Print name: _____

Position in company: _____

Annex IV: Exclusion Criteria Declaration to be completed by Tenderers

Upon honour and detail of supporting documentation required

It is MANDATORY to complete all parts highlighted in grey

The undersigned (insert name of the signatory of this form):

☐ Representing the following legal person: (only if the economic operator is a legal person)

Full official name: _____

Official legal form: _____

Full official address: _____

VAT registration number: _____

OR

☐ In [his][her] own name (only if the economic operator is a natural person)

➤ declares that the above-mentioned legal person³ is not in one of the following situations:

- a) is bankrupt or being wound up, is having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of proceedings concerning those matters, or is in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- b) has been convicted of an offence concerning professional conduct by a judgment of a competent authority of a Member State which has the force of *res judicata*;
- c) has been guilty of grave professional misconduct proven by any means which the contracting authorities can justify including by decisions of the European Investment Bank and international organisations;
- d) is not in compliance with all its obligations relating to the payment of social security contributions and the payment of taxes in accordance with the legal provisions of the country in which it is established, with those of the country of the contracting authority and those of the country where the contract is to be performed;
- e) has been the subject of a judgement which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation, money laundering or any other illegal activity, where such activity is detrimental to the European Union's financial interests;
- f) is a subject of an administrative penalty for being guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in a procurement procedure or failing to supply this information, or having been declared to be in serious breach of its obligations under contracts covered by the European Union's budget.

³ In case of NATURAL person, replace "the above-mentioned legal person" by "he or she"

- declares that the natural persons with power of representation, decision-making or control⁴ over the above-mentioned legal entity are not in the situations referred to in b) and e) above;
 - declares that the above-mentioned legal person⁵:
- g) has no conflict of interest in connection with the contract; a conflict of interest could arise in particular as a result of economic interests, political or national affinity, family, emotional life or any other shared interest;
- h) will inform the contracting authority, without delay, of any situation considered a conflict of interest or which could give rise to a conflict of interest;
- i) has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain, and has not accepted and will not accept any advantage, financial or in kind, to or from any party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, inasmuch as it is an incentive or reward relating to award of the contract;
- j) provided accurate, sincere and complete information to the contracting authority within the context of this procurement procedure;
- acknowledges that the above-mentioned legal person⁶ may be subject to administrative and financial penalties⁷ if any of the declarations or information provided prove to be false.
 - Confirm that the required supporting documentation, as indicated below, is provided and attached to this signed declaration.

In case of award of contract, the following evidence shall be provided upon request and within the time limit set by the contracting authority:

For situations described in (a), (b) and (e), production of a recent extract from the judicial record is required or, failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. Where the tenderer is a legal person and the national legislation of the country in which the tenderer is established does not allow the provision of such documents for legal persons, the documents should be provided for natural persons, such as the company directors or any person with powers of representation, decision making or control in relation to the tenderer.

For the situation described in point (d) above, recent certificates or letters issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the tenderer is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions.

For any of the situations (a), (b), (d) or (e), where any document described in two paragraphs above is not issued in the country concerned, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.

⁴ This covers the company directors, members of the management or supervisory bodies, and cases where one natural person holds a majority of shares.

⁵ In case of NATURAL person, replace "the above-mentioned legal person" by "he or she"

⁶ In case of NATURAL person, replace "the above-mentioned legal person" by "he or she"

⁷ As provided for in Article 109 of the Financial Regulation (EU, Euratom) 966/2012 and Article 145 of the Rules of Application of the Financial Regulation

If the tenderer is a legal person, information on the natural persons with power of representation, decision making or control over the legal person shall be provided only upon request by the contracting authority.

Date: _____ Signature of authorised representative: _____

Print name: _____

Position in company: _____

Annex V – Draft Contract

For information only

Contract for supply of goods & services (short-form) for the EMA Information Service

European Medicines Agency (hereinafter referred to as "the Agency"), which is represented for the purposes of the signature of this contract by **[name in full and title]**, of the one part, and

[Name of company] whose registered address is at **[complete]** (hereinafter referred to as "the Contractor"), represented for the purposes of the signature of this contract by **[name in full and title]**, a duly authorised officer of the Contractor of the other part,

Have agreed

1. Definitions

1.1 In these Conditions:

'Confidential information'

means any information intentionally or unintentionally provided directly or indirectly by either the Agency or the Contractor to the other in oral or documentary form or by way of electronically accessible media or other tangible form or by demonstrations;

'Conditions'

means the standard terms and conditions of purchase set out in this document and (unless the context otherwise requires) includes any special terms and conditions agreed in Writing between the Agency and the Contractor;

'Contract'

means the contract for the sale and purchase of the Goods and the supply and acquisition of the Services which is constituted by the Purchase Order and these Conditions (including all terms and conditions incorporated herein by reference);

'Delivery address'

means the loading bay of the Agency at 1-7 Westferry Loading Bay, Ontario Way, Canary Wharf, London, E14 4HA;

'Goods'

means the goods (including any instalment of the Goods or any part of them) described in the Purchase Order;

'Intellectual property rights'

means any database rights, copyright, trademarks, domain names, designs or patents (whether registered or unregistered or capable of registration) including but not limited to all other intellectual or

industrial property rights such as know-how, trade secrets and goodwill;

'Purchase Order'

means the Agency's purchase order to which these Conditions are annexed;

'Price'

means the price of the Goods and/or the charge for the Services as offered in the Contractor's response of **[complete]**;

'Services'

means the services (if any) described in the Purchase Order;

'Specification'

includes the specification, type and quality of the Goods or Services required in the Agency's invitation to tender and technical specifications of **[complete]** and offered in the Contractor's response thereto of **[complete]** and includes any plans, drawings, data or other information relating to the Goods or Services; and

'Writing'

includes letter, facsimile transmission and comparable means of communication.

1.2 Any reference in these Conditions to a statute or a provision of a statute shall be construed as a reference to that statute or provision as amended, re-enacted or extended at the relevant time.

1.3 The headings in these Conditions are for convenience only and shall not affect their interpretation.

2. Basis of purchase

2.1 The Purchase Order constitutes an offer by the Agency to purchase the Goods and/or acquire the Services subject to these Conditions.

2.2 These Conditions shall apply to the Contract incorporating the Contractor's standard master agreement as set out in the annex (the "Master Agreement"), but otherwise to the exclusion of any other terms and conditions and or conditions which might be implied by trade custom, practice or other course of dealing on which any quotation has been given to the Agency or subject to which the Purchase Order is accepted or purported to be accepted by the Contractor.

2.3 In the event of a conflict between these Conditions and the Agreement of the Contractor, the latter shall prevail to the exclusion of the conflicting provision in these Conditions with the exception of Articles 5.1, 5.2, 5.3, 5.4 and 5.5 of these Conditions which shall prevail.

2.4 The Purchase Order will lapse unless unconditionally accepted by the Contractor in Writing within 7 calendar days of its date, unless otherwise so stated in the Purchase Order.

2.5 No variation to the Purchase Order or these Conditions shall be binding unless said variation is required under clause 2.3 above or is agreed in Writing between the authorised representatives of the Agency and the Contractor.

3. Specifications

3.1 The quantity, quality and description of the Goods and/or the Services shall, subject as provided in these Conditions, be as specified in the Purchase Order and/or in any applicable Specification supplied by the Agency to the Contractor or agreed in Writing by the Agency. The Contractor shall supply the Goods and perform the Services to a high professional standard and in any event with reasonable skill and care. It shall perform the Services and provide the Goods in accordance with technical means, standards and procedures based on best professional practice in the relevant field and, in particular, with the ISO 9000 standards.

3.2 Any Specification supplied by the Agency to the Contractor, or specifically produced by the Contractor for the Agency, in connection with the Contract, together with the copyright, design rights or any other Intellectual Property Rights in the Specification, shall be the exclusive property of the Agency. The Contractor shall not disclose to any third party or use any such Specification except to the extent that it is or becomes public knowledge through no fault of the Contractor, or as required for the purpose of the Contract.

3.3 The Contractor shall comply with all applicable regulations or other legal requirements concerning the manufacture, packaging, packing and delivery of the Goods and the performance of the Services.

3.4 The Contractor shall not unreasonably refuse any request by the Agency to inspect and test the Goods during manufacture, processing or storage at the premises of the Contractor or any third party prior to despatch, and the Contractor shall provide the Agency with all facilities reasonably required for inspection and testing.

3.5 If as a result of inspection or testing the Agency is not satisfied that the Goods will comply in all respects with the Contract, and the Agency so informs the Contractor within 7 calendar days of inspection or testing, the Contractor shall take such steps as are necessary to ensure compliance.

3.6 The Goods shall be marked in accordance with the Agency's instructions and any applicable regulations or requirements of the carrier, and properly packed and secured so as to reach their destination in an undamaged condition.

4. Price of the Goods and Services

4.1 The Price of the Goods and the Services shall be as stated in the Purchase Order and, unless otherwise so stated, shall be:

4.1.1 exclusive of any applicable value added tax; and

4.1.2 inclusive of all charges for packaging, packing, shipping, carriage, insurance and delivery of the Goods to the Delivery Address and any duties, imposts or levies other than value added tax.

4.2 No increase in the Price may be made (whether on account of increased material, labour or transport costs, fluctuation in rates of exchange or otherwise) without the prior consent of the Agency in Writing.

4.3 The Agency shall be entitled to any discount for prompt payment, bulk purchase or volume of purchase customarily granted by the Contractor, whether or not shown on its own terms and conditions of sale.

5. Terms of payment

5.1 The Contractor shall be entitled to invoice the Agency on or at any time after delivery of the Goods or performance of the Services, as the case may be, and each invoice shall quote the number of the Purchase Order.

5.2 Payment of the charges under the contract shall be made only if the Contractor has fulfilled all its contractual and legal obligations by the date on which the invoice is correctly submitted.

5.3 Unless otherwise stated in the Purchase Order, the Agency shall pay the Price of the Goods and the Services no later than 30 days from receipt and verification by the Agency of a proper invoice with a breakdown of the Price or, if later, after acceptance of the Goods or Services in question by the Agency. Within four months of completion of the Services and/or delivery of the Goods the Contractor shall submit an admissible invoice, indicating the Contract reference number and the Agency reference which shall be communicated from time to time, for payment.

5.4 The Agency shall be entitled to set off against the Price any sums owed to the Agency by the Contractor.

5.5 Payments shall be executed in Euro or in Pounds Sterling according to the currency of the Contract. The Agency shall use the monthly accounting exchange rate established by the European Commission and published on its website, applicable on the day on which the payment order is issued by the Agency. The costs of the transfer shall be borne by the Agency.

6. Delivery

6.1 The Goods shall be delivered to, and the Services shall be performed at, the Delivery Address on the date or within the period stated in the Purchase Order, in either case during the Agency's usual business hours.

6.2 Where the date of delivery of the Goods or of performance of the Services is to be specified after the placing of Purchase Order, the Contractor shall give the Agency reasonable notice of the specified date.

6.3 The time of delivery of the Goods and of performance of the Services is of the essence of the Contract.

6.4 A packing note quoting the number of the Purchase Order must accompany each delivery or consignment of the Goods and must be displayed prominently.

6.5 If the Goods are to be delivered, or the Services are to be performed, by instalments, the Contract will be treated as a single contract and not severable.

6.6 The Agency shall be entitled to reject any Goods delivered which are not in accordance with the Purchase Order, and shall not be deemed to have accepted any Goods until the Agency has had a reasonable time to inspect them following delivery or, if later, within a reasonable time after any latent defect in the Goods has become apparent.

6.7 The Contractor shall supply the Agency in good time with any instructions or other information required to enable the Agency to accept delivery of the Goods and performance of the Services.

6.8 The Agency shall not be obliged to return to the Contractor any packaging or packing materials for the Goods, whether or not any Goods are accepted by the Agency.

6.9 If the Goods are not delivered or the Services are not performed on the due date then, without prejudice to any other remedy, the Agency shall be entitled to deduct from the Price or (if the Agency has paid the Price) to claim from the Contractor by way of liquidated damage for delay one per cent of the Price for every week's delay, up to a maximum of ten per cent.

7. Risk and property

7.1 Risk of damage to or loss of the Goods shall pass to the Agency upon delivery at the Delivery Address to the Agency in accordance with the Contract.

7.2 Title to the Goods shall pass to the Agency upon delivery.

8. Warranties, liability and indemnity

8.1 The Contractor warrants to the Agency that the Goods:

8.1.1 will be of satisfactory quality (within the meaning of the Sale of Goods Act 1979, as amended) and fit for any purpose held out by the Contractor or made known to the Contractor in Writing at the time the Purchase Order is placed;

8.1.2 will be free from defects in design, material and workmanship;

8.1.3 will correspond with any relevant Specification or sample; and

8.1.4 will comply with all statutory requirements and regulations relating to the sale of the Goods.

8.2 The Contractor warrants to the Agency that the Services will be performed by appropriately qualified and trained personnel, with due care and diligence and to such high standard of quality as it is reasonable for the Agency to expect in all the circumstances.

8.3 Without prejudice to any other remedy, if any Goods or Services are not supplied or performed in accordance with the Contract, then the Agency shall be entitled:

8.3.1 to require the Contractor to repair the Goods or to supply replacement Goods or Services in accordance with the Contract within 7 days; or

8.3.2 at the Agency's sole option, and whether or not the Agency has previously required the Contractor to repair the Goods or to supply any replacement Goods or Services, to treat the Contract as discharged by the Contractor's breach and require the repayment of any part of the Price which has been paid.

8.4 Subject to clause 8.5 below and save for indirect or consequential loss, the Contractor shall indemnify the Agency in full against all claims, liability, damages, costs and expenses (including legal and other professional expenses) awarded against, suffered, incurred, or agreed to be paid by the Agency as a result of or in connection with:

8.4.1 breach of any warranty given by the Contractor in relation to the Goods or the Services;

8.4.2 any claim that the Goods infringe, or their importation, use or resale, infringes, the patent, copyright, design right, trade mark or other intellectual property rights of any other person, except to the extent that the claim arises from compliance with any Specification supplied by the Agency;

8.4.3 any liability under the Consumer Protection Act 1987 in respect of the Goods;

8.4.4 any act or omission of the Contractor or its employees, agents or sub-contractors in supplying, delivering and installing the Goods; and

8.4.5 any act or omission of any of the Contractor's personnel in connection with the performance of the Services.

8.5 The Contractor's liability shall be capped at twice the amount payable under the Contract, but shall be limited in respect of claims arising (1) from death or personal injury caused by the negligence of the Contractor, (2) due to fraud or fraudulent misrepresentation of the Contractor, or (3) under clause 13.1.

8.6 In the event of an action being brought by a third party against the Agency in connection with the performance of this Contract which does not fall within 8.4 above, the Contractor shall assist the Agency including in the event of any alleged breach of Intellectual Property Rights. Expenditure incurred by the Contractor to this end may be borne by the Agency at its sole discretion.

8.7 Neither the Contractor nor the Agency shall be liable to the other or be deemed to be in breach of the Contract by reason of any delay in performing, or any failure to perform, any of its obligations in relation to the Goods or the Services, if the delay or failure is beyond that party's reasonable control. Without prejudice to the generality of the foregoing, the following shall be regarded as causes beyond either party's reasonable control: Act of God, explosion, flood, tempest, fire or accident; war or threat of war, sabotage, insurrection, civil disturbance or requisition; acts, restrictions, regulations, bye-laws, prohibitions or measures of any kind on the part of any governmental, parliamentary or local authority; import or export regulations or embargoes; strikes, lock-outs or other industrial actions or trade disputes (whether involving employees or either the Contractor or the Agency or of a third party); difficulties in obtaining raw materials, labour, fuel, parts or machinery; power failure or breakdown in machinery.

9. Termination

9.1 The Agency shall be entitled to cancel the Purchase Order in accordance with the termination provisions in the Master Agreement.

10. Notice

10.1 Any notice or other communication relating to the Contract shall be made in Writing and shall bear the number of the Purchase Order and shall be sent to the appropriate address set out in the Purchase Order or as each party may notify to the other. Ordinary mail shall be deemed to have been received by the Agency on the date on which it is registered by the department responsible and referred to in the Purchase Order. All email and facsimile communications are deemed received on the working day following transmission. All notices or other communications shall be sent to the respective addresses set out in the Purchase Order.

11. Confidentiality

- 11.1 The Contractor undertakes to treat in the strictest confidence and not make use of or divulge or disclose to any third parties any Confidential Information. The Contractor shall continue to be bound by this undertaking after the termination or expiry of this Contract.
- 11.2 The Contractor shall obtain from each member of their Contractor's staff, any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the performance of the Contract, an undertaking that they will respect the confidentiality of any of the Confidential Information and that they will not divulge or disclose to any third parties or use for their own benefit or that of any third party any Confidential Information not available publicly, even after termination or expiry of this Contract.

12. Intellectual Property Rights

- 12.1 The Contractor represents and warrants that the Intellectual Property Rights arising, or utilised in the performance of this Contract are or shall be original and will not infringe any Intellectual Property Rights owned by any third party (including, but without limitation to, all moral rights).
- 12.2 The Contractor assigns to the Agency, with full title guarantee and free from all third party rights, the Intellectual Property Rights arising or created hereunder and hereby assigns to the Agency, by way of present assignment of future rights, all such Intellectual Property Rights that may come into existence in the future.
- 12.3 The Contractor shall, promptly at the Agency's request, do or procure to be done all such further acts and things and the execution of all such other documents as the Agency may from time to time require for the purpose of securing for the Agency the full benefit of the Services, including all right, title and interest in and to the Intellectual Property Rights and all other rights assigned to the Agency in accordance herewith.

13. Intellectual Property Rights Indemnity

- 13.1 The Contractor shall indemnify and hold the Agency harmless from all claims and all direct, indirect and consequential liabilities (including loss of profits, loss of business, depletion of goodwill and similar losses), costs, proceedings, damages and expenses (including legal and other professional fees and expenses) awarded against, suffered, incurred or agreed to be paid by the Agency as a result of or in connection with any alleged or actual infringement, whether or not under English law, of any third party's Intellectual Property Rights or other rights arising out of the use or supply of the Goods or the Services or either party's performance of this Contract. The Contractor's liability under this indemnity shall not be subject to the exclusions and limitations of liability set out in clause 8.5.

14. General

- 14.1 The Purchase Order is personal to the Contractor and the Contractor shall not assign or transfer or purport to assign or transfer to any other person any of its rights or sub-contract any of its obligations under the Contract without prior consent in Writing from the Agency.
- 14.2 Notwithstanding any other provision of this Contract, nothing in this Contract confers or purports to confer any right to enforce any of its terms on any person who is not a party to it and the provisions of the Contracts (Rights of Third Parties) Act 1999 shall not apply.

- 14.3 No waiver by the Agency of any breach of the Contract by the Contractor shall be considered as a waiver of any subsequent breach of the same or any other provision.

- 14.4 If any provision of the Contract shall become or shall be declared by any court of competent jurisdiction to be invalid or unenforceable in any way, such invalidity or unenforceability shall in no way impair or affect any other provision all of which shall remain in full force and effect.

- 14.5 The Contract and any other matter or dispute arising out of or in connection with it (including non-contractual disputes and claims) shall be governed by the laws of England and Wales, and the Contractor irrevocably agrees to submit to the exclusive jurisdiction of the Courts of England and Wales.

15. Access, inspection and audits

- 15.1 The Agency and the European Anti-Fraud Office may check or have an audit on the performance of the Contract. It may be carried out either directly by its own staff or by any other outside body authorised to do so on its behalf. Such checks and audits may be initiated during the performance of the Contract and during a period of five years which starts running from the date of expiry of the Contract. The audit procedure shall be deemed to be initiated on the date of receipt of the relevant letter sent by the Agency. Audits shall be carried out on a confidential basis.

- 15.2 The Contractor shall, or shall procure that its subcontractors shall gather, compile, correlate, collect and otherwise maintain all relevant accounts, records, books and other information in original documentary form or on easily accessible electronic media, arising in connection with the performance of the Contract for a period of five years which starts running from the date of expiry of the Contract.

- 15.3 The Contractor shall allow the Agency's staff and outside personnel authorised by the Agency the appropriate right of access to sites and premises where the Contract is performed and to all the information, including information in electronic format, needed in order to conduct such checks and audits. The Contractor shall ensure that the information is readily available at the moment of the check or audit and, if so requested, that information be handed over in an appropriate form.

- 15.4 On the basis of the findings made during the audit, a provisional report shall be drawn up. It shall be sent to the Contractor, which shall have 30 days following the date of receipt to submit observations. The final report shall be sent to the Contractor within 60 days following the expiry of that deadline. On the basis of the final audit findings, the Agency may recover all or part of the payments made and may take any other measures which it considers necessary.

- 15.5 By virtue of Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities and Regulation (EC) No 883/2013 of the European Parliament and the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF), OLAF may also carry out on-the-spot checks and inspections in accordance with the procedures laid down by European Union law for the protection of the financial interests of the Agency against fraud and other irregularities. Where appropriate, the findings may lead to recovery by the Agency.

15.6 The Court of Auditors shall have the same rights as the Agency, notably right of access, for the purpose of checks and audits.

16. Duration

The Contract is concluded for a period of 48 (forty-eight) months.

17. Price Revision

Revision of Price shall be made according to the Master Agreement.

Signatures

For the Contractor,
[Company name/forename/surname/title]

Date: _____

For the Agency,
[forename/surname/title]

Date: _____

Annex VI – [Tenderer's name] Terms and Conditions