EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 February 2015
EMA/96238/2015 Rev.1

Technical specifications for service concession

Pharmacovigilance Training - ref. EMA/2014/35/RE

Table of contents

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Technical specifications for training concession (pharmacovigilance)

No. EMA/2014/35/RE

1. Title of the invitation for a concession

This document contains the Technical Specifications for the invitation for proposals as to the delivery of a training concession in the area of pharmacovigilance, reference no. EMA/2014/35/RE.

The concession notice for this invitation has been published in the Official Journal of the European Union ref. S 37 on 21 February 2015.

Executive summary and indicative timetable

Item	Summary
Authority	European Medicines Agency hereinafter referred to as "EMA" or "the Agency".
Purpose	This call for submission of proposals aims to put into place a concession arrangement with an economic operator for the delivery of professional, large-scale training and meeting programmes tailored towards specific learning objectives in the area of pharmacovigilance, including EudraVigilance, international standardisation and Article 57.
Type of agreement	One concession agreement is expected to be signed. The agreement will lay down the legal, technical and administrative provisions governing the relations between the Agency and the concessionaire during its period of validity.
Duration of concession agreement	Four years with two possible extensions (4 + 2 + 1). Maximum possible duration: seven years.
Places of delivery	1. EMA premises at 30 Churchill Place, Canary Wharf, London E14 5EU, United Kingdom 2. Alternative sites in London 3. Other EEA countries
Volume (indicative)	The estimated annual concession volume is approx. 160 full days of training, plus 5 Information Days, and additional ad hoc training courses, as required. These figures may vary over the period of validity of the concession agreement.
Joint Offers	Offers from consortia & partnerships are permitted.
Launch in OJEU	21 February 2015
Deadline for request of clarifications from EMA	10 April 2015 Requests to be sent in writing to: training_concession@ema.europa.eu

Item	Summary
Closing date for receipt of proposals	17 April 2015 Please see the *Invitation to submit a concession proposal* for detailed delivery instructions.
Completion of evaluation of proposals	May 2015 (estimated)
Start of services	July 2015 (estimated)

2. Objectives and context of the concession

The European Medicines Agency ("the Agency" or "EMA") 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 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. The Agency's budget is subject to checks and audits by the Court of Auditors.

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 network.

The Agency also gives scientific advice and protocol assistance 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 EU Network Training Centre is a joint EMA/HMA (Heads of Medicines Agencies) initiative to harmonise training in Europe through implementing a common online platform for scientific and regulatory training, based on a competency matrix and accompanied by a training strategy, curriculum and methodology. In this context, the Agency aims to put in place a first concession in the area of training for pharmacovigilance and related IT systems and standards to support the content development and organisational and logistical training aspects in this area. The stakeholders (target) of this training will be mainly National Competence Authorities within all EU and EEA-EFTA states, pharmaceutical industry, sponsors of clinical trials and EMA but should be also open to international participation.

3. Subject of the concession

The Agency considers entering into a concession agreement for the delivery of professional, large-scale training and meeting programmes tailored towards specific learning objectives in the area of pharmacovigilance including all IT system related aspects such as EudraVigilance in support of electronic reporting of adverse drug reaction reporting, signal detection and management the electronic submission of information on medicines to the Article 57 database (also referred to as XEVMPD), the submission process to the PSUR Repository as well as the use of international formats, standards and terminologies.

3.1. Scope

The successful applicant will act as the conference organiser for the Agency for the following educational offerings (training courses and information days):

- EudraVigilance specific topics
- Medical literature monitoring
- Signal detection and management
- Pharmacovigilance audits, inspections and Pharmacovigilance System Master File (PSMF)
- Pharmacovigilance referrals
- Risk management plans
- Periodic Safety Update reports (PSURs)
- Regulatory aspects in pharmacovigilance
- Electronic submission of information on medicines
- International formats, standards and terminology topics
- Training courses and information days on demand (including webinars)

The exact frequency of the training courses and information days will be determined by the Agency, depending on the stakeholders' interest in the courses offered.

Subject to availability, the courses and information days will mostly take place at the Agency's premises in Canary Wharf, London (or such other premises occupied by the Agency from time to time). The provisions of section 3.8 shall apply to the use of the Agency's premises for the courses and information days.

If meeting room facilities are not available at the Agency's premises, it will be the concessionaire's responsibility to secure and pay for an alternative site in London, preferably in the Canary Wharf area.

There will be instances where these courses will also be organised in collaboration with national competent authorities in one of the countries of the EEA. In such instances it will be the responsibility of the concessionaire to liaise directly with the EU Network Training Centre (EU NTC)[1], and to secure and pay the necessary meeting room facilities.

[1] http://www.hma.eu/otsg.html?&L=0

3.2. Rationale

The rationale for the training and meeting concession with regard to the scope as outlined in section 3.1. is the delivery of professional, large-scale training and meeting programmes for the Agency tailored towards specific learning objectives in the context of pharmacovigilance and related IT programmes.

The delivery of these wide-ranging, highly customised and extensive programmes is absolutely essential to reach all stakeholders that have reporting and other pharmacovigilance obligations towards the Agency and national competent authorities in the EEA. The concessionaire will be instrumental in achieving these objectives from an administrative point of view, taking into account the high volume of stakeholder interaction required.

3.3. Key learning objectives

The exact learning objectives for each training course and information day will be defined by the Agency as necessary at the time of the training programme development. The Agency will also determine the composition of the training/information day programme committee, the composition of which will be determined by the subject matter, but will typically include at least one EMA staff member plus other experts. Initial guidance as regards learning objectives is provided in the table under point 6. ('Estimated concession volume').

3.4. Target audience

The target audience of these training and meeting programmes of the Agency in the area of pharmacovigilance is as follows: Representatives from national competent authorities, commercial and non-commercial organisations, marketing authorisation holders, Small and Medium Sized Enterprises (SMEs), academia as well as any other interested parties. The table under point 6. provides the key stakeholders targeted for each proposed training module.

3.5. General terms and conditions

The organisation of a course will require a minimum of 10 participants. In cases where there are less than 10 interested participants the course shall be cancelled and re-scheduled at a future date which shall be agreed with the Agency. Registration fees shall be refunded by the concessionaire to the participants who have already paid. Any other expenses arising from the cancellation (e.g. room hire costs etc.) shall be borne by the concessionaire.

Acknowledgements of registration for training courses and information days shall be dispatched within 24 hours.

It is anticipated that the concessionaire will update on a daily basis their registration portal with the number of available spaces. Once all available spaces have been filled, a waiting list on a first-come, first-served basis shall be created.

English will be the official language for all training courses and meetings and associated materials. Where training is organised locally in an EEA country, it may be necessary for the concessionaire to provide a trainer with local language skills, although training material will be provided in English only.

Publication of all communication and promotional material in the context of the activities outlined in section 3.1. will require specific approval of the Agency.

Ownership of copyright of all materials developed within the framework of the activities specified in section 3.1. remains with the Agency.

All training sessions and information days shall be recorded and the recordings subsequently be made available for training purposes to staff at the European Medicines Agency and at National Competent Authorities in EEA countries. The recording of training courses and information days taking place at the Agency's premises will be the responsibility of the EMA Audiovisual Team. The concessionaire shall be responsible for the recording of all events taking place outside the Agency (the relevant technical specifications will be provided as required).

3.6. Pricing Strategy

The pricing model shall be based on the following general principles:

- **Waiver of fees:**

  a) Training courses:

  - for up to five attendees from the European Medicines Agency (excluding speakers)
  - for one participant per national competent authority in EEA countries and from national competent authorities that are part of the EU enlargement programme (up to a maximum of five per module)

  b) Information days:

  - for up to ten attendees from the European Medicines Agency in information days
  - for one participant per national competent authority in EEA countries and from national competent authorities that are part of the EU enlargement programme (up to a maximum of ten per module)

  Registrants from the European Medicines Agency and national competent authorities shall not have the right for first refusal. All registrations shall be treated on a first-come, first-served basis.

- **Price reductions:**

	Description	Discount
A	For additional participants from national competent authorities in the EEA, non-commercial organisations and universities	50%
B	For participants from SMEs	35%
C	For participants who register for more than one course ('multiple course discount')	20%
D	For participants who register for all 17 modules of course T.9 'Regulatory aspects in pharmacovigilance' (see courses marked 'as part of T9' in the table provided under section 6. 'Estimated concession volume', page 13 ff)	25%

- The concessionaire will cover travel and accommodation expenses and a daily allowance or honorarium for instructors/speakers (see also section 3.8.2.).

- Participants from SMEs (micro-, small- and medium-sized enterprises) will need to send proof of their SME status to the training/meeting organiser along with their registration form.
- The concessionaire may, in agreement with the Agency, limit the number of attendees with discounted fees per meeting in order to cover its meetings costs.
- Prices for training modules that may be developed during the validity of the concession agreement and that are not listed under Section 6. 'Estimated concession volume', shall be subject to agreement with the Agency.
- The concessionaire will pay for meeting room facilities, refreshments and lunches.

3.7. Price revision

Registration fees provided in the price list (Annex I) shall be fixed and not subject to revision during the first year of the performance of the concession agreement.

From the beginning of the second year of performance of the concession, prices may be revised upwards or downwards each year in accordance with the formula set out below, where such revision is requested by one of the concession parties by notice served no later than three months before the anniversary of the date on which the agreement became effective.

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 (http://epp.eurostat.ec.europa.eu).

Revision shall be calculated in accordance with the following formula:

$$A_r = A_0 \times \frac{I_r}{I_0}$$

where

A_r	=	revised total amount;
A_o	=	total amount in the original application;
I_o	=	index for the month in which the validity of the application expires;
I_r	=	index for the month corresponding to the date of receipt of the letter requesting revision of prices.

3.8. Support from the European Medicines Agency

The Agency will contribute, on the basis of its coordination role and as specified in this paragraph 3.8, to the preparation of the training courses and information days as outlined in section 3.1. taking into account the need for these programmes to support the pharmacovigilance activities in the EEA.

For each training topic the Agency shall appoint a coordinator responsible for the development, implementation and coordination of the training or meeting and who shall act as the contact point for the concessionaire.

Depending on availability, the Agency will assist in securing meeting rooms at its premises for training courses taking place at the Agency. The Agency has in place a policy on the recuperation of costs incurred when hosting external organisations' events at its premises. This policy (provided in Annex VI) foresees that the external organisation shall be charged a cost per paying participant in the event. The concessionaire shall pay the Agency for use of the Agency's premises in accordance with the policy set out at Annex VI (or such other policy as notified by the Agency to the concessionaire from time to time). Guidance on the payment procedure is provided in the document 'Instruction paper for external

organisations', as attached to Annex VI. The recording of training courses and information days taking place at the Agency's premises will be the responsibility of the EMA Audiovisual Team.

3.9. Roles and responsibilities of the concessionaire

The following provides an overview of the roles and responsibilities of the concessionaire. Detailed roles and responsibilities will vary from event to event and shall be agreed on a case-by-case basis and in advance with the responsible Agency coordinator.

3.9.1. Material and technical support

The concessionaire shall:

- Work with the Agency to develop an annual training plan.
- Support the Agency in preparing and developing course programmes and content. The concessionaire is expected to deliver a first draft for input by the Agency.
- Work with the Agency to develop and update the training material.
- Assist in the drafting and proofreading of new or modified training materials. It is anticipated that all materials shall be reviewed by the Agency prior to the organisation of each training.
- Be responsible for the printing and distribution/provision of the training material.
- Collect attendee and instructor feedback and provide the originals of such feedback to the Agency after each training course.
- Offer follow-up training for participants in the form of webinars.
- Supply instructors with a CD (or other electronic media) including updated training course material, whenever substantial updates have been implemented.
- Supply all participants with a CD (or other electronic media) of the training course material (password protected).
- Supply all past participants with a CD (or other electronic media) including updated training course material whenever significant updates have been implemented.
- Provide refreshments during breaks and lunches.
- Where applicable, identify and pay costs associated with hiring suitable venues for training other than the Agency.
- Provide meeting management services.

3.9.2. Instructors / Speakers

The concessionaire shall:

- Establish a pool of committed instructors approved by the Agency (professional instructors and volunteer instructors from national competent authorities as well as pharmaceutical industry, academia or other relevant public health or standardisation institutions). CVs of all instructors are to be made available to the Agency.
- Ensure and facilitate the availability of instructors for each course (and back-up instructors in case of non-availability).

- Include where possible both volunteer instructors from industry or national competent authorities and professional instructors for each course.
- Remunerate instructors/speakers as follows:

    a) Training:

    Instructors shall be paid/reimbursed travel and accommodation, in addition to which they may choose to receive a daily allowance for other expenses on production of original receipts, or receive an honorarium.

    b) Information Days:

    All speakers shall have their registration fee waived.
- Organise 'train-the-instructor' sessions at the premises of the Agency.
- Reimburse travel and accommodation costs for volunteer instructors from national competent authorities when they attend the 'train-the-instructor' session.
- Organise follow-up training for instructors if requested by the Agency.
- Prepare training standard operating procedures (SOPs) including aspects such as competency assessment.
- Prepare instructor competency evaluation forms subject to the approval of the Agency.
- Perform the competency assessment of training participants, as required.

3.9.3. Training in EEA countries

The concessionaire shall:

- Organise training in EEA countries as agreed with the Agency.
- Identify and pay costs associated with hiring suitable venues for training in EEA countries.
- Provide meeting management services.
- If requested, ensure that at least one instructor will have local language skills in support of the training to be conducted.

3.9.4. Conference services

The concessionaire shall:

- Recruit and register the participants and collect the fees.
- Ensure compliance of applicable laws and regulation relating to the processing of personal data and privacy of participants.
- Provide relevant information to participants including travel and accommodation information.
- Provide participant lists to the Agency.
- Distribute, collect and summarise course and instructor evaluation forms and provide feedback (including copies of the evaluation forms) after each training course for improvement to instructors and to the Agency.

- Facilitate training of instructors and participants with regard to material and system updates (e.g. webinars).
- Provide certificates of attendance as appropriate and agreed in advance with the Agency.

3.9.5. Promotion

The concessionaire shall:

- Prepare promotional material in collaboration with the Agency.
- Provide all promotional material to the Agency within a reasonable timeframe (minimum 14 working days) for approval before publication and release.
- Provide all promotional activities associated with the programme including brochures for attendees, FAQs and electronic newsletters and a communication plan (e.g. rationale for the programme, value and benefits, who should participate, how to participate etc.).
- Ensure that the Agency logo is shown in all communication and information distributed relating to the training event (note: the Agency logo must not be used by the concessionaire outside the courses/meetings subject of this concession agreement).

3.9.6. Certification

The concessionaire shall maintain an electronic record of attendance and certified users accessible by the Agency.

3.9.6.1. Attendance certificates

The concessionaire shall issue attendance certificates to all participants in training courses and information days.

3.9.6.2. Competency assessments / User certificates

In relation to certain training courses, and subject to approval by the Agency, the concessionaire shall:

- Perform competency assessment on behalf of the Agency.
- Distribute and collect competency assessment forms (to be archived at the Agency).
- Communicate competency assessment results to participants.
- Provide user certificates to the participants.
- Provide post-training support.

3.9.7. Additional roles and responsibilities relating to the organisation of 'Information Days'

The concessionaire shall:

- Organise information days as agreed at the Agency's premises or in locations in the EEA.
- Facilitate programme committee meetings and development of the programme content. Planning meetings shall be hosted by the Agency as necessary.
- Invite speakers from a list of suitable candidates supplied by the Agency.

- Provide templates for slide presentations.
- Produce official meeting material based on the documents provided by the Agency.
- Coordinate participants' materials and handouts.
- Implement revisions of the meeting material based on feedback from the participants, speakers and the European Medicines Agency.
- Provide all promotional activities associated with the programme, including brochures for attendees, FAQs and electronic newsletters, and a communication plan (e.g. rationale for the programme, value and benefits, who should participate, how to participate).

3.10. Reporting

The concessionaire shall collect attendee and instructor feedback and provide such feedback in summarised format (including copies of original feedback) to the Agency after each training course.

At the end of each calendar year the concessionaire shall provide a summary report of all training activities during the past twelve months, including statistics.

At the end of each calendar year the concessionaire shall provide a financial report of all training activities including the organisation of information days during the past twelve months.

The concessionaire shall provide the Agency with an annual audit report of its financial statements relating to the services provided on behalf of the Agency. The audit is to be performed by an independent auditor. The first such audit shall be due within three (3) months following the first anniversary of the coming into force of the concession agreement.

4. Participation

4.1. Agreements on public procurement

Participation in this call for proposals 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 applicants 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 procedure is not, however, open to applicants from countries which have ratified the Multilateral Agreement on Government Procurement ("GPA").

4.2. Consortia & Partnerships

If the applicant intends to form a consortium or partnership, including subcontracting, in order to deliver this concession agreement it must identify the lead organisation or the legal entity to take responsibility for the applicant and the eventual concession agreement. If applying on behalf of a consortium the applicant must list the names and addresses of all the member organisations of the consortium in its submission.

The following documents must be provided with the concession proposal:

(i) A document signed by the applicant stating clearly the identity, roles, activities and responsibilities of partners and specifying the volume/proportion for each partner.

(ii) A letter of intent by each partner stating its unambiguous undertaking to collaborate with the applicant if it wins the concession and the extent of the resources that it will put at the applicant's disposal for the performance of the concession.

(iii) If requested under points 8, 9, and 10 any documents regarding the exclusion and/or financial and technical capacity for any partner.

If such documents are not provided, the Agency shall assume that the applicant does not intend to form any consortia or partnership.

5. Additional documentation available to applicants

- Further information about the work of the Agency can be obtained on its website: http://www.ema.europa.eu.
- Further information on the topic of pharmacovigilance can be found at: *http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000258.jsp&mid=WC0b01ac05800241de*
- Information on micro-, small- and medium-sized enterprises (SME) can be found at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000059.jsp&mid=WC0b01ac05800240cc

6. Estimated concession volume

The subject of this concession is the organisation of face-to-face trainings and information days.

The estimated annual requirements in the area of pharmacovigilance training are provided in the table below.

The individual topics and modules are provided as an indication only and, as such, are not binding. The combination of individual modules will be agreed annually in advance by the Agency and may be subject to change during the course of the concession agreement. The estimated concession volume provided may vary over the period of validity of the concession and will be subject to annual revision. It shall be agreed annually in advance with the Agency.

The exact frequency of training courses will be determined by the Agency and discussed with the concessionaire depending on the stakeholders' interest in the courses offered. The duration of the training courses, which is based on a modular approach, can be amended by the Agency taking into account initial experience and feedback from attendees. The Agency also reserves the right to amend the requirements for competency assessment for each of the courses.

As a general guidance, an estimation of attendance figures is provided below; these figures are indicative only and are not to be considered as binding:

- Information days: 100 to 130
- Hands-on training courses: 10 to 18
- Other training courses: 50 to 60
- Other training courses aimed at stakeholder group 1 (i.e. regulators) only: 18 to 20

Topic T=Topic M=Module	**Type** T=Training I=Information Day	**Duration** (in days)	**Key learning objective(s)**	**Stakeholder** 1=Regulators 2=MAHs 3=Sponsors of clinical trials 4=Others	**Training Method** F=face-to-face C=Competency assessment	**Frequency** A=annually D=on demand
T1: ADR reporting and access to EudraVigilance						
T1.M1: Regulatory and procedural aspects	T	0.5	– Describe the role and key features of EudraVigilance (EV) – Understand the adverse reaction reporting requirements (expedited reporting and reporting in special situations) and processes in line with GVP module VI based on several case studies	1, 2, 4	F (**as part of T 9**)	2 x A
T1.M2: Electronic reporting principles based on new ISO ICSR standard and ICH/EU ICSR Implementation Guide	T	1	– Understand the key differences between the new ICSR ICH E2B(R3) and the current ICH E2B(R2) specifications and the implications for ADR reporting in the EU – Discuss the principles of the ICH/EU E2B(R3) Implementation Guide – Describe how to approach backwards and forwards compatibility between ICH E2B(R2) and ICH E2B(R3) – Understand the key principles of the HL7 based ICSR Acknowledgement Message	1, 2, 3, 4	F C	18 x A D if additional offerings are required
T1.M3: EudraVigilance hands-on electronic reporting of ICSRs in the new ICH E2B(R3) format	T	1.5	– Understand the key functionalities of the enhanced EV system functionalities – Apply the ICH E2B(R3) ICSR reporting principles based on different reporting scenarios using EV electronic reporting facilities EVWEB – Apply ICH rules to safety reporting – Describe the Registration process with EudraVigilance – Understand the concepts of electronic transmission of ICSRs – Describe the EudraVigilance Gateway – Describe the Webtrader functions – Explain the reporting processes for fully-automated organisations, Post-function users, and EVWEB users	1, 2, 3, 4	F C	20 x A D if additional offerings are required

Topic T=Topic M=Module	**Type** T=Training I=Information Day	**Duration** (in days)	**Key learning objective(s)**	**Stakeholder** 1=Regulators 2=MAHs 3=Sponsors of clinical trials 4=Others	**Training Method** F=face-to-face C=Competency assessment	**Frequency** A=annually D=on demand
			– Create, validate and send safety messages – Create, validate and send follow-up reports, nullification reports, literature reports, parent-child reports and study reports – Reports with medical and drug history – Apply EudraVigilance business rules – Create and send acknowledgments of received ICSR messages – Query, view, browse and download safety reports – Query, view and browse MedDRA through the EVWEB			
T1.M4: EudraVigilance Access Policy	T	0.25	– Understand the principles of access to EV based on the needs and responsibilities of various stakeholder groups – Describe the procedural and technical aspects of obtaining access to EV data sets	1, 2, 3, 4	F (**as part of T9**)	2 x A
T2: Medical Literature Monitoring						
T2.M1: Regulatory, procedural and technical aspects in line with Detailed Guidance on medical literature monitoring and GVP module VI	T	0.25	– Discuss the key principles of the medical literature monitoring services provided by the Agency – Understand the obligations of the Agency and MAHs – Describe procedural and technical aspects related to literature screening and adverse reaction reporting	1, 2, 4	F (**as part of T9**)	2 x A
T3: Signal detection and management						
T3.M1: Assessor-based signal detection and management	T	0.5	– Describe the key principles of signal detection in EudraVigilance – Understand electronic reaction monitoring reports (eRMRs) based on EudraVigilance data – Understand the signal management process – Describe the validation and confirmation of signals – Discuss the presentation of confirmed signals to the PRAC, issue of	1	F	4 x A

Topic T=Topic M=Module	**Type** T=Training I=Information Day	**Duration** (in days)	**Key learning objective(s)**	**Stakeholder** 1=Regulators 2=MAHs 3=Sponsors of clinical trials 4=Others	**Training Method** F=face-to-face C=Competency assessment	**Frequency** A=annually D=on demand
			– PRAC recommendations and subsequent regulatory outcomes			
T3.M2: Key principles, processes and responsibilities of MAHs/regulators in signal detection and management	T	0.5	– Describe definitions and procedural aspects outlined in GVP module IX – Understand electronic reaction monitoring reports (eRMRs) and ICSR details based on EudraVigilance data – Discuss obligations of MAHs in signal detection, validation and notifications of the Agency and Member States – MAHs' involvement in relation to PRAC recommendations for signals	1, 2	F (**as part of T9**)	2 x A D if additional offerings are required
T3.M3: EudraVigilance data warehouse hands-on for regulators	T	2.5	– Understand the key features of the EudraVigilance Data Warehouse and Analysis System (EVDAS) for the purpose of assessments during the signal management cycle or any other assessment procedure (e.g. PSURs) – Perform routine and ad-hoc queries based on various data retrieval scenarios	1	F C	4 x A
T3.M4: EudraVigilance data warehouse hands-on for regulators "What's new"	T	1	– Understand new and updated key features of the EudraVigilance Data Warehouse and Analysis System (EVDAS) for the purpose of assessments during the signal management cycle or any other assessment procedure (e.g. PSURs) – Perform routine and ad-hoc queries based on various data retrieval scenarios	1	F C	10 x A
T3.M5: EudraVigilance data warehouse hands-on for MAHs	T	1	– Understand the access to EudraVigilance data – Discuss the key features of the EudraVigilance Data Warehouse and Analysis System (EVDAS) for the purpose of access to eRMRs, ICSRs and Article 57 data outputs – Run the electronic Reaction Monitoring Report (eRMR) – Understand and	2	F in combination with T3.M2 C	12 x A (maybe also combined with T3.M2) D if additional offerings are required

Topic T=Topic M=Module	**Type** T=Training I=Information Day	**Duration** (in days)	**Key learning objective(s)**	**Stakeholder** 1=Regulators 2=MAHs 3=Sponsors of clinical trials 4=Others	**Training Method** F=face-to-face C=Competency assessment	**Frequency** A=annually D=on demand
			– interpret the key principles and content of eRMRs – Understand other features available to MAHs in support of signal detection			
T3.M6: EudraVigilance data warehouse hands-on for MAHs "What's new"	T	0.5	– Understand new or updated key features of the EudraVigilance Data Warehouse and Analysis System (EVDAS) for the purpose of access to eRMRs, ICSRs and Article 57 data outputs	2	F in combination with T3.M2 C	D where required
T4: PhV inspections and PhV Master File						
T4.M1: PhV Master File - Regulatory and procedural aspects incl. the role of the Qualified Person Responsible for pharmacovigilance	T	0.25	– Understand the key principles and content of a Pharmacovigilance System Master File (PSMF) in line with GVP module II – Describe the regulatory aspects of preparing and updating a PSMF	1, 2, 4	F (**as part of T9**)	2 x A
T4.M2: How to prepare for PhV audits and inspections	T	0.25	– Describe how to prepare for PhV audits and inspections in compliance with GVP modules III and related procedures and GVP module IV – Discuss lessons learned from PhV inspections and audits	1, 2, 4	F (**as part of T9**)	2 x A
T5: PhV referrals						
T5.M1: Regulatory and procedural aspects and FAQs	T	0.5	– Understand the different referral types related to pharmacovigilance based on EU legislation – Describe the procedural aspects and transparency aspects – Discuss frequently asked questions in the context of pharmacovigilance referrals	1, 2, 4	F (**as part of T9**)	2 x A
T5.M2: Referrals assessor training	T	0.25	– Discuss key principles related to referral assessments – Discuss practical aspects and frequently asked questions	1	F	4 x A

Topic T=Topic M=Module	**Type** T=Training I=Information Day	**Duration** (in days)	**Key learning objective(s)**	**Stakeholder** 1=Regulators 2=MAHs 3=Sponsors of clinical trials 4=Others	**Training Method** F=face-to-face C=Competency assessment	**Frequency** A=annually D=on demand
T5.I: Referrals Information Day	I	1	Provide a forum to discuss aspects such as: – Implementation following referral procedures – Public hearings, patient and healthcare professional involvement – Benefit/risk evaluation in the context of referrals assessments – Frequently asked questions from MAHs – Submission requirements and procedural aspects of the referrals assessment procedure	1, 2, 3, 4	F	1 x A
T6: Risk Management Plans						
T6.M1: Key principles related to risk management plans	T	0.25	– Understand the terminology and principles of risk management – Discuss the responsibilities for risk management – Describe procedural aspects related to risk management plans (incl. submission, updates, assessment) in line with GVP module V	1, 2, 4	F (**as part of T9**)	2 x A
T6.M2: Format and content of risk management plans	T	0.25	– Describe content of a Risk Management Plan in line with GVP module V and points to consider based on practical examples – Discuss frequently asked questions	1, 2, 4	F (**as part of T9**)	2 x A
T6.M3: Risk minimisation measures - Selection of tools and effectiveness indicators	T	0.25	– Understand the principles of risk minimization measures based on the principles set out in GVP module XVI – Describe approaches to assess the effectiveness of risk minimization measures	1, 2, 4	F (**as part of T9**)	2 x A
T6.M4: Risk management plan assessors training	T	1	– Discuss the principles of assessment of risk management plans – Discuss practical aspects and frequently asked questions	1	F	4 x A
T6.M5: Fundamentals of conducting post-authorisation studies	T	0.25	– Describe definitions, principles and procedural aspects for conducting post-	1, 2, 3, 4	F (**as part of T 9**)	2 x A

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in the EU			authorisation studies in line with GVP module VIII – Understand methods of post-authorisation studies – Discuss the impact on risk management systems			
T6.I: Risk Management Information Day	I	1	Provide a forum to: – Discuss the experience with Risk Management Plans from the point of view of assessors of Medicines Regulatory Authorities in the EU and at international level and MAHs – Discuss frequently asked questions and lessons learned – Understand achievements and latest developments at EU and international level	1, 2, 4	F	1 x A
T7: Periodic Safety Update Reports (PSURs)						
T7.M1: Regulatory principles and processes related to PSURs	T	0.25	– Discuss the procedural aspects of PSUR submissions – Understand the key principles related to the list of European Union reference dates and frequency of submission of PSURs – Understand the principles for the evaluation of the risk-benefit balance within PSURs	1, 2, 4	F (**as part of T9**)	2 x A
T7.M2: Format and content of PSURs	T	0.25	– Describe the format and content of PSURs in line with GVP module VII – Discuss frequently asked questions	1, 2, 4	F (**as part of T9**)	2 x A
T7.M3: PSUR assessor training	T	1	– Discuss key principles related to PSUR assessments	1	F	4 x A
T7.I: PSUR Information Day	I	1	Provide a forum to discuss aspects such as: – Implementation experience and questions based on the ICH E2C (R2) format and content – Benefit/risk evaluation in the context of PSUR assessments – Frequently asked questions related to GVP Module VII – Application of the EU reference date list for PSUR submissions – Submission requirements and procedural aspects of	1, 2, 3, 4	F	1 x A

Topic T=Topic M=Module	**Type** T=Training I=Information Day	**Duration** (in days)	**Key learning objective(s)**	**Stakeholder** 1=Regulators 2=MAHs 3=Sponsors of clinical trials 4=Others	**Training Method** F=face-to-face C=Competency assessment	**Frequency** A=annually D=on demand
			the PSUR single assessment procedure – PSUR Repository functionalities – Direct and binding product information updates			
T8: Clinical trials						
T8.M1: SUSAR reporting and access to the EuraVigilance Clinical Trial Module (EVCTM)	T	0.25	– Discuss reporting requirements for SUSARs based on various case scenarios – Describe how to access SUSARs in EVCTM	1,3, 4	F (**as part of T9**) C	2 x A D if dedicated offerings are required
T8.M2: Preparation of Annual Safety Reports (ASRs) Development Safety Update Reports (DSURs)	T	0.25	– Discuss the requirements for the preparation of ASRs/DSURs	1, 3, 4	F (**as part of T9**)	2 x A D if dedicated offerings are required
T8.I: Clinical Trials Information Day	I	1	– Provide a forum to discuss the latest developments related to clinical trials	1, 2, 3, 4	F	1 x A
T9: Regulatory aspects in pharmacovigilance	T	5	Programme based on a combination of modules as outlined under T.1 to T.9 plus additional modules outlined below	1, 3, 4	F	2 X A
T9.M1: Definitions and methods in pharmacovigilance	T	0.25	– Describe key definitions based on EU legislation and consensus fora such as ICH and CIOMS Expert Working Groups – Discuss practical examples based on exercises to illustrate key definitions applied in pharmacovigilance	1, 3, 4	F	2 X A
T9.M2: Medication errors	T	0.25	– Describe the principles of defining and classifying medication errors – Understand reporting requirements in line with EU legislation and in the context of national patient safety reporting requirements	1, 3, 4	F	2 X A
T9.I: Pharmacovigilance Information Day		1	– Provide a forum to discuss latest developments in pharmacovigilance based on topics T1 to T9	1, 2, 3, 4	F	1 x A
T10: Electronic submission of information on medicines						

Topic T=Topic M=Module	**Type** T=Training I=Information Day	**Duration** (in days)	**Key learning objective(s)**	**Stakeholder** 1=Regulators 2=MAHs 3=Sponsors of clinical trials 4=Others	**Training Method** F=face-to-face C=Competency assessment	**Frequency** A=annually D=on demand
T10.M1: ISO Identification of Medicinal Products (IDMP) standards	T	1	– Understand the data models and data elements of the ISO IDMP standards and their application in the context of the EU Implementation Guides – Discuss frequently asked questions – Describe messaging formats applied in the European context	1, 2, 3, 4	F C	12 x A D if additional offerings are required
T10.M2: Electronic submission of information on medicines – hands on	T	1	– Understand the regulatory background – Describe the data models and data structures – Describe the electronic messaging processes on the basis of the Agency's data entry tool and practical examples – Understand the functionalities of the Agency's data entry tool – Understand how to perform queries in the Agency's medicinal product information management tool – Discuss how to access information on medicines	1, 2, 3, 4	F C	12 x A D if additional offerings are required
T10.M3: eXtended EV Medicinal Product Dictionary (Art57-XEVMPD)	T	2	– Understand the concepts related to the electronic submission of information on medicines authorized in the EU to the XEVMPD – Describe the format and the data elements of the XEVPRM for authorised medicinal products – Discuss practical examples of medicinal products and substances – Use of the XEVMPD data entry tool also known as EVWEB (hands-on-training)	2, 3	F C	10xA D if additional offerings are required
T10.I: Electronic submission of information on medicines Information Day	I	1	– Discuss latest development in the context of the electronic submission of information on medicines – Understand the implementation of the ISO IDMP standards in the EU – Discuss frequently asked questions	1, 2, 3, 4	F	1 x A

6.1. Costs involved in preparing and submitting a proposal

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

6.2. Period of validity of the proposal

Applicants must enclose a confirmation that the proposal is valid for nine months from the final date for submission of the proposal.

7. Concession agreement details

A draft concession agreement is attached to these Technical Specifications as Annex IV. Applicants must confirm acceptance of the draft agreement and terms and conditions of the proposal as part of their response.

The Agency wishes to conclude a concession agreement for the delivery of professional, large-scale training and meeting programmes tailored towards specific learning objectives in the area of pharmacovigilance.

The concession agreement shall be valid for an initial period of four years with the possibility of two renewals. The first renewal shall be for two years, and the second for one year (maximum possible duration is seven years).

This concession agreement will not be subject to the Transfer of Undertakings (Protection of Employment) Regulations 2006 ("TUPE").

8. Exclusion criteria

All applicants and partners 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 applicant shall provide the documents mentioned as supporting evidence in Annex II before signature of the concession agreement and within a deadline given by the Agency. This requirement applies to all members of the consortium in case of joint application and to partners.

9. Financial and economic capacity

Requirements:

Applicants must be in a stable financial position and have the economic and financial capacity to perform the concession.

Evidence required:

The documents or information listed below must be presented as evidence of compliance with the economic and financial capacity.

If the applicant 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. a copy of the most recent audited accounts that cover the last 3 years of trading or for the period that is available if trading for less than 3 years;

2. a statement of the applicant's overall turnover, profit & loss and cash flow position for the most recent full year of trading (or part year if full year not applicable) and an end period balance sheet, where this information is not available in audited form at 1 above;

3. if the applicant 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 concession at the disposal of the applicant for the period of the concession agreement; in such case the Agency may require that the successful applicant(s) and such entities are jointly liable for the execution of the concession;

4. details of the applicant's professional indemnity insurance in respect of their business and with particular relevance to this invitation for a concession.

If, for some exceptional reason which the Agency considers justified, the applicant 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 Agency considers appropriate.

The documentation supplied in response to this section will be reviewed to assess the general financial health of the applicant.

The Agency reserves the right to request at a later stage that the applicant provide documentation in relation to the selection criteria (economic and financial capacity) from any concession partner.

10. Technical and professional capacity

Requirements:

The criteria for this concession agreement are:

- Authorisation of the applicant to perform the concession under national law. The applicant must be established as a recognised legal entity and be registered in a relevant professional or trade register.
- Experience in delivering training courses and meeting organisation as described in the technical specifications.
- Measures established to ensure high quality and timely services to customers.
- Sufficient manpower involved in meeting and conference services (minimum three staff) and suitably qualified managerial staff with at least three years' experience in meeting and conference organisation, and access to a pool of qualified instructors with at least three years' experience in delivering training in the area of pharmacovigilance.

Applicants 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.

- Authorisation to perform the concession 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 training and meeting organisation.

- 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 applicant who are able to fulfil the requirements of this concession as stipulated above, in the last three years.
  - Applicants must provide Curricula Vitae for its managerial staff, in particular those of the persons responsible for providing the services.
  - Applicants should also provide 3 Curricula Vitae of trainers without indication of names clearly showing the qualifications and professional experience within the relevant area.

    Please submit Curricula Vitae without indication of any name or date of birth. Each Curriculum Vitae should bear a number only and the proposal should include a separate list showing the association between these numbers and actual names.

    The Agency requests that Curricula Vitae are submitted using the Europass template: http://europass.cedefop.europa.eu/en/documents/curriculum-vitae

The Agency reserves the right to request at a later stage that the applicant provide the documentation in relation to the selection criteria (technical and professional capacity) from any concession partner.

11. Award criteria

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

Stage 1: Qualitative award criteria

The qualitative award criteria shall account for 60% of the weighting for this call for proposals.

Applicants are requested to provide the following documentation to enable an assessment of the award criteria. Applicants should provide responses on each of the technical criteria in separate documents (maximum two A4 pages per sub-criterion with the possibility of providing annexes where requested), clearly marked with the appropriate reference.

- Criterion A: Management and reporting
  - Please provide details of how the concession agreement will be managed, including proposed interaction with the Agency.
  - Please describe your organisation's approach to evaluate, report and follow-up on trainings delivered. Please provide sample reporting templates.
- Criterion B: Instructors
  - Please provide details of how your organisation will ensure the ongoing availability of a pool of qualified and experienced instructors.
  - Please describe your policy on replacement of instructors and briefing of new instructors.
- Criterion C: Organisation & Cancellation policy
  - Please describe your organisation's approach to organising a typical training course (including registration process, support on the day, attendance certificates, follow-up). Please describe your organisation's cancellation policy.

- Please provide details of how your organisation will promote the various training offers, taking into consideration the different stakeholder groups that the courses are aimed at; please provide samples of proposed promotional material, if available.

The qualitative award criteria which will apply to this concession, points available and minimum scores are set out in tabular format below. Any applicant not achieving the minimum scores indicated below for each sub-criterion shall be eliminated and not evaluated further. Where the minimum scores have been achieved, an overall total qualitative score out of 60% shall be calculated.

Ref.	Criterion	Maximum points available	Minimum points that must be achieved
A	**Management and reporting**	300	180
A.1	Management	150	90
A.2	Evaluation and reporting	150	90
B	**Instructors**	400	240
B.1	Availability and selection	200	120
B.2	Replacements and briefing	200	120
C	**Organisation & Cancellation Policy**	300	180
C.1	Approach	150	90
C.2	Promotion	150	90
	TOTAL	1000	600

Stage 2: Price

Price shall account for 40% of the weighting for this concession.

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

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

For the purpose of evaluation, "price" in this formula shall be the amount titled 'Overall total cost' arising from the calculation based on the scenarios for evaluation of price provided in the costing sheet in Annex I.

Stage 3: Final ranking of applicants

Following evaluation of price, the points for price (out of 40%) and the points for the qualitative award criteria (out of 60%) shall be added together (Stage 1 and 2) to arrive at a grand total to two decimal places and to determine the ranking of the applicants.

12. Proposal to be submitted

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

- A letter enclosing the proposal on the official letter headed paper of the applicant and signed by an authorised representative of the applicant (applicants should note that the Agency does not accept electronic/scanned signatures).
- Costing sheet (Annex I)
- Completed declaration in Annex II relating to Exclusion Criteria.
- Documentation requested to enable assessment of Selection Criteria (points 9 and 10 above).
- Documentation requested to enable assessment of Award Criteria (point 11 above).
- An information sheet on the applicant (Annex V)
- A statement to confirm that information provided in this proposal 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 call for proposals could result in the applicant being excluded from future concession agreements with the Agency.
- Confirmation of acceptance of the draft concession agreement and terms and conditions of the call for proposals.
- Applicants must enclose a confirmation that the proposal is valid for nine months from the final date for submission of the proposal.
- 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 call for proposals.
- Documents as requested in relation to proposed partnerships.
- Proposals submitted by consortia or by groups of service providers must indicate the role, title and experience of each member or of the group.
- Applicants are requested to make use of the checklist given in Annex III to ensure that no enclosure has been omitted in their response.

Annexes

I	Costing sheet
II	Exclusion criteria statement and detail of supporting documentation required
III	Summary Checklist of Documents which applicants must submit
IV	Draft concession agreement
V	Applicant information sheet
VI	Agency Policy/0062 (16-SEP13) +Instruction paper for external organisations