EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 March 2014
EMA/90376/2014

Open Invitation to Tender - EMA/2014/01/PH

Annex VI - Service Level Agreement (SLA)

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7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8668
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
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1. Introduction

1.1. Purpose of this document

This Service Level Agreement (SLA) contains the particulars of the service levels required of the contractor appointed as a result of the Invitation to tender EMA/2014/01/PH (hereinafter referred to as "the Contractor"). Service levels are defined in terms of:

- the quality of output from the services to be delivered;
- the time taken to deliver the individual services required; and
- management of the services to be delivered.

Service levels are separately defined for the five work streams, namely:

1. Supply of scientific and medical literature for the purpose of monitoring of the safety and benefit-risk profile for the defined substances
2. Screening of supplied scientific and medical literature and recording of all screening activities
3. Processing of individual cases related to suspected adverse reactions identified as a result of the scientific and medical literature screening activities screening of supplied scientific and medical literature screening activities
4. Follow-up of ICSR related to suspected adverse reactions identified as a result of the scientific and medical literature screening activities
5. Service and operations management and periodic reporting

The Agreement also sets out the communication channels between the Contractor and the European Medicines Agency (hereinafter "EMA" or "the Agency"), and the reporting required of the Contractor, together with related processes.

This document also sets out what will occur in the event that the defined service levels are not complied with.

1.2. Contact Information

Whereas:

- The Contractor has appointed an individual as the nominated service operations manager for the services governed by the SLA in accordance with section 11 "Contractual details" of the Technical Specifications for this contract; and
- The Agency has appointed a Medical Literature Monitoring (MLM) manager, who is responsible for the management of these activities from the Agency's perspective. The Agency MLM manager will appoint coordinators for each work stream:
    1. Appendix 1a to this SLA sets out the names and contact details for the Agency MLM manager and coordinators.
    2. The Agency will be responsible for maintaining Appendix 1a to this SLA.
    3. Appendix 1b to this SLA also sets out the names and contact details of the Contractor's service operations manager.
    4. The Contractor shall be responsible for maintaining Appendix 1b to this SLA.

2. Service levels

2.1.1. Set up phase

- Initial training of all Contractor staff as defined in sections IX.a of the Technical specifications for open invitation to tender (hereafter referred to as the Technical specifications) has to be completed by the contractor no later than two months after entry into force of the contract.
- The tracking system(s) as referenced in the Technical specifications in sections III.b, III.c, V.a and VII.b is to be set up by the Contractor and approved by the Agency within two months after entry into force of the contract.
- Standard Operating Procedures ("SOPs"), related Work Instructions ("WINs") and all applicable training materials are to be established by the Contractor and agreed by the EMA within one month after entry into force of the contract.
- Standard Operating Procedures are to be established in the form prescribed in Appendix 2 to this SLA. Work Instructions are to be established in the form prescribed in Appendix 3 to this SLA.
- As part of the process of establishment of the SOPs, WINs, templates and tracking system(s) described above, each artefact is to have been reviewed, approved and signed off by the EMA. The sign-off by the EMA is to be evidenced by means of an Acceptance Sheet..
- Templates for correspondence with authors of scientific and medical literature are to be established as part of the work and in accordance with the timelines for setting up the SOPs and WINs referred to above.
- A service desk as referenced in the Technical specifications (section VII.b) and run through an email contact address should be established to receive queries from stakeholders within one month after entry into force of the contract. The specifications for the operation of the service desk have to be reviewed, approved and signed off by the EMA. .

2.1.2. Production phase

- All recordable events must be recorded, documented, fully traceable and auditable in accordance with the Technical Specifications. The tracking system(s) must be available for access by the EMA at any time during EMA business hours[1].
- Weekly activity reports and meetings to report on progress are to be arranged and managed in accordance with provisions of clause 4.3.1 by the Contractor's service operations manager.
- Monthly activity reports are to be arranged and managed in accordance with provisions of clause 4.3.1 by the Contractor's service operations manager.
- The service desk run through an email contact address should be maintained to receive queries from stakeholders regarding the identification of reportable literature articles. Queries should be acknowledged to the sender within 1 calendar day and a response should be sent within 3 calendar days. Calendar days refer to week days with the exception of weekends.

[1] http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000247.jsp&mid

2.1.2.1. Supply of scientific and medical literature for the purpose of monitoring of the safety and benefit-risk profile for the defined substances

- The supply of accurate and exhaustive scientific and medical literature as referred to in section II.b of the Technical specifications must be made daily (Daily shall refer to calendar days with the exception of weekends).

2.1.2.2. Screening of supplied scientific and medical literature and recording of all screening activities

- Searches of the medical and scientific literature should be performed daily (daily shall refer to calendar days with the exception of weekends).
- All literature articles identified through the searches of the medical and scientific literature should be reviewed daily (Daily shall refer to calendar days with the exception of weekends).
- Ad hoc screening of scientific and medical literature should be completed within the timelines as defined by the Agency at the time of the request.

2.1.2.3. Processing of individual cases related to suspected adverse reactions identified as a result of the screening activities

- All ICSRs identified in the screened scientific and medical literature are to be submitted to EudraVigilance in line with the timelines specified below:
    - Serious adverse reactions, should be entered in EudraVigilance immediately and no later than seven calendar days,
    - Non-serious adverse reactions, should be entered in EudraVigilance within three calendar weeks.
- Day zero for the timelines related to the entry in EudraVigilance is the date on which the Contractor becomes aware of a publication containing the minimum information for an ICSR to be reportable. For further information refer to GVP module VI, chapter VI. App2.7 “Day zero”.
- ICSRs entered in EudraVigilance are to be transmitted electronically within one calendar day to the national Competent Authority in EEA Member States based on the primary source country or where not available to the country of the primary author of the article.
- One attempt to follow-up with the primary author(s) should be made for serious adverse reactions within 15 calendar days of first being identified through a search of the medical literature.
- Any new information related to ICSRs should be processed within seven calendar days following receipt of new information related to suspected serious adverse reactions.

2.1.2.4. Translation of non-English language literature articles

- All literature articles that are requested to be translated into English should be translated within the timelines as defined by the Agency at the time of the request.
- All requests for translations should be tracked.

2.1.2.5. Ad hoc service for screening of scientific and medical literature in the context of signal evaluation

- All ad hoc requests for screening of scientific and medical literature in the context of signal evaluation should be completed within the timelines as defined by the Agency at the time of the request.
- All requests for ad hoc screening should be tracked.

2.1.3. Accuracy

The accuracy of the work conducted by the contractor should be measured. The contractor should review service desk queries and the service satisfaction surveys in order to identify articles and ICSRs that have been missed from the searches and screening. The following activities should be monitored for accuracy:

- For the searching of supplied scientific and medical literature the number of articles missed from conducting searches should be measured and reported along with actions taken to address the reason why they were missed.
- For the screening of supplied scientific and medical literature the number of ICSRs missed by screening should be measured and reported along with actions taken to address the reason why they were missed.
- For the entry into EudraVigilance of individual cases related to suspected adverse reactions identified as a result of the screening activities the number of errors made should be monitored and reported along with actions taken to address the issue.
- The entry of information into the tracking system should be monitored for completeness and accuracy
- Corrective actions should be taken immediately for identified issues and rectifications should be implemented within one week.

3. Key performance indicators

A list of key performance indicators by work stream is provided below, the method on how to measure these is to be agreed with the contractor:

No.	Workstream	KPIs
1.	Supply of scientific and medical literature for the purpose of monitoring of the safety and benefit-risk profile for the defined substances	• Timely supply of literature articles • Timely provision of requested literature article translations
2.	Screening of supplied scientific and medical literature and recording of all screening activities	• Timely screening of literature article • Availability and timely update of the tracking system • Timely provision of ad hoc literature screening activities
3.	Processing of individual cases related to suspected adverse reactions identified as a	• Timely entry of ICSRs in

No.	Workstream	KPIs
	result of the scientific and medical literature screening activities screening of supplied scientific and medical literature screening activities	EudraVigilance • Timely submission of ICSRs to NCAs
4.	Processing of individual cases related to suspected adverse reactions identified as a result of the scientific and medical literature screening activities screening of supplied scientific and medical literature screening activities	• Timely provision of listing of ICSRs that have been generated as a result of the literature screening activities for publication at the EudraVigilance restricted area
5.	Follow-up of ICSR related to suspected adverse reactions identified as a result of the scientific and medical literature screening activities	• Timely follow-up with primary author(s) and tracking od activities • Timely entry of any new follow-up information in EudraVigilance
6.	Service and operations management and periodic reporting	• Timely submission of the reports (weekly and monthly) • Availability of the tracking system • Timely correction of identified issues • Timely response to queries received through the service desk

3.1. Quality & service satisfaction

In addition to meeting the requirements with regard to the work to be done within the described periods of time as set out above, the Contractor is required to meet appropriate levels of quality and accuracy of the work done.

This requirement will be measured through carrying out service satisfaction surveys of the Agency's stakeholders (marketing authorisation holders and national Competent Authorities in EEA Member States) that should be open for a 2 week period and carried out every 6 months, following successful completion of the pilot phase. A summary report on the results of the survey should be completed no later than 2 weeks after the end date of the survey. The report may be published.

An analysis of the results should be reported as part of the monthly meetings described in section 4.2.2.

4. Communication and reporting

4.1. Communication channels

The following communication channels shall be used as most appropriate:

- Telephone
- Video-conferencing
- Agency's's electronic meeting tool – Adobe Connect®
- Electronic mail
- Postal services

The contact points are set out in Appendix 1a & b to this SLA.

4.2. Meetings

4.2.1. Weekly meetings

In addition to the weekly meetings for the work streams 1, 2, 3 & 4 described in section 2 above, there shall be weekly meetings between the service managers. Weekly meetings shall in principle be held via teleconference or Adobe Connect.

Weekly meetings shall be arranged by the Contractor personnel responsible (the workstream leads and the service manager) as appropriate to the meeting. In each case, the Contractor staff member responsible shall:

- organise the meeting, ensuring that all required attendees are in a position to attend, or have indicated their acquiescence to the meeting proceeding in their absence;
- propose the draft agenda;
- organise the preparation of minutes of the meeting, including the roll of those present and those that have apologised, the decisions taken, the action items brought forward and added, and the disposition of action items;
- ensure that issues are dealt with and tracked either through a tacking system, or by means of the meeting action item mechanism.
- the meetings shall, as a minimum, address the following:
  - status of activities,
  - status of interactions with third parties (stakeholders),
  - issues (new, in the process of being addressed, and to be closed),
  - management of the activities:
    - Performance against key performance indicators
    - Staff performance (including six-monthly performance evaluations of staff members as they fall due)
    - Workload.

4.2.2. Other meetings

In principle, there should be four face-to-face meetings per annum at the EMA's premises to discuss progress of the contract as a whole. Attendees should be service manager and workstream leads. Contractor staff should:

- organise the meeting, ensuring that all required attendees are in a position to attend, or have indicated their acquiescence to the meeting proceeding in their absence;
- propose the draft agenda;
- organise the preparation of minutes of the meeting, including the roll of those present and those that have apologised, the decisions taken, the action items brought forward and added, and the disposition of action items;
- ensure that issues are dealt with, tracked and followed through.

Attendance at these meetings by Contractor staff shall be at the Contractor's cost.

4.3. Reporting

4.3.1. Workstreams

Reporting for the workstreams 1, 2, 3 & 4 shall take place weekly at the weekly meetings, and be recorded in the minutes of the meeting. Translation and ad hoc screening of scientific and medical literature requests should be included where applicable. Such reporting shall reference items being tracked.

The coordinator for each workstream shall prepare a report as at 31 March, 30 June, 30 September and 31 December each year. The report shall be made available to the Agency within two weeks of the relevant date and shall provide:

- a statistical summary of the work done during the period, cumulatively since the beginning of the contract, and compared with the previous quarter;
- a statistical report of the resources expended during the period, cumulatively since the beginning of the contract, and compared with the previous quarter;
- an analysis of performance against the key performance indicators;
- an analysis of the significant issues encountered and their resolution;
- a listing of open issues, noting in particular any that have remained unresolved for longer than two weeks;

4.3.2. Contract

For the set up phase and the pilot phase the Contractor service operation manager shall prepare a summary report. The report shall be made available to the EMA within one week and provide the details as outlined below for the monthly summary reports.

For each specific contract as a whole, the Contractor service operation manager shall prepare a monthly summary report. The report shall be made available to the EMA within one week of the relevant date and shall provide:

- a statistical summary of the work done during the period, cumulatively since the beginning of the contract, and compared with the previous quarter;
- a statistical report of the resources expended during the period, cumulatively since the beginning of the contract, and compared with the previous quarter;
- an analysis of performance against the key performance indicators;
- an analysis of the significant issues encountered and their resolution;

- a listing of open issues, noting in particular any that have remained unresolved for longer than two weeks.

Within four weeks of the end of a specific contract, if such does not fall on one of the days noted in the previous paragraph, a report shall be prepared that provides:

- a statistical summary of the work done during the period since the last quarterly report and cumulatively since the beginning of the contract;
- a statistical report of the resources expended during the period since the last quarterly report and cumulatively since the beginning of the contract;
- an analysis of performance against the key performance indicators;
- an analysis of the significant issues encountered and their resolution;
- There should be no open issues at the end of the specific contract.

4.3.3. Ad-hoc Reporting

- The Contractor shall furnish reports to the EMA on specific issues as requested by the Agency where the Agency deems the circumstances so require.
- The Contractor may furnish reports to the EMA on specific issues that it identifies as necessary, having previously agreed that need with the EMA.

4.4. Escalation procedure

[To be proposed by the tenderer]

5. Non-compliance with Service Levels

5.1. Set-up activities

Progress of the set-up activities will be monitored at the weekly meetings. Any deviations will be discussed will be discussed and the appropriate remedial action will be agreed. The effective execution of such remedial action will be monitored through to completion at the subsequent weekly review meeting.

In the event that the deviation is not addressed in the agreed timelines, the escalation procedure as set out in section 4.4 above will be invoked.

In the context of the escalation procedure, the Agency and the Contractor shall confirm or amend the remedial action(s) with specific timelines. In the event that the amended remedial action(s) agreed fall upon the Contractor and are not taken forward in the agreed timescale, the EMA reserves the right to a credit of 5% (five percent) against the total value to be invoiced by the Contractor for set-up for each complete week beyond the agreed time limit for remedial action that set-up activities remain incomplete, provided that this time limit falls more than one month after signature of the first specific contract. The EMA shall claim such a credit only after giving notice that it intends to do so at least one week before the time limit in question.

5.2. Ongoing operations

Compliance with service levels will be monitored jointly by the Contractor and the EMA in the course of the weekly review meetings by work stream. Any deviations will be discussed and the appropriate remedial action will be agreed. The effective execution of such remedial action will be monitored through to completion at the subsequent weekly review meeting.

In the event that the deviation is not addressed in the agreed timelines, the escalation procedure as set out in section 4.4 above will be invoked.

In the event that the negative deviation, or instances of deviations due to the same cause(s), persist, or the remedial action(s) agreed at the relevant weekly review meeting is/are not taken forward as defined over a period of one month, the escalation procedure as set out in section 4.4 above is to be invoked.

In the context of the escalation procedure, the Agency and the Contractor shall confirm or amend the remedial action(s) with specific timelines. In the event that the amended remedial action(s) agreed fall(s) upon the Contractor and is/are not taken forward in the agreed timescale, and the related service level continues not to be complied with, the EMA reserves the right to a credit of 2% (two percent) against the total value to be invoiced by the Contractor for the activity in respect of which the service level has not been met for the period between the start date and the date from which the relevant service level is complied with. The start date shall be the 14th calendar day after the EMA gives notice that it intends to claim the credit.

6. Document Information

6.1. Revision History

Version	Who	When	What
0.1	EMA	26/03/2014	Draft (Annex VI to open invitation to tender EMA/2014/01/PH)

7. Appendices

7.1. Appendix 1a: Contact details EMA *[to be provided after the award of the contract]*

7.2. Appendix 1b: Contact details Contractor *[to be provided after the award of the contract]*

7.3. Appendix 2: SOP Template

7.4. Appendix 3: WIN Template

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Appendix 2

Standard operating procedure

Title:		
Status: **DRAFT (CONFIDENTIAL)**		Document no.:
Lead author	Approver	Effective date:
Name:	Name:	Review date:
Signature:	Signature:	Supersedes: n/a
Date:	Date:	TrackWise record no.:

<This SOP Template is effective 19-MAR-10 and supersedes the previous version dated 15-DEC-09.

INSTRUCTIONS

Complete this SOP by typing in the body of each section. Do not change the headings in this document.

Since a SOP is generally intended to become a public document (i.e. available on the Agency external website) ensure that it will be understood by third parties who are not familiar with Agency terminology.

Delete these drafting note paragraphs and the instructions under each header when typing in the SOP.>

1. Purpose

<Text>

<Type the purpose of this procedure in free text that is clear, concise and focused. Add a justification or objective, were required. The purpose may specifically exclude other uses, document types or activities. For instance, "This SOP is not applicable to documents not created by the Agency". Keep the list limited.>

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8668
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
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2. Scope

<Text>

<Type the scope of this procedure in free text. The scope identifies the positions/Sections/Sectors/Units to whom the procedure is applicable as defined under responsibility in section 9. For instance, "This SOP applies to XYZ Unit only".>

3. Responsibilities

<Text>

<Type the responsibilities for this procedure. For example, "It is the responsibility of each Head of Sector to ensure that this procedure is adhered to within their own sector. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.">

4. Changes since last revision

<Text>

<Briefly list the changes that have been made and are included in this version of the SOP. Changes from previous versions recorded under this heading are to be replaced by the most recent changes. If extensive changes are made, type "Extensive revision to rewrite SOP".

If the SOP is new, type " New SOP" under this heading.

If the SOP has been reviewed and reissued without any changes at all, type "SOP reviewed and reissued without any changes".>

5. Documents needed for this SOP

<Text>

<List the reference numbers and titles of the forms, templates, annexes, etc needed for this SOP; one per line. Provide details of location, for example:

- *on X: drive (e.g. located in X:\Templates\Others\...)*
- *in Word (e.g.located in Word\File\New\...)*
- *URL (e.g. located at http://www.ema.europa.eu/htms/general/sop/sop.htm), etc.*

Active hyperlinks in the final document (Word or PDF) are not mandatory although they may be useful. Databases required for execution of the procedure may be listed but their location need not be specified.>

6. Related documents

<Text>

<List the numbers and titles of the documents related to and needed as reference documents for this SOP, e.g. other SOPs or WIN referred to in the procedure, guidance documents; one per line. The location of SOPs/WIN is not required but they should be listed in sequential order by their reference number.>

7. Definitions

<Text>

<Define any terms with a special meaning and all acronyms and abbreviations used in this SOP; one per line in alphabetical order.>

8. Process map(s)/ flow chart(s)

<Text>

<A process map/flow chart must always be inserted. Right click on the process map/flow chart in PowerPoint from Slide Sorter View and select copy. Paste here by selecting Edit\Paste Special\Microsoft PowerPoint Slide Object. Remember to save changes in the original flow chart as a PowerPoint file for future revisions.>

9. Procedure

Step	Action	Responsibility
{No. of step in flow-chart }	*{Details of the action to be taken. Write the instructions as straightforward commands, wherever possible—"Do X" rather than "X is to be done at this point".* *There is no need to include "Start of procedure" and "End of procedure" as the first and last steps.}*	*{The job title or function (not name) of persons responsible to do the action.}*

10. Records

<Text>

<Describe where hard copy and electronic records (generated using the forms and templates referred to in this SOP) are stored - a physical location, the name of a database and/or or a reference to an applicable SOP.

For example, "When completed and approved the original, signed hard copy of the form is filed in the master file.>

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Appendix 3

Work instructions

Title:		
Applies to: <Text>		
Status: **DRAFT (CONFIDENTIAL)**		Document no.:
Lead Author	Approver	Effective Date:
Name:	Name:	Review Date:
Signature:	Signature:	Supersedes: N/A
Date:	Date:	TrackWise record no.:

*<**This WIN template is effective 19-MAR-10 and supersedes the previous version dated 15-DEC-09.***

INSTRUCTIONS

Complete these WIN by typing in the body of the sections provided. Do not change the pre-defined headings. However, you may include additional headings, if required.

Since WIN are generally intended to become a public document (i.e. available on the Agency external website) ensure that they will be understood by third parties who are not familiar with Agency terminology. In such cases, definitions may be appropriate.

Delete these blue and italic paragraphs and the instructions under each header when typing in the WIN.>

1. Changes since last revision

<Text>

<Briefly list the changes that have been made and are included in this version of the WIN. Changes from previous versions recorded under this heading are to be replaced by the most recent changes. If extensive changes are made, type "Extensive revision to rewrite WIN".>

<If the WIN are new, type " New WIN" under this heading.>

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

<If the WIN have been reviewed and reissued without any changes at all, type "WIN reviewed and reissued without any changes".>

2. Records

<Text>

<Describe where hard copy and electronic records (generated using the forms and templates referred to in these WIN) are stored - a physical location, the name of a database and/or or a reference to an applicable SOP/WIN.

For example, "When completed and approved the original, signed hard copy of the form is filed in the master file.

If no records are generated, type "Not applicable" under this heading.>

3. Instructions

<Text>

<You are free to use an appropriate format for these WIN. You could include e.g. a flow chart or a set of instructions or both, pictorial images, screenshots, etc. You may delete the table below if you choose not to describe a sequence of actions.>

Step	Action	Responsibility
{No. of step}	*{Details of the action to be taken. Write the instructions as straightforward commands, wherever possible—"Do X" rather than "X is to be done at this point".* *There is no need to include "Start of procedure" and "End of procedure" as the first and last steps.}*	*{The job title or function (not name) of persons responsible to do the action.}*