23 March 2016
EMA/215889/2016
European Medicines Agency

Ex ante publicity for negotiated procurement procedure: Activiti training for business users

EMA/2016/32/HR

The European Medicines Agency (hereinafter referred to as "the Agency") intends to procure training in the use of the Activiti workflow management tool, through conclusion of a framework contract with a maximum of two economic operators in priority order for a period of four years.

The scope of this contract shall be:

To offer a set of learning activities on the basis of established objectives and target audience need. These may take the form of classroom courses, live web-learning, e-learning, blended learning, conferences, special events, individual or support group work, facilitating communities of practice, and support to other forms of informal learning.

The contractor will be required to develop or identify appropriate materials, including course materials, (paper and multimedia), self-study manuals, level identification, knowledge evaluation tests, bibliographies and web references designed to support independent and/or informal training. Support may also be commissioned for more informal sessions (e.g. 'tips and tricks'). Face-to- face, EMA specific, interventions are to be delivered mainly in the Agency's premises in the Canary Wharf area of London.

EMA is introducing Activiti as a workflow and case management tool. The tool will be used in a specific process to manage and track a new business process to implement the Clinical Data Publication policy.

There is a strong public demand to share clinical trial data that support marketing authorisations. EMA is committed to continuously extend its approach to transparency. Its policy on publication of clinical data is part of this approach:

- Reactive release of data under Access to Documents legislation
- Publication of information through the EU clinical trials register (current legislation)
- Proactive publication of clinical data submitted for the marketing authorisation process (new policy)

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

- Transparency under the new clinical trial regulation (development of EU portal and database)

There are three main objectives of the policy:

- To enable public scrutiny, establishing trust and confidence in the regulatory system
- To avoid duplication of clinical trials, limiting unnecessary patient exposure
- To enable application of new knowledge in future research, increasing efficiency of medicine development learning from experience

The policy scope is clinical data: clinical reports (i.e. clinical overviews, clinical summaries and clinical study reports - CSRs, together with appendices and individual patient data (IPD) and clinical data for marketing authorisation submitted under the centralised procedure.

Public access to the clinical data is enabled through publication on the EMA public website that follows the Commission Decision. Publication is planned 60 days after the Commission Decision.

Process

At a given point prior to the Commission Decision, the marketing authorisation applicant will submit to EMA a redaction proposal of the relevant material. EMA will review the material and exchange with the marketing authorisation applicant/company. Following these exchanges the EMA will issue its redaction conclusion and the company will then send to EMA the final redacted version. Following the Commission Decision this final redacted version is published by EMA on its clinical data publication website. This process is new for EMA and will go live in Q3/ 2016.

The workflow and case management tool, Activiti, will be integrated with a receipt Gateway (upload system used at EMA). The Activiti tool will be integrated with a publication tool, Liferay. It will also be integrated to an internal database concerning specific actions being completed. Activiti will notify Liferay to proceed with publication and Liferay will pull the specific document set from a repository to be actioned for digital rights protection and watermarking. Following correct completion of these actions the document set can be sent forward in the automated process for publication to the relevant website. Liferay will inform Activiti that the documents have been published and it, in turn, will inform stakeholders that the documents have been published.

The contractor will be asked to offer a set of learning activities on the basis of established objectives and target audience need. These may take the form of classroom courses, live web-learning, e-learning, blended learning, conferences, special events, individual or support group work, facilitating communities of practice, and support to other forms of informal learning.

The contractor may also be required to develop or identify appropriate materials, including course materials, (paper and multimedia), self-study manuals, level identification, knowledge evaluation tests, bibliographies and web references designed to support independent and/or informal training. Support may also be commissioned for publicity or more informal ‘tips and tricks’ sessions.

Further to the above the initial nature of training requirement will encompass:

- Use of Activiti to track and manage the new business process
- How to query Activiti on steps and status of cases the business process
- How to assign cases, how to view workload assigned to individuals
- How to select specific documents to track
- How to add notes or comments to a case
- How to schedule cases
- How to add notes to a case
- EMA overall business process how it works with Activiti, intervention points, integration to document repository, integration to product data base, publication tool: face to face training
- sustainable online or multi-media training material on the business process
- virtual assistance to support new users
- Reports, how to run a standard query about the status of a case/document/ document set,

A negotiated tender with an indicative budget of €120,000 is planned to be launched in April 2016 and the contract awarded will be for four years. Tenderers will be required to provide prices in Euro.

Interested economic operators meeting the minimum criteria below may express their interest by sending an e-mail to: training.tender@ema.europa.eu copied to Karen.Roskilly@ema.europa.eu together with the name, address and business details before **12 Noon BST on 6 April 2016.**

The following minimum technical requirements shall apply to this framework contract:

- Compliance with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to Directive 2014/24/EU;
- The language and format of all material and learning events must be in English.
- Must offer bespoke training design and delivery in Activiti.
- Training material must be available in electronic format as well as being available on paper, with no price differentiation. If hard copy material is requested by the Agency, this should be provided using FSC paper, and printed double-sided. Plastic folders should be avoided.
- Availability of specialist learning and development consultant to design bespoke material in late Q2 2016 and Q3, and delivery in late Q3 2016, to support the launch of this project.

Interested economic operators should comply, at least, with the following criteria:

- All tenderers must have authorisation to perform the contract under national law.
- The average annual turnover of the tenderer must be of a minimum value of Euro 60,000 for each of the last two financial years.
- The tenderer must have at least 24 months' experience in providing bespoke, in-company software training.
- The tenderer must have at least two trainers who have a good knowledge of Activiti and with at least 24 months' experience in delivering bespoke, in company software training.

This publication does not constitute any obligation on the part of the Agency to invite any economic operator having expressed its interest to tender. Only the candidates invited to tender by the Agency will be admissible. Registering interest to receive an invitation to tender in a negotiated procedure of this type does not create any legal right or legitimate expectation on the part of any economic operator.