EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Technical specifications for open invitation to tender

Procurement Procedure EMA-2012-09-IF External Service Providers for Enterprise Infrastructure Support: provision of resources for Oracle database and middleware product management

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1. Title of the invitation to tender

This document contains the Technical Specifications for the Open Invitation to Tender no. EMA/2012/09/IF for External Service Providers for Enterprise Infrastructure Support: provision of resources for Oracle database and middleware product management.

The contract notice for this open tender has been published in the Official Journal of the European Union OJ S 39, dated 25th February 2012.

1.1. Glossary

Term	Description
Benchmark	In the context of this tender a benchmark is not a minimum requirement, rather it is a point of reference for a measurement.
Business domain	The business context in which the system operates. The currently identified types are: Medicines information Pharmacovigilance Regulation
CFT	Call for tender. In this document, used interchangeably with the term ITT
Charges	The amount payable covering all the services provided, exclusive of VAT
Contractor	A tenderer to which a framework contract has been awarded.
eCTD	Electronic common technical document
Effort	The amount of work required to complete a task.
Evaluation Committee	A committee made up of staff from the European Medicines Agency ("the Agency") which is tasked with evaluating the tender responses. The committee may call upon technical experts for assistance; such experts may be non-Agency staff.
ICH E2B	A data exchange standard for the submission of information on adverse reactions in connection with the use of pharmaceuticals for human use.
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.(www.ich.org)
IT consultancy	The provision of expert advice in the area of IT
IT services provider	The provision of individuals and/or services in the area of IT to companies
ITT	Invitation to tender. Although, in this document, the term ITT can used interchangeably with the term CFT, the term ITT is preferred.
Mark up	The percentage or amount by which a seller

Term	Description
	increases his buy-in price when determining his selling price
Mark up (total)	See Total mark up, the preferred term.
Methodology & Techniques	These terms are used in this document to describe (a) the principles, methods, rules and procedures employed by discipline; and (b) procedures used to accomplish a particular task.
Methodology	A collection of methods, practices, procedures and rules used by those who work in some field.
Middleware	Software that connects two otherwise separate components in a multi-tier system. Specifically, in the context of this tender, products that link the database layer to the web layer.
Pharmacovigilance	The detection, assessment, understanding and prevention of the adverse effects of medicines
Staff turnover	Turnover refers to the number of employees who have left the company within a given period of time – normally expressed as a percentage of the total staff employed and calculated annually
Standards	A rule or set of rules or requirements which are widely agreed upon and supported by an organisation regarded as authoritative.
Tenderer	An economic operator or group of economic operators which is submitting a response to this invitation to tender.
Time and materials orders	Time and materials orders, which correspond to the order of a number of days for defined profiles
Time and means orders	See Time and materials orders, which is the preferred term in this document.
Tools	This term is used in this document to describe software that facilitates the accomplishment of a task via simple deployment and configuration.
Total mark up	The accumulated mark up taken by each successive contractor and subcontractor. The difference between the selling price and the price charged by the lowest subcontractor in the chain.
Tracking system	Systems that record the status of transactions at pre-defined points in a process

2. Executive summary

This tender aims to put into place contractual arrangements, on a time and materials basis, which will enable the European Medicines Agency ("the Agency") to specify and acquire services and artefacts provided by resources not employed directly by the Agency. These resources will contribute expertise directly to the management and administration of the Agency's onsite Oracle database and middleware products and installations.

Item	Summary
Publishing Authority	European Medicines Agency, hereinafter referred to as "the Agency".
Purpose	This tender aims to put into place contractual arrangements with one or more companies for the provision of services, on a time and materials basis, that will enable the Agency to acquire resources not employed directly by the Agency in the domain of the management and administration of Oracle product-based information and communication technology systems. These resources will contribute expertise directly to the design, construction, implementation and administration of the Oracle technology stack hosting in-house and vendor-supplied applications.
Tender	External Service Providers (ESP) for Enterprise Infrastructure Support – provision of resources for Oracle database and middleware product management
Contracts	The Agency intends to sign multiple, cascading framework contracts in order of priority. The framework contracts lay down the legal, financial, technical and administrative provisions governing the relations between the Agency and the Contractor during their period of validity. A maximum of three contracts ranked in order of priority is expected to be signed. Framework contracts do not constitute orders. Orders are placed through Specific Contracts. The framework contract will define the unit costs for work at the Agency's premises of the personnel to be used to undertake the services provided as described in this Invitation to Tender. Based on these costs, Specific Contracts may be concluded according to the Terms and Conditions of this Invitation to Tender and of the corresponding financial proposal of the Contractor. Tenderers should ensure that they read the full details in 4.1.5.2. General description of framework contracts See ***Annex 7 Draft Framework Contract, including draft Specific Contract***.
Duration of framework contracts	Two years with two possible extensions of one year each. Maximum possible duration: Four years
Place of delivery	At the Agency's premises at 7 Westferry Circus, Canary Wharf, London E14 4HB, United Kingdom.
Particulars of delivery	Delivery of services must be in conformity with the placed orders, which will be time and materials based Specific Contracts. Unless otherwise specified in the Specific Contract, services will be carried out by the Contractor during the Agency's normal working days and normal working hours, as specified in the Draft Service Level Agreement – see ***Annex 5, Draft Service Level Agreement***.
Volume (indicative)	The resulting framework contracts will replace framework contracts in respect of which the financial envelope has been exhausted.

Item	Summary
	The Agency estimates, without this being binding, that the total annual resource requirement for time and materials services is expected to represent approximately 1000 person-days per annum.
Joint Offers	Permitted.
Variants	Not permitted.
Subcontracting	Permitted. The Contractor may subcontract to another contractor but no further levels of subcontracting will be permitted. Information on all subcontractors must be included in the Tenderer's response to this Invitation to Tender. For details see Section 6.2. Subcontracting.
Closing Date for receipt of Tenders	**12.00 noon (UK time), Monday 2nd April 2012**
Opening of Tenders	**European Medicines Agency, 7 Westferry Circus, Canary Wharf, London E14 4HB at 14.00, Wednesday 4th April 2012**
Meeting at the Agency	Tenderers should be prepared to present at the Agency their written tenders and demonstrate their expertise, to provide answers to queries or questions that the Agency's Evaluation Committee might have as part of the evaluation process. It is anticipated that the meetings, if required, will take place in June 2012. Tenderers will be given a minimum of 4 working days' notice if they are required to attend such a meeting. Tenderers should note that this meeting is a mandatory part of the evaluation process and that refusal of an invitation shall result in the exclusion of the Tenderer from any further part in the procurement procedure.
Tender assessment procedure	The assessment of Tenderers and offers will take place in four main phases: <u>Exclusion of Tenderers</u>: The purpose of this phase is to determine whether a tenderer is qualified to participate in the tender procedure. <u>Selection of Tenderers</u>: This phase consists of two sections: • Financial and economic capacity • Professional and technical capacity The purpose of this phase is to assess whether a tenderer has the financial, economic, professional and technical capacity necessary to perform the services. <u>Evaluation of Offers</u>: This phase consists of two sections;

Item	Summary
	• Technical evaluation of the offer • Financial evaluation of the offer The purpose of this phase is to choose the best offers of those submitted by tenderers which are not excluded and which meet the selection criteria. Signature of the Contract(s)

3. Objectives and context of the invitation to tender

3.1. Introduction to the European Medicines Agency

3.1.1. Who we are

In accordance with EU Regulation 2309/93 which laid down the Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and the establishment of a European medicines agency, the European Medicines Agency[1] ("the Agency") began its activities in 1995 with funding from the European Union. EU Regulation 2309/93 was repealed by EU Regulation 726/2004 as amended by Regulation 1235/2010, which now governs the activities of the Agency. The Agency is a decentralised body of the European Union and is based in London, United Kingdom. The Agency has a staff of around 800, in addition to which there are a number of people working at the Agency as contractors, mainly on ICT projects. The Agency staff consists of nationals from the majority of EU member states.

The Agency is headed by the Executive Director, Guido Rasi, and governed by a supervisory body, the Management Board.

3.1.2. What we do

The Agency's Mission is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health.

Legal role

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

The Agency provides the Member States and the institutions of the EU the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

Principal activities

Working with the Member States and the European Commission as partners in a European medicines network, the European Medicines Agency:

[1] Then known as the European Agency for the Evaluation of Medicinal Products

- provides independent, science-based recommendations on the quality, safety and efficacy of medicines, and on more general issues relevant to public and animal health that involve medicines;
- applies efficient and transparent evaluation procedures to help bring new medicines to the market by means of a single, EU-wide marketing authorisation granted by the European Commission;
- implements measures for continuously supervising the quality, safety and efficacy of authorised medicines to ensure that their benefits outweigh their risks;
- provides scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;
- recommends safe limits for residues of veterinary medicines used in food-producing animals, for the establishment of maximum residue limits by the European Commission;
- involves representatives of patients, healthcare professionals and other stakeholders in its work, to facilitate dialogue on issues of common interest;
- publishes impartial and comprehensible information about medicines and their use;
- develops best practice for medicines evaluation and supervision in Europe, and contributes alongside the Member States and the European Commission to the harmonisation of regulatory standards at the international level.

Guiding principles

- The Agency is strongly committed to public and animal health.
- The Agency makes independent recommendations based on scientific evidence, using state-of-the-art knowledge and expertise in its field.
- The Agency supports research and innovation to stimulate the development of better medicines.
- The Agency values the contribution of its partners and stakeholders to its work.
- The Agency assures continual improvement of its processes and procedures, in accordance with recognised quality standards.
- The Agency adheres to high standards of professional and personal integrity.
- The Agency communicates in an open, transparent manner with all of its partners, stakeholders and colleagues.
- The Agency promotes the well-being, motivation and ongoing professional development of every member of the Agency.

Central Authorisation Procedure

This procedure results in a single marketing authorisation (called a 'Community marketing authorisation') that is valid across the European Union. The centralised procedure is compulsory for human medicines that are:

- derived from biotechnology processes, such as genetic engineering;
- intended for the treatment of HIV/Aids, cancer, diabetes or neurodegenerative disorders;
- officially designated 'orphan medicines' (medicines used for rare diseases).

For medicines that do not fall within these categories, companies may submit an application for a centralised marketing authorisation to the Agency, as long as the medicine concerned is a significant

therapeutic, scientific or technical innovation, or if its authorisation would be in the interest of public health. This option may be extended to generic medicinal products authorised by the Community, provided that this in no way undermines either the harmonisation achieved when the reference medicinal product was evaluated or the results of that evaluation.

Applications through the centralised procedure are submitted directly to the Agency. Evaluation by the Agency's relevant scientific committee takes up to 210 days, at the end of which the committee adopts an opinion on whether the medicine should be marketed or not. This opinion is then transmitted to the European Commission, which issues a formal decision on the authorisation of the product.

Once a Community marketing authorisation has been granted, the marketing-authorisation holder can begin to make the medicine available to patients and healthcare professionals in all EU countries.

Pharmacovigilance

The safety of medicines is constantly monitored by the Agency through a pharmacovigilance network. The decision to approve a drug is based on it having a satisfactory balance of benefits and risks within the conditions specified in the product labelling. This decision is based on the information available at the time of approval. The knowledge related to the safety profile of the product can change over time through expanded use in terms of patient characteristics and the number of patients exposed. In particular, during the early post-marketing period the product might be used in settings different from clinical trials and a much larger population might be exposed in a relatively short timeframe.

Once a product is marketed, new information will be generated, which can have an impact on the benefits or risks of the product; evaluation of this information should be a continuing process, in consultation with regulatory authorities. Detailed evaluation of the information generated through pharmacovigilance activities is important for all products to ensure their safe use. The agency takes action if adverse drug reaction reports suggest changes to the benefit-risk balance of a medicinal product. The benefit-risk balance can be improved by reducing risks to patients through effective pharmacovigilance that can enable information feedback to the users of medicines in a timely manner.

Innovation

The Agency supports innovation and research by providing scientific advice and special support for small and medium-sized enterprises developing new medicinal products and is active in the field of advanced therapy medicinal products such as gene therapy and human tissue engineered products. It also supports the development of orphan medicinal products (drugs for the treatment of rare diseases or for a disease not likely to generate sufficient profit to justify research and development).

Network

The Agency works with a network of experts provided by the national competent authorities of the EU member states as well as those from the EEA countries. The experts serve either as members of the scientific committees, working parties or scientific assessments teams. They are not permitted to have any direct financial or other interests in the pharmaceutical industry which could affect their impartiality.

International Co-operation

In the international area, the Agency works with the World Health Organisation, the World Organisation for Animal Health and the US Food and Drug Administration, amongst others, on a number of initiatives.

3.1.3. Future

In the short term, the Agency's work is being shaped by a number of factors in the rapidly developing medicines regulation environment, most notably the entry into force of the new pharmacovigilance legislation and anti-falsification legislation and the new ISO standards on individual case safety reports and identification of medicinal products.

The Agency is facing a steady growth in activities relating to the evaluation and supervision of medicinal products bringing with it an increased workload.

3.1.4. For further information on the Agency

Please refer to our website: http://www.ema.europa.eu/

3.2. Introduction to ICT systems at the European Medicines Agency

3.2.1. Communities served

Information Technology at the Agency serves staff and contractors within the Agency in support of their daily activities. In addition, in line with the overarching EU Telematics implementation strategy, the Agency is putting into place systems in support of the European Medicines Regulatory Network as a whole. This network comprises the competent authorities in the domain of the regulation of medicinal products. In the context of the provision of information, patients and healthcare professionals are also stakeholders, as is pharmaceutical industry in connection with the development and authorisation of medicinal products.

3.2.2. The Agency's administrative and business projects and systems

The Agency terms the systems and infrastructure that directly support the Agency in its day to day activities 'Administrative and Business ICT Systems'. In addition to systems made available by the European Commission or acquired off the shelf and implemented, the Agency has designed and built systems tailored to its requirements.

These applications are designed and implemented to support:

- The core activities of the Agency, namely the evaluation of marketing authorisation applications, pharmacovigilance, and specific tasks allocated by legislation
- The administrative functions necessary to enable the Agency to execute these core activities

The projects and systems supporting the operations of the Agency comprise:

3.2.2.1. SIAMED (Sistema de informacion Automatizada sobre MEDicamentos)

SIAMED is a system developed jointly with WHO[2] for computer assisted medicines registration.

A new version (SIAMED II) of this application is under development, which aims to:

- reflect - and integrate into – the workflows, current and future, in use at the Agency;
- maintain a history of products from "cradle to grave" through the use of a unique identifier, allowing easy cross-referencing amongst the various systems;
- integrate with - and take advantage of - electronic submission;

[2] World Health Organisation

- communicate with other systems, including - but not limited to - EudraVigilance, EudraPharm, EUTCT[3], ECD[4] and ERP[5];
- provide a flexible and adaptable tracking system, able to cope with regulatory changes;
- provide flexible and user-friendly reporting;
- provide selective access to part of the information to external stakeholders.

Release 3.0 supports the business processes covering Marketing Authorisation and Post Authorisation Applications.

3.2.2.2. Paediatrics Database

The Paediatrics Database is used to receive, process and store applications accompanying paediatric implementation plans submitted to the Agency.

3.2.2.3. DREAM (Document and Record Management System)

The Agency has implemented Documentum, a central controlled electronic repository for documents providing file management functionality, as its document management system. The system comprises a central vault linked to a desktop client that was made available to all working at the Agency. The system was customised to meet key requirements of the Agency's operations. The desktop client has been phased out and was replaced by a web client in August 2010.

In implementing its document management system the Agency sought to:

- Increase the overall efficiency of document management and handling within the Agency
- Provide better control of the Agency's documents
- Enable more efficient publishing of documents via the Internet
- Provide an underlying platform which can support the improvement of the Agency's business processes and meet the Agency's needs as these change.

3.2.2.4. MMD (Management of Meeting Documents System)

In the interests of increasing efficiency and reducing the use of paper, the Agency has implemented the MMD system for sharing of meeting documents enabling meeting participants to access these documents both on and off the Agency's premises. The system is based on Documentum and uses its web client. This implementation enables:

- Better control of documents submitted to and worked on at Agency meetings
- Secure electronic access to current versions of documentation inside and outside the Agency
- Improved editing of meeting documents

3.2.2.5. MMS (Meetings Management System)

MMS is a system developed by the Agency to control meetings organised by the Agency and the logistics associated with those meetings.

[3] EU Telematics Controlled Terms
[4] Eudra Common Directory
[5] EMA Resource Planning

MMS controls the room booking process, the process for inviting reimbursed and non-reimbursed meeting participants and includes a workflow to assure appropriate authorisations. The system also provides summarised finance-related information as an input into the Agency's budgetary control system. The system was implemented in order to:

- Automate meeting room bookings
- Increase overall efficiency of the invitation process and reduce use of paper
- Automate input into the financial systems and hence increase control efficiency

3.2.2.6. ERP (EMA Resource Planning System)

The Agency is implementing an enterprise resource planning system to interface with operational systems and provide integrated support for financial and administrative purposes. The product being implemented is SAP. The ERP system will enable administrative and financial gains in efficiency to be realised, allowing the increased administrative workload arising from the growth of the Agency to be absorbed while reducing duplication of data-entry and barriers to inter-operability. A first financial module was rolled out in January 2011. A first human resources module is currently in the realisation phase.

3.2.2.7. ECD (Eudra Common Directory)

The ECD is a directory of individuals and organisations relevant to the operations of the Agency. The central directory is used both as a contacts management database and as the repository of information underlying user management for information technology purposes.

3.2.2.8. Experts Database

The Experts Database is a list of European Experts that may participate in the Agency's work. This includes members of the CHMP[6], CVMP[7], COMP[8], HMPC[9], PDCO[10] and their working parties. It also includes any expert who is taking part in any other scientific activity of the Agency.

3.2.2.9. eRMS (Electronic Records Management System)

The formal electronic system to manage records at the Agency is being introduced to replace existing manual systems. It will be a module based on the existing EDMS in the Agency.

3.2.2.10. Activity specific databases

A number of such databases (e.g. scientific memory, orphan drugs database) have been built in response to specific business requirements across the areas of interest of the Agency. The medium term strategy is to integrate these with SIAMED II.

3.2.2.11. ActiTrak

ActiTrak is an internally developed application for the recording of time for costing purposes. The system is also used to support the Agency's flexible working arrangements. This has been replaced recently by the SAP CATS system.

[6] Committee for Human Medicinal Products
[7] Committee for Veterinary Medicinal Products
[8] Committee for Orphan Medicinal Products
[9] Herbal Medicinal Products Committee
[10] Paediatric Committee

3.2.2.12. Regulation 1049 Request Tracking ("Ask EMA")

This system will support the Agency in the implementation of Regulation (EC) No 1049/2001 on access to Agency documents.

3.2.2.13. Plasma Master File

The Plasma Master File (PMF) Database core functionalities cater for the need to ensure immediate retrieval of PMF data

The main core functionalities include:

1. Administrative information by procedures/PMF Certificate Holders, including coordinators and Agency project managers.
2. Blood collection, testing, storage and transport centres and list of blood products.
3. Testing viral markers

The information will be entered electronically by the Holders of PMF Certificates at the submission of the procedure.

3.2.2.14. Electronic Signature

This project will implement the use of electronic signature in the Agency and its ICT systems.

3.2.2.15. Electronic Declaration of Interest Form

This project will provide an electronic format of the Declaration of Interests form for Experts that can be:

- easily integrated into the Agency's Expert Database
- easily provided in redacted format in response to external requests for these documents and published on-line

3.2.2.16. The Agency's Public Website and Content Management System

This system provides the Agency with a powerful content management and publishing system. The most visible component of this is the Agency's public website (http://www.ema.europa.eu)

3.2.2.17. GxP Inspections System

This system supports the Agency in its coordination of inspections relating to good clinical practice, good manufacturing practice and good pharmacovigilance practice.

3.2.2.18. ENCePP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance)

This system supports the activities of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance. It consists of a general inventory of research institutions, a database of research resources in the field of pharmacoepidemiology and pharmacovigilance and a register of publicly accessible resources for the registration of pharmacoepidemiological and pharmacovigilance studies.

3.2.3. The EU Telematics Systems and Projects

As part of the implementation of the European pharmaceutical policy and legislation, the Agency was given the responsibility for implementing the EU Telematics Strategy. This strategy aims to increase efficiency and transparency and to facilitate the operation of procedures electronically.

The EU Telematics systems have been conceived as a central set of pan-European systems and information repositories for use by all stakeholders, access by the different classes of stakeholder being limited by legislative provision or by well-founded confidentiality requirements. In addition, a secure means of communication between regulators (EudraNet) is in place and a set of tools enabling the exchange of information between regulators and industry is available.

The EU Telematics systems are designed to be separate from local systems in each agency (including the Agency), but to be able to exchange information with these local systems. The EU Telematics systems support regulatory activities in the areas of manufacturing (EudraGMP), the monitoring of post-authorisation risk-benefit balance of medicines (EudraVigilance), clinical trials (EudraCT) and marketing authorisation applications (electronic submissions). EudraPharm provides information on medicinal products to all stakeholders and will be used in support of different regulatory activities.

The implementation and operation of the systems is aimed at supporting the monitoring of post authorisation risk-benefit balance of medicines in the European Union, increasing efficiency across the European Medicines Regulatory Network, and increasing transparency and the availability of high quality information on medicinal products to the general public. In most cases the system responds to a requirement laid down in legislation. The systems are described individually below.

3.2.3.1. EudraNet

EudraNet is a secure, private electronic network used by the Agency and linking the members of the European Medicines Regulatory Network. It is used to channel electronic mail between members of the European Medicines Regulatory Network in a secure manner. In addition, it is used as a channel for members of the European Medicines Regulatory Network to access the EU Telematics systems securely.

3.2.3.2. EudraLink

EudraLink is the European Medicines Regulatory Network's secure file transfer system for the exchange of information for regulatory purposes. It operates independently of the EudraNet, and can thus be used by applicants and marketing authorisation holders, as well as the regulatory organisations within the network, to transfer files.

3.2.3.3. EudraVigilance

EudraVigilance is the European Union's system monitoring the safety of medicines through safety reports. It is designed to receive, process, store and make available information submitted electronically using the E2B format agreed at ICH[11]. Reports are received via a gateway similar to the eSubmission Gateway described elsewhere in this document.

EudraVigilance supports in particular the:

[11] In the case of veterinary medicinal products, the international forum is VICH.

- Electronic exchange of suspected adverse reaction reports (referred to as Individual Case Safety Reports) between the European Medicines Agency (the Agency), national Competent Authorities, marketing authorisation holders, and sponsors of clinical trials in the EEA[12];
- Early detection of possible safety signals associated with medicinal products for human use;
- Early detection of possible safety signals associated with medicinal products for veterinary use;
- Continuous monitoring and evaluation of potential safety issues in relation to reported adverse reactions;
- Decision making process, based on a broader knowledge of the adverse reaction profile of medicinal products especially in the frame of risk management.

There are two EudraVigilance projects/systems: EudraVigilance Human deals with medicinal products for human use and EudraVigilance Veterinary for veterinary use.

Further information is available on the following websites: http://eudravigilance.ema.europa.eu and http://eudravigilance.ema.europa.eu/veterinary/

3.2.3.4. EudraPharm

EudraPharm is the Union's database of authorised medicinal products. It contains the information currently published by means of the summary of product characteristics, the package leaflet and the labelling, but stored in structured format to enable advanced searching and presentation in contexts suitable for the person consulting the database. This information will eventually be made available via the Eudra data warehouse.

Further information can be found on the following website: www.eudrapharm.eu

3.2.3.5. EudraCT

EudraCT is the Community's electronic database containing registrations of clinical trials. It contains the information submitted by sponsors (both commercial and non-commercial) in the Clinical Trials Application Form. It informs national competent authorities of ongoing clinical trials in all member states and EEA countries thereby enabling an overview of multi-state trials. The system is also able to alert national competent authorities in case of early interruption or termination for reasons of safety or lack of efficacy; suspension or prohibition; a refusal from the national competent authority or a negative opinion from the Ethics Committee in a given Member State.

EudraCT is also the base system upon which the information collection, storage, processing and publication requirements of Regulation no. 1901/2006 on Medicinal Products for Paediatric Use has been built. The database for paediatric clinical trials went live in March 2011.

Further information can be found on the following website: http://eudract.ema.europa.eu/

Related to EudraCT is the Clinical Trials Register (See https://www.clinicaltrialsregister.eu/). The EU Clinical Trials Register website provides access to information on clinical trials in the European Union (EU) member states and the EEA and clinical trials which are conducted outside the EU/EEA if they form part of a paediatric investigation plan (PIP).

3.2.3.6. EudraGMP

EudraGMP is a system that

[12] European Economic Area

- allows the submission of GMP certificates and manufacturing and importation authorisations by national competent authorities on-line and via an XML22-based interface using the gateway;
- enables the submission of non-compliance with GMP information that results from inspection activity;
- allows the sharing of information on planned inspection activity on manufacturing sites in third countries;
- permits the consultation of the GMP, authorisation, non-compliance and inspection coordination information that results from the above submissions; and
- supports the exchange of information constituting "rapid alerts" arising out of faulty manufacture.

This system is used by inspectors of good manufacturing practice. Further information can be found on the following website: http://eudragmp.eudra.org

3.2.3.7. European Review System (EURS)

The European Review System is a system that enables national competent authorities and the Agency to receive, validate, store and make available for review marketing authorisation applications submitted in eCTD[13] format. The system's key benefit is its ability to take advantage of the lifecycle management functionality built into the eCTD exchange standard, and display a series or sequence of submissions in respect of a single product in such a way as to enable the reviewer to see immediately the full extent of the currently valid documentation, as well as the submission history showing what has changed.

3.2.3.8. Eudra Data Warehouse

The systems making up the EU Telematics applications contain between them data relating to the development, authorisation and manufacturing of medicinal products across Europe. In order to derive the greatest possible benefit from this information, the data warehouse is being implemented to enable users to collate and query this information across all the systems to maximum effect.

3.2.3.9. EUTCT (EU Telematics Controlled Terms)

EUTCT is a central repository and publication system under development for controlled term lists used in the European Medicines Regulatory Network.

Controlled term lists may be defined as lists of terms that have been enumerated explicitly. All terms in a controlled term list should have an unambiguous, non-redundant definition.

Work on controlled terms has been undertaken in the European context, notably by the European Directorate for the Quality of Medicines & Healthcare as well as the Nordic Council on Medicines. In the international arena, the European Union has participated in the development of MedDRA[14] through ICH.

The implementation for EU Telematics is the support system known as "EU Telematics Controlled Terms", or EUTCT. It comprises:

- An agreed set of controlled term lists (including, for example, country code, route of administration, ATC (Anatomic Therapeutic Chemical) code);

[13] Electronic Common Technical Document, a guideline issued by the International Conference on Harmonisation (www.ich.org)
[14] Medical Dictionary for Drug Regulatory Activities

- A central repository of controlled terms that serves the entire European Medicines Regulatory Network:
- For each controlled term list, a list of agreed terms translated into all official languages of the European Union as appropriate, with agreed definitions and a unique identifier for each term;
- A process and an infrastructure enabling the controlled update of the controlled term lists with agreed terms in a timely manner. These are likely to include a new committee that meets regularly, sets of domain experts to propose terms and definitions, and a mechanism for assuring translation into all the official languages in an accurate and timely manner; and
- A process to provide, wherever possible, the controlled term lists to the participating stakeholders.

As part of a future version, EUTCT will also provide a central repository of information on medicinal products and substances.

3.2.3.10. eAF (Electronic Application Form)

A system providing MAHs with downloadable forms enabling them to submit marketing applications as structured and pre-validated data, speeding up validation of submitted forms and automating input to consumer databases.

3.2.3.11. Central Repository

A system providing a more effective and efficient way to distribute eCTD dossiers submitted via the Centralised procedure to member-state NCAs

3.2.3.12. eSubmission Gateway

A system providing secure electronic submission of eCTDs, eliminating manual intervention before validation

3.2.3.13. EPITT (European Pharmacovigilance Issues Tracking Tool)

A database facilitating the sharing of information of the medicinal products for human use between the National Competent Authorities and the Agency, in particular related to tracking of safety issues and signals and monitoring of the implementation of the Pharmacovigilance Working Party recommendations.

3.2.3.14. Standards for Electronic Submission

Published standards are available within vol. 2B of Notice to Applicants- http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm/

Information on standards being developed in the context of the electronic submission of information in support of marketing authorisation applications, or variations thereto is available on the website of the TIGes (Electronic Submissions Telematics Implementation group) - http://esubmission.ema.europa.eu/tiges/.

3.3. ICT Standards

3.3.1. The Agency's Information and Communication Technology Standards

The Agency develops and implements information systems in accordance with a defined set of technology standards. These technology standards are collected together in a formal document which is updated regularly via the Agency's ICT Standards Committee. The current version of the document is in ***Annex 6, EMA ICT Standards***.

The Agency's ICT standards include RUP@EMA, the standard methodology used at the Agency for developing software.

The expertise sought in this Invitation to Tender is explicitly that which is set out in ***Annex 4*, Required Skills per Profile** which is itself an instantiation of the Information and Communication Technology Standards.

3.3.2. Oracle architecture and products

Enterprise applications at the Agency are currently implemented on a twin-site data centre managed by a dedicated ICT Infrastructure sector. One section is responsible for the management and administration of the Agency's Oracle database and middleware products and services.

The principal database architecture is a physical cluster of Intel x86 64-bit servers running Red Hat Enterprise Linux. The main database products supported include

- Oracle Database Server Enterprise Edition 10gR2, 11gR2
- Oracle Real Applications Cluster (RAC)
- Oracle Cluster File System (OCFS 2)
- Oracle Automatic Storage Management (ASM) 11gR2
- Oracle Data Guard
- Oracle Recovery Manager (RMAN)

The principal middle tier architecture is a virtual cluster of Intel x86 32-bit servers running Red Hat Enterprise Linux. The main middleware products supported include

- Oracle Application Server (OAS) 10gR2
- Oracle WebLogic Server 11gR1

Additional Oracle middleware products supported include:

- Oracle Business Intelligence EE
- Oracle Enterprise Manager Grid Control
- Oracle Warehouse Builder
- Oracle Internet Directory and Single Sign-On
- Oracle BPEL Process Manager

4. Subject of the tender

4.1. Description of the Services

The services to be provided consist of the provision of appropriately skilled individuals to participate in the team supporting and managing the products listed in section 3.2.2. Tenderers should note, however, that the above list represents only currently implemented products. New products are anticipated. Where new products are introduced the services will include the provision of appropriately skilled individuals to participate in their support. The services are to be provided at the Agency's premises in London. The services may be requested on a full-time or *ad hoc* basis (i.e. the requirement may be for work to be carried out on the basis of a limited number of days to be supplied non-consecutively). These services will be subject to conditions that are set out in the form of a Service Level Agreement (SLA) (see ***Annex 5, Draft Service Level Agreement***), annexed to the draft Framework Contract in ***Annex 7, Draft Framework Contract, including draft specific contract.***

In order to facilitate the assessment of the appropriateness of the skills relating to individuals, descriptions of the expected skill combinations for given roles within a team are provided below (See section 4.1.3. Detailed specifications of the profiles required). These descriptions are known as profile descriptions and are used as the basis for requesting services once the Framework Contract is effective. A request for services will comprise a given number of days of an individual fulfilling the requirements set out in one of the profiles described below.

Information on the following aspects is provided in the sections below:

- The services that are to be provided:
  - Nature of the work
  - Required profiles
- How the contract will be operated
- Required elements of the Service Level Agreements (SLAs)

4.1.1. Provision of resources for Oracle database and middleware product management

The services to be provided are in connection with the following products:

- Listed in section 3.3.2 Oracle architecture and products,
- Other Oracle products that may be acquired.

4.1.2. Overview of the Profiles Required

A list of the various profiles required in order to carry out the services on a time and materials basis is given below with a summary of the required experience in number of years. Unless explicitly stated, the required experience is mandatory.

Full descriptions of each profile can be found later in this document.

Profile	Experience in IT [min no of years]	Experience in Role [min no of years]
Database Administrator (DBA)	6	5
Middleware Administrator (MWA)	6	4
Business Intelligence Administrator (BIA)	6	4

4.1.3. Detailed specifications of the profiles required at entry level

4.1.3.1. Database Administrator

4.1.3.1.1. Languages

- English is mandatory at level 3 (fluent)

4.1.3.1.2. Third level qualifications

- Relevant third level qualifications are desirable.

4.1.3.1.3. Relevant professional qualifications

- Relevant professional qualifications (e.g. Oracle Database Administrator Certification) are very desirable.

4.1.3.1.4. General experience

- Years of relevant IT experience: Minimum of 6 years mandatory.
- Relevant business experience is desirable in any one or more of the following domains:
  - Medicines information
  - Pharmacovigilance
  - Regulation
- Experience in multicultural organisations is desirable.
- Experience in the public sector is desirable.
- Excellent team and collaboration skills are desirable.
- Strong attention to detail is desirable.
- Highly organised and motivated individual is desirable.

4.1.3.1.5. Project experience

- In the domain of Oracle database administration:
  - Number of years: 5 years minimum mandatory
- In the domain of Oracle Real Application Clusters:
  - Number of years: 3 years minimum mandatory
- In relation to the relevance of the experience:
  - Demonstrable experience of administering mission-critical high-availability production Oracle databases is very desirable.
  - Demonstrable experience of successful database administration in a Linux / UNIX environment is very desirable.
  - Experience of SAP database administration is desirable.

4.1.3.1.6. General characteristics

Competences in the role

- Demonstrable competences in the role are mandatory. These include:
  - Database creation, configuration, management, and monitoring using Oracle Enterprise Manager Grid Control
  - Experience of both OLTP and Data Warehouse technologies
  - Investigation, analysis, and resolution of errors and problems, including liaison with relevant vendor technical support
  - Assistance with design, development, and implementation best practices
  - Database backup and recovery
  - Database performance tuning
  - Management of standby databases using Oracle Data Guard
  - Application of software patches and upgrades
  - Design, implementation, and monitoring of database security policies
  - Experience in working in an environment with technical teams comprised of developers, testers, analysts and system administrators;
- Communication abilities are very desirable. These include:
  - Able to summarise and present successfully key technical issues to the relevant stakeholders (peers, architects, analysts, testers, management and business users) considering the background of the audience
  - Able to communicate in a succinct, clear and understandable manner
  - Interact at executive, team and business levels
  - Liaise with different technical teams, such as system administrators, testers and application support, understanding their requirements.
- Time management capabilities are very desirable. These include:
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to recognise the need to escalate issues as they become apparent;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.
- Supervisory experience
  - Number of years: No minimum
- Leadership capabilities
  - Demonstrable leadership capabilities are not required.

4.1.3.1.7. Specific knowledge

- Expertise per software Individual Skills List

  - Ability to use the relevant products and tools as specified in ***Annex 4: Required Skills per Profile*****.**

- General trends in the domain of expertise
  - Knowledge and understanding of general trends in the domain of expertise are very desirable
- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are very desirable

4.1.3.2. Middleware Administrator

4.1.3.2.1. Languages

- English is mandatory at level 3 (fluent)

4.1.3.2.2. Third level qualifications

- Relevant third level qualifications are desirable.

4.1.3.2.3. Relevant professional qualifications

- Relevant professional qualifications (e.g. Oracle Application Server or Oracle WebLogic Certification) are very desirable.

4.1.3.2.4. General experience

- Years of relevant IT experience: Minimum of 6 years mandatory.
- Relevant business experience is desirable in any one or more of the following domains:
  - Medicines information
  - Pharmacovigilance
  - Regulation
- Experience in multicultural organisations is desirable.
- Experience in the public sector is desirable.
- Excellent team and collaboration skills are desirable.
- Strong attention to detail is desirable.
- Highly organised and motivated individual is desirable.

4.1.3.2.5. Project experience

- In the domain of Oracle application server administration:
  - Number of years: 4 years minimum mandatory
- In the domain of Oracle WebLogic server administration:
  - Number of years: 1 year minimum mandatory
- In the domain of Oracle BPEL server administration:
  - Number of years: 2 year minimum mandatory
- In the domain of middleware administration (Oracle Internet Directory, Oracle Single Sign On, Oracle HTTP and WebCache, and Adobe LiveCycle servers)

Number of years: 2 year minimum very desirable

- In relation to the relevance of the experience:
  - Demonstrable experience of administering mission-critical high-availability production Oracle middleware servers is very desirable.

- Demonstrable experience of successful middleware server administration in a Linux / UNIX environment is very desirable.

4.1.3.2.6. General characteristics

Competences in the role

- Demonstrable competences in the role are mandatory. These include:
  - Installation, configuration, management, and monitoring of middle-tier web and application servers
  - Investigation, analysis, and resolution of errors and problems, including liaison with relevant vendor technical support
  - Assistance with web and application design, development, and implementation best practices
  - Support for testing and deployment of java applications
  - Ability to write and review LDIF scripts to search or modify custom LDAP schemas
  - Application of software patches and upgrades
  - Design, implementation, and monitoring of security policies
  - Experience in working in an environment with technical teams comprised of developers, testers, analysts and system administrators;

  Communication abilities are very desirable. These include:
  - Able to summarise and present successfully key technical issues to the relevant stakeholders (peers, architects, analysts, testers, management and business users) considering the background of the audience
  - Able to communicate in a succinct, clear and understandable manner
  - Interact at executive, team and business levels
  - Liaise with different technical teams, such as system administrators, testers and application support, understanding their requirements.
- Time management capabilities are very desirable. These include:
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to recognise the need to escalate issues as they become apparent;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.
- Supervisory experience
  - Number of years: No minimum
- Leadership capabilities
  - Demonstrable leadership capabilities are not required.

4.1.3.2.7. Specific knowledge

- Expertise per software Individual Skills List

  - Ability to use the relevant products and tools as specified in ***Annex 4: Required Skills per Profile*****.**

- General trends in the domain of expertise
  - Knowledge and understanding of general trends in the domain of expertise are very desirable
- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are very desirable

4.1.3.3. Business Intelligence Administrator

4.1.3.3.1. Languages

- English is mandatory at level 3 (fluent)

4.1.3.3.2. Third level qualifications

- Relevant third level qualifications are desirable.

4.1.3.3.3. Relevant professional qualifications

- Relevant professional qualifications (e.g. Oracle Business Intelligence Foundation 10 Certified Implementation Specialist) are very desirable.

4.1.3.3.4. General experience

- Years of relevant IT experience: Minimum of 6 years mandatory.
- Relevant business experience is desirable in any one or more of the following domains:
  - Medicines information
  - Pharmacovigilance
  - Regulation
- Experience in multicultural organisations is desirable.
- Experience in the public sector is desirable.
- Excellent team and collaboration skills are desirable.
- Strong attention to detail is desirable.
- Highly organised and motivated individual is desirable.

4.1.3.3.5. Project experience

- In the domain of Oracle Business Intelligence administration:
  - Number of years: 4 years minimum mandatory
- In relation to the relevance of the experience:
  - Demonstrable experience of administering Oracle Business Intelligence is very desirable.
  - Demonstrable experience of providing successful Business Intelligence solutions from complex data warehouses is very desirable.

4.1.3.3.6. General characteristics

Competences in the role

- Demonstrable competences in the role are very desirable. These include:
  - Installation and configuration of OBIEE
  - Capacity planning and architecture review
  - Experience with integration of OBIEE and 3rd party applications
  - Merging numerous OBIEE projects into a single repository

  - Administering complex configuration management and version control for greater than 10 concurrent BI projects
  - Building the BI Server metadata repository
  - Building dashboards
  - Defining security settings
  - Configuring and managing cache files
  - Ability to create, publish, schedule, and deliver reports
  - Experience with BI Publisher Desktop Template Builder
  - Experience of Data Warehouse technologies
  - Investigation, analysis, and resolution of errors and problems, including liaison with relevant vendor technical support
  - Assistance with design, development, and implementation best practices
  - Experience in working in an environment with technical teams comprised of developers, testers, analysts and system administrators
  - Capacity to assist in training the users of the system
- Communication abilities are very desirable. These include:
  - Able to summarise and present successfully key technical issues to the relevant stakeholders (peers, architects, analysts, testers, management and business users) considering the background of the audience
  - Able to communicate in a succinct, clear and understandable manner
  - Interact at executive, team and business levels
  - Liaise with different technical teams, such as system administrators, testers, and application support, understanding their requirements.
- Time management capabilities are very desirable. These include:
  - Ability to manage one's own time, even in the face of stressful situations;
  - Ability to recognise the need to escalate issues as they become apparent;
  - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.
- Supervisory experience
  - Number of years: No minimum
- Leadership capabilities
  - Demonstrable leadership capabilities are not required.

4.1.3.3.7. Specific knowledge

- Expertise per software Individual Skills List
  - Ability to use the relevant products and tools as specified in ***Annex 4: Required Skills per Profile*.**

- General trends in the domain of expertise
  - Knowledge and understanding of general trends in the domain of expertise are very desirable
- General trends in IT as a whole
  - Knowledge and understanding of general trends in IT as a whole are very desirable

4.1.4. Advanced levels of the profiles

The requirements detailed in section 4.1.3. describe the minimum requirements for Contractor personnel providing the service to the Agency. These are called entry level requirements. At the Agency's discretion, Contractor personnel, under certain conditions as per the list below, can be asked to provide a more advanced level of the service within the same profile. The Agency requires all Contractor personnel providing services to start at entry level.

Within every profile, a maximum of five levels is foreseen, called:

- Entry level (See section 4.1.3.)
- Level 2
- Level 3
- Level 4
- Level 5

A move to a more advanced level is at the discretion of the Agency and subject to fulfilling all of the following conditions:

- While providing services to the Agency, the individual has gained considerable and measurable additional experience (See Note 1 below) compared to the current level.
- While providing services to the Agency, the individual has successfully followed a relevant training course since starting to provide the service at the current level. The relevance of the training is established by the Agency.
- The individual has satisfactorily provided the service to the Agency for at least 12 person months at the current level.

Note 1: This will be established via peer reviews organised by the Agency.

At the next level of service, the Contractor may make an additional charge of no more than 5% for the service based on the charge at the previous level.

4.1.5. Operation of the contract

This section describes:

- The contractual arrangements that the Agency is looking to put in place for provision of the service described in section 4. Subject of the tender;
- The mechanism by which these contracts will be executed and how performance will be measured

4.1.5.1. Overview of the operation of the contract

The objective of the procurement procedure is to put into place contractual arrangements with one or more companies for the provision of services, on a time and materials basis, that will enable the Agency to acquire resources not employed directly by the Agency in the domain of the management and administration of Oracle product-based information and communication technology systems. To that end, the Agency intends to sign multiple, cascading framework contracts (see section 4.1.5.2.) in order of priority.

Framework contracts do not constitute orders. Orders are placed through service requests (see section 4.1.5.4.) resulting in specific contracts (see section 4.1.5.3.).

During the execution of a specific contract, the Contractor is required to provide the Agency with reports on its performance (see section 4.1.5.10.).

A specific contract is executed against a Service Level Agreement (SLA) with quality indicators (see section 4.1.5.8.).

Failure to meet the terms of the SLA may invoke the use of the cascade, i.e. the Agency may send a request to the next company in the cascade to provide the service initially requested from or contracted to the company where that company has failed to meet the terms in the service level agreement.

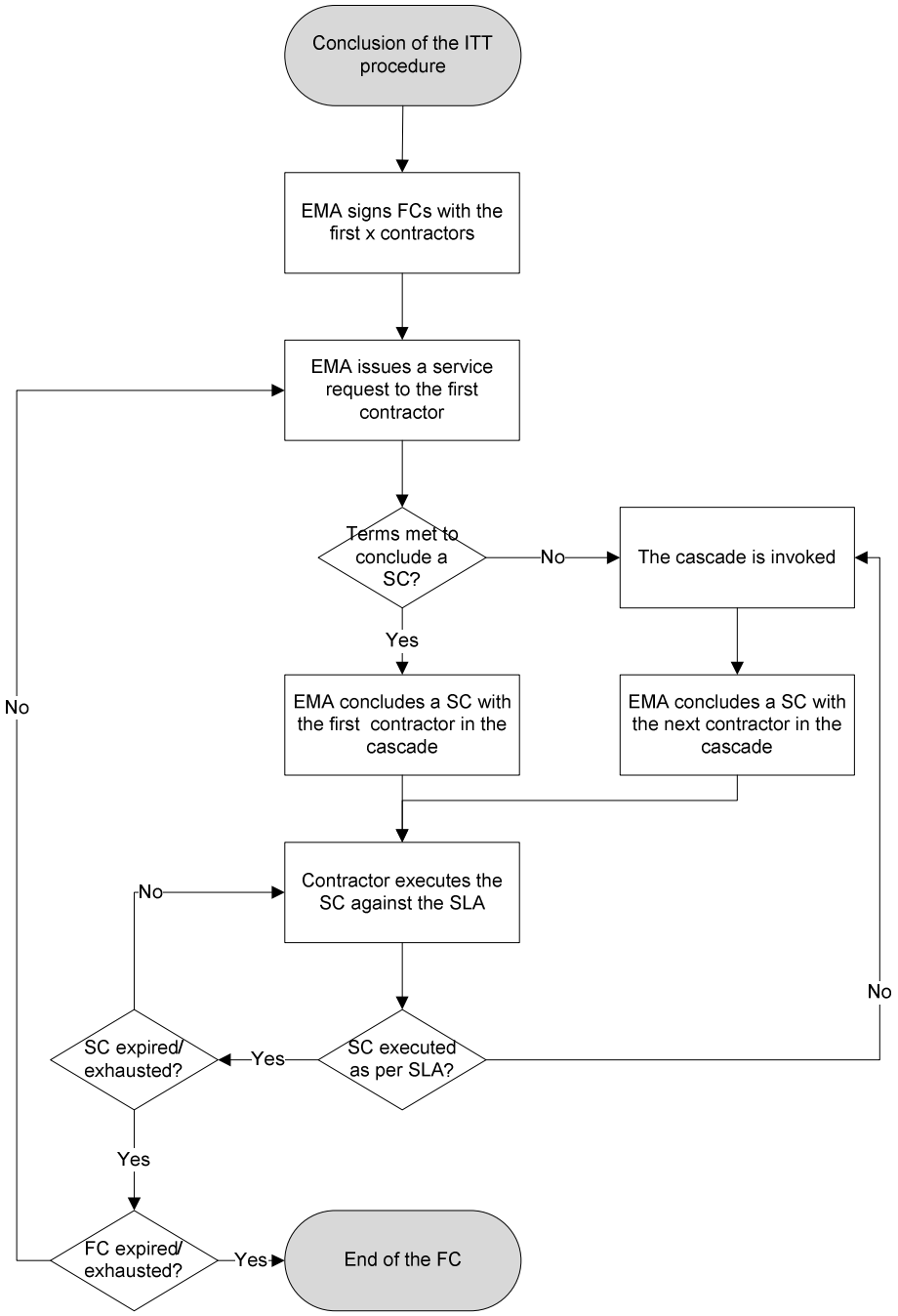

Figure 1: Overview of the operation of the contract

The sections below describe in detail how the contracts will be operated.

4.1.5.2. General description of framework contracts

A framework contract lays down the basic terms and conditions governing the relations between the Agency and the Contractor during the period of validity of the contract, particularly as regards duration, subject, price, implementing conditions and the overall quantity of services required.

It is the Agency's intention to sign multiple cascading framework contracts as a result of this Invitation to Tender. A framework contract will be awarded to a first priority Contractor and up to two other Contractors ranked in order following the evaluation procedure. If, for example, the first priority Contractor is unable to fulfil the requirements of an order within the requisite timelines or provides an unsatisfactory service, the Agency has the option to go to the second priority Contractor in such a cascade and then to the third until the order is fulfilled.

Framework contracts will be concluded for an initial period of two years, with two possible extensions of one year each, giving a maximum possible duration of four years.

Signature of a framework contract imposes no obligation on the Agency to order services. Only the implementation of the framework contract through Specific Contracts is binding for the Agency.

A draft Framework Contract, containing full terms and conditions, is included in ***Annex 7: Draft Framework Contract, including draft Specific Contract*.**

4.1.5.3. Specific contracts implementing framework contracts

The conclusion of a framework contract does not in itself constitute a confirmed order to a supplier. Orders are placed by means of specific contracts, which are contractual documents that contain the specific conditions for concluding and executing selected programmes of work between the Agency and the Contractor. The framework contract will define the unit costs for work at the Agency's premises of the personnel to be used to undertake the work required in this Invitation to Tender. Based on these costs, orders will then be placed and specific contracts concluded to confirm those orders according to the terms and conditions included as part of the draft Framework Contract annexed to this Invitation to Tender and of the corresponding financial proposal of the Contractor.

A draft Specific Contract can be found as an annex to the draft Framework Contract in ***Annex 7: Draft Framework Contract, including draft Specific Contract*.**

4.1.5.4. Process for ordering services

The ordering process for time and materials orders is as follows:

1. A profile specification for each profile required will be drawn up by the Agency and the template is included in ***Annex 10: Standard Profile Specification & Request Form***. Where the Agency does not provide a profile specification, the default specification for the relevant profile (See section 4.1.3. Detailed specifications of the profiles required) will be considered by the Contractor.
2. A request form is completed by the Agency, in which the request for services is summarised and timelines are given for responses from the Contractor. A template example is included in ***Annex 10: Standard Profile Specification & Request Form***.
3. The request form, accompanied by the profile specifications and any other relevant documentation is sent by e-mail to the first priority Contractor in the cascade.

4. If the first priority Contractor has been given the opportunity to provide these services and has failed to comply with the relevant timelines (as defined in this section and section 4.1.5.8.) or is unable to provide the services or has provided services unacceptable to the Agency (as defined in this section and section 4.1.5.8.), the Agency may send the documents to the next Contractor in the cascade and the process will continue until the request is satisfactorily fulfilled.

5. The Contractor is required to acknowledge receipt of the Request Form and associated documents by e-mail to the Agency within two working days of the date on which the Request Form was sent out by the Agency.

6. The Contractor is then required to indicate willingness to make an offer or to decline to make an offer by the date specified in the Request Form, which will be a maximum of 3 working days from the date on which the Request Form was sent out by the Agency **(Benchmark 1)**. If the Contractor declines to make an offer or fails to respond by the due date indicating its willingness to make an offer, the Agency will then forward the Request Form to the next Contractor in the cascade.

7. Having confirmed willingness to make an offer, the Contractor is required to propose to the Agency by e-mail the CVs of candidates matching the requirements given in the profile specification form(s) accompanying the Request Form. The response must be sent to the Agency by the final offer date specified in the Request Form **(Benchmark 2)** with a formal confirmation from the Contractor that the proposed service has been verified by the Contractor to match the requirements. The Europass CV template must be used as per the Agency's instructions as set out in the annexes to the draft Framework Contract. The Europass CV can be downloaded from the following website:

   http://europass.cedefop.europa.eu/europass/home/vernav/Europass+Documents/Europass+CV.csp

8. The Agency will assess the CVs. If no candidates are acceptable for an interview: see step 12 below.

9. If one or more CVs are found to be acceptable: all candidates proposed must be available for interview at the Agency in the two weeks following the sending of the CVs.

10. If the Contractor does not comply with the timelines specified, the Contractor will be deemed to have not respected the requirements and the Agency may forward the Request Form and documents to the next Contractor in the cascade.

11. If the Agency accepts a candidate(s) as a result of interviews, the Agency will send an e-mail to the Contractor indicating that the candidate(s) has been accepted and will request a formal offer from the Contractor. Having conducted up to 3 interviews without identifying a suitable candidate the Agency reserves the right to go to the next contractor in the cascade.

12. If a candidate(s) is found to be unacceptable to the Agency, the Agency will advise the Contractor by e-mail and will give feedback, wherever possible, on the reasons why the candidate(s) has been rejected. If the final offer date in the Request Form has not yet been reached, the Agency may permit the Contractor to forward more CVs for consideration. If the final offer date has been reached, the Contractor will be deemed not to have fulfilled the requirements **(Benchmark 3)** and the Agency may forward the Request Form to the next Contractor in the cascade.

13. Once a candidate has been confirmed and a formal offer received from the Contractor, the Agency will draw up the Specific Contract which will include the details of the work to be carried out, the start date, the duration in man-days and any other relevant information. The Specific Contract will be signed in the relevant number of copies by the Agency's signatory and will then be forwarded to

the Contractor for signature. The Contractor will return the contract to the Agency within ten working days. The Specific Contract becomes effective from the date of the last signature.

14. The Contractor will return one copy of the signed contract to the Agency, retaining the other copies for its own files.
15. Where a Specific Contract is already in place prior to the dispatch of a request for services (e.g. where there is a replacement of the Contractor's personnel), steps 13-14 will not apply.
16. The Contractor's personnel will commence work on a mutually convenient date, normally the start date stipulated in the request form, and time and at the location stipulated in the Request Form. For time and materials contracts, this will normally be at the Agency's premises in Canary Wharf, London, UK.

The Contractor will be expected to present proposals which meet the requirements specified in the Request Form and associated documents. Personnel proposed must match the requested profile description and persons whose CVs have been proposed in the tender should be available to work on the Specific Contracts concluded with the Agency. The Contractor must present to the Agency **at least two suitably qualified candidates** for each profile required and these persons must be available for interviews, which are attended at the cost of the Contractor. Persons proposed must be available at the start date as identified in the Request Form.

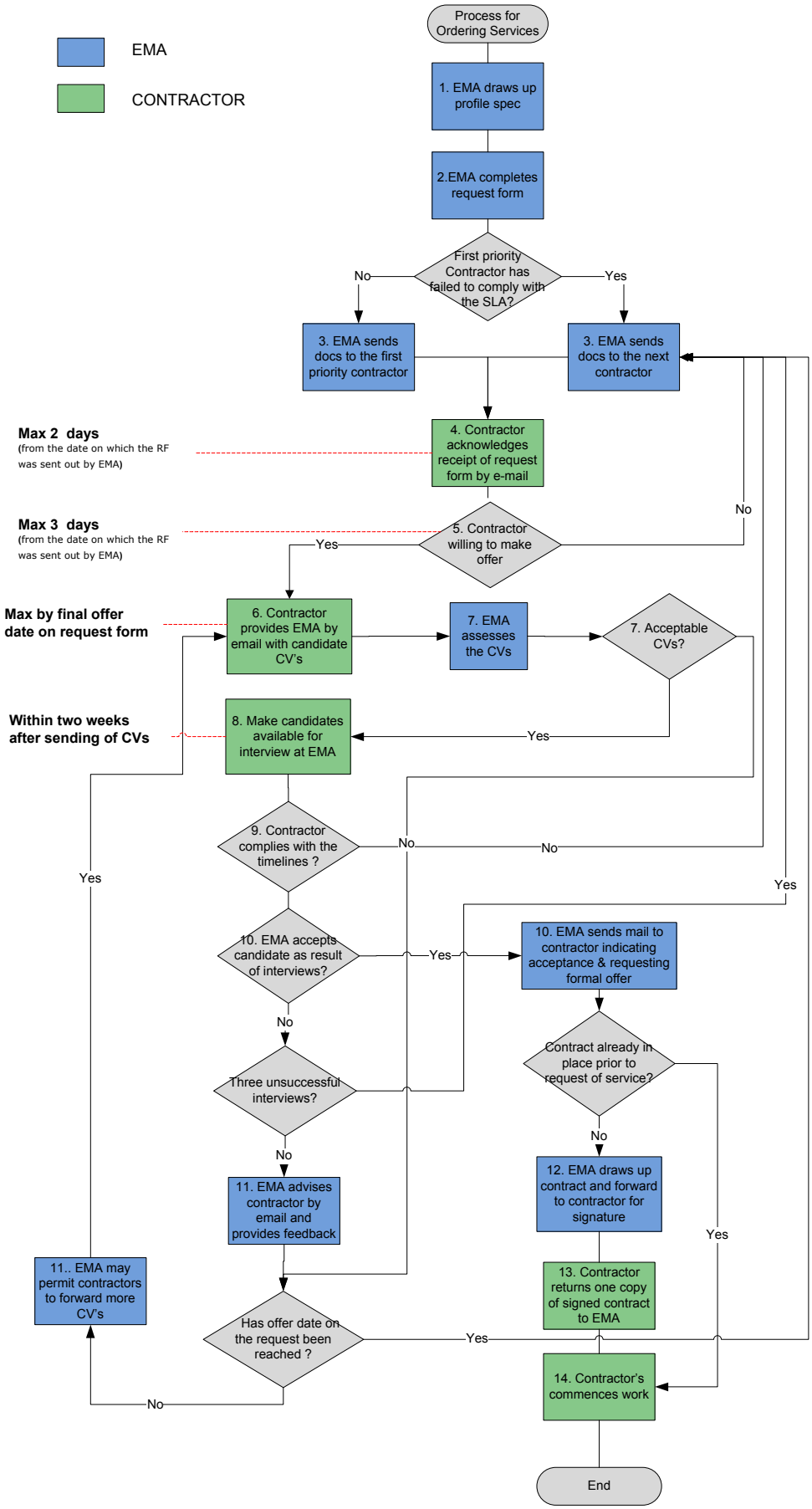

Figure 2: Diagrammatic presentation of the process for ordering services

Table 1. Benchmarks

Number	Purpose	Benchmark
Benchmark 1	For timely indication of willingness to make an offer or to decline	A maximum of 3 working days from the date on which the Request Form was sent out by the Agency
Benchmark 2	For timely provision of CVs	The response must be sent to the Agency by the final offer date specified in the Request Form
Benchmark 3	For success or failure to provide the requested service	If the final offer date has been reached without provision of acceptable Candidates, the Contractor will be deemed not to have fulfilled the requirements

4.1.5.5. Replacement of Contractor personnel not initiated by the Agency

Where there is a need to replace personnel in normal circumstances (excluding situations of force majeure) and this is not initiated by the Agency, the following process shall be followed:

1. As soon as the Contractor learns that the original person will no longer be able to carry out the work, the Contractor is obliged to immediately inform the Agency. The Contractor shall give one month's notice (20 working days) to the Agency.
2. The process as described in section 4.1.5.4. Process for ordering services will be followed so that the replacement is present at Agency premises ten days before the end of the period of notice of the outgoing resource.
3. If the Contractor does not propose suitable replacement staff in due time, the Agency may:
   - 3.1. either immediately cancel the relevant profile from the SC, and invoke the cascade;
   - 3.2. or apply a penalty of 10 days free of charge.
4. The Contractor shall arrange sufficient training (during the handover period where possible) to guarantee continuity of the service provided to the Agency.
5. A handover of at least 10 working days, free of charge for the Agency, will take place.
6. If no handover is possible, at least 15 working days must be provided by the replacement person free of charge for the Agency. The days free of charge will be the first 15 working days of the period to be worked by the replacement person.
7. Any such replacement will be effected at no additional cost to the Agency.

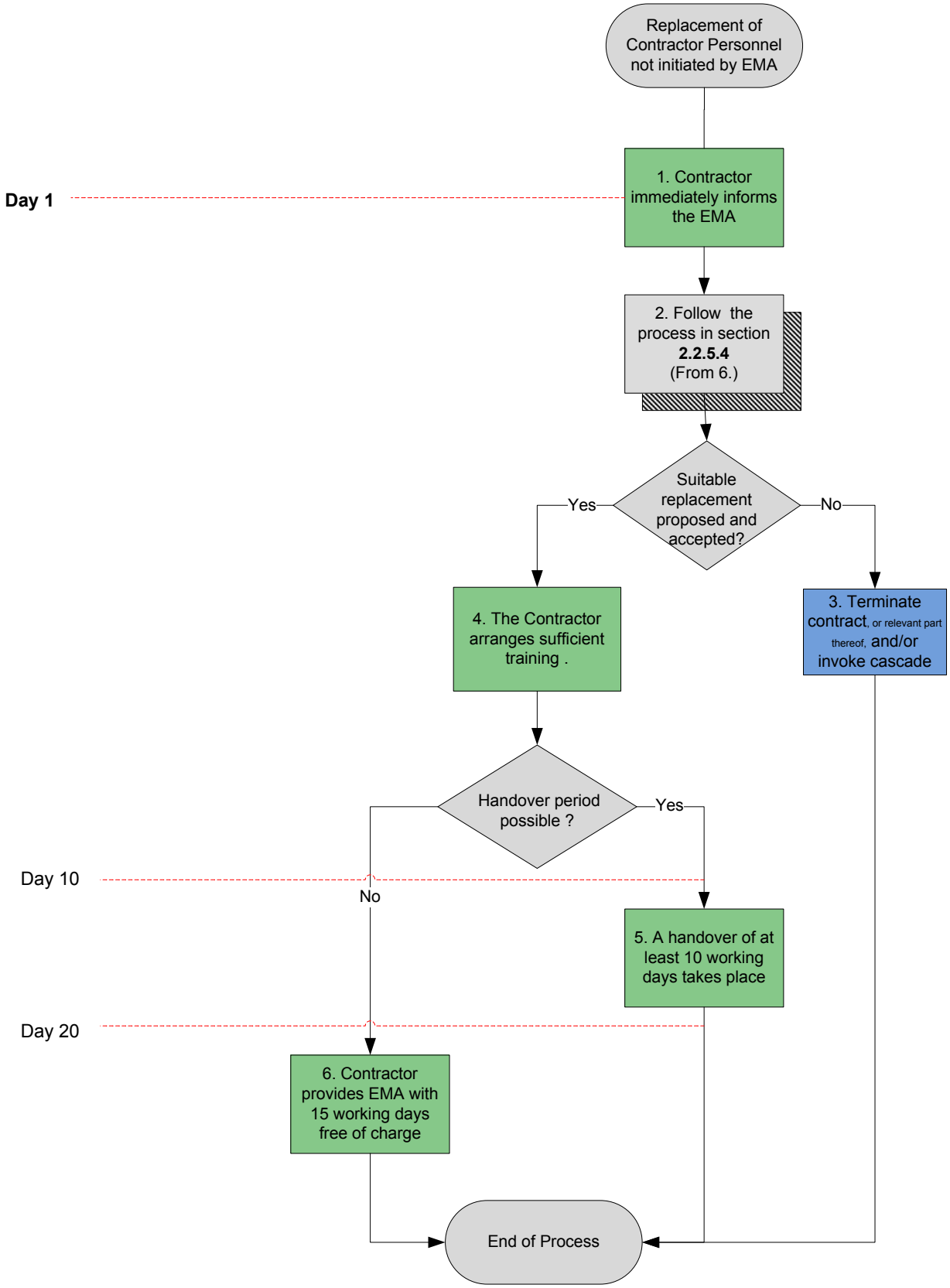

Figure 3: Diagrammatic presentation of the process for replacement

4.1.5.6. Languages

The required services must be provided in English.

4.1.5.7. Place of work

Work is to be executed on an *intra muros* basis (see below). The Agency will indicate on all Request Forms where the work has to be undertaken.

4.1.5.7.1. Intra muros

Intra muros work will be undertaken at the Agency's premises at 7 Westferry Circus, Canary Wharf, London E14 4HB, UK. The infrastructure will be provided by the Agency.

Personnel providing the service will use only the standard software packages in use at the Agency, the named Member States Competent Authority in the EU or EEA or industry partner and no other software may be installed or used without the written authorisation of the Agency.

4.1.5.8. Quality monitoring

For the purposes of this section, a benchmark is a point of reference for the measurement of the performance of an activity against which the Contractor will be assessed.

The benchmarks defined below are used to measure the quality of the service delivery (See section 4.1.5.12. Service Quality Indicators and Service Quality Benchmarks)

Penalties may be imposed (See section 4.1.5.9.) where the Contractor either fails to meet quality expectations either by a substantial margin in a single instance or consistently over a period of time.

4.1.5.8.1. Quality of the service delivery

Monitoring of the quality of service delivery will measure whether the Contractor is delivering a standard of service in line with expectations. CVs should meet the profile specifications in terms of the characteristics requested in the context of that which is described per profile in this invitation to tender and should be delivered in a timely manner. In addition, administrative activities in connection with setting up and maintaining the arrangements with individuals should be carried out in a timely and efficient manner. Finally, management of Contractor personnel should be pro-active and such that it contributes to efficient execution of projects and tasks.

The mechanism for monitoring will involve the periodic execution of the following:

- measurement of acceptability by means of invitations to an interview
- measurement of timely delivery of CVs
- measurement of the efficiency with which contractual arrangements are finalised with selected profiles in the context of known notice periods

Table 2. Benchmarks

Number	Purpose	Benchmark
Benchmark 4	For provision of qualitative CVs	An average of three acceptable (deemed compliant by the Agency with the profile description and/or invited for interview) CVs across all requests
Benchmark 5	For timely delivery (i.e. from step 6 - 13 above) of resources	An average of three weeks across all requests

Number	Purpose	Benchmark
Benchmark 6	For availability of resources	Availability of the resource (i.e. on the date on which the resource effectively starts to provide the service), following the Agency's notification of intention to proceed (see step 11 in section 4.1.5.4.), is no later than the known notice period, or two weeks where there is no notice period.
Benchmark 7	For compliance with notice period	Full compliance with the rule that requires the Contractor to provide the Agency with at least one month's notice (20 working days) when a resource discontinues his collaboration on an Agency project (e.g. because he has given the Contractor notice) where this is not desired by the Agency.
Benchmark 8	For audit success	The Contractor is expected to pass all audits by the Agency as per section 4.1.5.8.3. *Quality audits*

4.1.5.8.2. Quality of the work delivered by time and materials resources

Monitoring of the quality of work delivered by resources will measure the delivery of the services required in respect of their timeliness and the extent to which they meet the qualitative expectations of the Agency.

Monitoring will be carried out in the following manner:

Quality of the work of a resource

- Before commencing a task, the Contractor's personnel will agree on the scope of the task, the technical approach and the workload estimate with Agency staff.
- Progress monitoring: all resources will report on a weekly basis via timesheets showing the number of hours spent per agreed task and progress on the task.
- Monitoring of deliverables: upon delivery of a deliverable, Agency staff will review the quality of what is delivered on the basis of its fitness for purpose.

Table 3. Benchmarks

Number	Purpose	Benchmark
Benchmark 9	For quality of resources	An average of 1% per annum of all personnel of the Contractor currently providing services for the Agency to not meet expectations (***See Note 1 below***).
Benchmark 10	For turnover of resources	An average of 4% per annum of all personnel of the Contractor currently providing services for the Agency to leave the Agency where this is not desired by the Agency

Note 1:

Whether expectations are met will be established by adherence to the profile description (See section 4.1.5.4.), the service level agreement and the quality of service (*inter alia* established via peer reviews).

Where the resource either fails to meet the benchmarks in a single instance or consistently over a period of time, the Agency may terminate the collaboration with this resource immediately. The Contractor will be required to replace the affected resource immediately.

4.1.5.8.3. Quality audits

The Agency will audit the Contractor's processes related to the delivery of the service. Three types of audit are foreseen. Costs for these audits will be covered by the Agency. It is not foreseen that any costs will be incurred by the Contractor, except for their own business time which cannot be invoiced to the Agency.

- Short-notice point audit:
  - Notice period: 24 hours
  - Content: Request to provide documented evidence that a specific step in the processes related to the delivery of the service has been provided
  - Maximum frequency: One per month
- Shallow system audit announced in advance:
  - Notice period: 5 working days
  - Content: On-site (Contractor's premises) audit of all auditable processes and systems (cf. Infra)
  - Maximum duration: 0.5 days
  - Maximum frequency: One per quarter
- In-depth system audit announced well in advance:
  - Notice period: 10 working days
  - Content: On-site audit (Contractor's premises) of all auditable processes and systems (cf. Infra)
  - Maximum duration: 2 days
  - Maximum frequency: One per year

The auditable processes will be part of the SLA with a possibility of revision on conclusion of Specific Contracts. The set of auditable processes and systems will consist of at least:

- The processes and quality systems specified in this ITT
  - E.g.: The process described in sections 4.1.5.4. Process for ordering services, 4.1.5.5. Replacement of Contractor personnel not initiated by the Agency, 4.1.5.10. Reporting requirements
- The processes and information the Tenderer has referred to in his response to this ITT as far as relevant to the delivery of the service.

4.1.5.9. Measures in cases of underperformance

If the contractor fails to meet the above benchmarks in respect of one or more of the quality indicators for a period of 3 consecutive months from the start date of the contract or during the preceding 12 month period, the Agency may decide to bypass the contractor for a period and to address requests for services to the next contractor in the cascade.

All profiles provided by the next contractor in the cascade as a result of the above measures will continue to be resourced by that contractor.

These measures will be applicable for a minimum of the next three service requests (irrespective of the type of profile) following the 3 consecutive months of failure to meet the benchmarks or until such

time as the contractor has demonstrated that it has taken all necessary measures to remedy and resolve this situation.

The measures above may be applied under the following conditions:

- The period of measurement is the last 12 months or, if the duration of the framework contract is less than twelve months, from the start of the framework contract.
- The minimum number of requests must be 10 during the period of measurement.

At the end of the application of these measures, a new period of measurement of the quality indicators will be initiated.

4.1.5.10. Reporting requirements

The Contractor must provide the following reports to the Agency in English:

- Timesheets signed by individual contractors:
  - Using the standard Agency tool
  - Monthly
- Report on consumption per resource:
  - A monthly report to be provided to the Agency's ICT Project Office detailing the number of man-days worked by each individual contractor working on time and materials contracts in the preceding month, including cumulative totals from preceding months and the number of man-days remaining on the individual's current assignment. This report must be provided by the end of the second calendar week of the month following the month to which the report refers.
- Report on quality of service delivery:
  - A quarterly report to be provided, by the end of the second calendar week of the month following the end of the quarter, to the Agency's ICT Project Office, detailing:

    The number of requests received from the Agency

    The number of requests fulfilled

    Those outstanding at the end of the quarter

    The number of candidates proposed for time and materials orders

    The values of the quality indicators (see sections 4.1.5.4. Process for ordering services and 4.1.5.8. Quality monitoring)

    The risks identified and the problems encountered (with the measures taken for the mitigation of risks and for correction of problems, and a follow-up of previous measures)

The exact content and layout of the respective reports shall be agreed between the Agency and the Contractor following signature of the Framework Contract.

Upon request of the Agency, Contractors will be required to attend a quarterly meeting at the Agency's premises in London to review performance, the status of the contract and the planning for the next period.

4.1.5.11. Interfaces, roles and responsibilities

4.1.5.11.1. On the Contractor's side

- The Contractor nominates a contract manager in charge of the Framework Contract. He will be responsible for all contractual relations with the Agency. The Contract Manager must be reachable by the Agency during Agency working hours. In case of absence, a back-up person must be designated.
- The Contractor must designate a single main contact person, and at least one back-up person in case of absence, who will take care of all requests addressed to it by the Agency.
- The Contractor shall provide a single contact office with telephone number, postal address, e-mail address.
- The Contractor must provide a list of all persons responsible for the management of the customer's relationship with the Agency, with a list of their roles and responsibilities.

4.1.5.11.2. On the Agency's side

- The Agency's ICT Project Office is the single point of contact for the Contractor for the purpose of the day-to-day operation of the Framework Contract and will liaise internally in the Agency as and when required.
- The Agency's ICT Budget and Financial Service is responsible for renewals, amendments, payments and payment-related issues.

4.1.5.12. Service Quality Indicators and Service Quality Benchmarks

The Service Level Agreement sets out the quality indicators and benchmarks against which the services must be provided and the penalties (see section 4.1.5.9.) which will apply if the Contractor fails to meet or exceed the benchmarks. Failure to meet the benchmarks in the SLA may lead to penalties or any other measures stipulated in the Framework Contract or the Specific Contract.

The quality indicators are defined in Table 4 below:

Table 4. Quality indicators

Category		Service Quality Indicators	Reference to usage/point of measurement	Value	Service Quality Benchmarks
Process for ordering services	1	Compliance with timeline to indicate willingness to make an offer or decline	For every service request: Section 4.1.5.4. Process for ordering services: Step 6	Time [working days]	See Benchmark 1 in section 4.1.5.4. Process for ordering services: Step 6
	2	Compliance with timeline for sending the response	For every service request: Section 4.1.5.4. Process for ordering services: Step 7	Time [working days]	See benchmark 2 in section 4.1.5.4. Process for ordering services: Step 7
	3	Success or failure to provide the requested service	For every service request: Section 4.1.5.4. Process for ordering services: Step	Y/N	See benchmark 3 in section 4.1.5.4. Process

Category		Service Quality Indicators	Reference to usage/point of measurement	Value	Service Quality Benchmarks
			12		for ordering services: Step 12
Quality of the service delivery	4	Acceptability of the provided CVs	Every quarter across all service requests with a confirmed willingness to offer	Number	See benchmark 4 in section 4.1.5.8.1. Quality of the service delivery
	5	Timely delivery of resources	Quarterly average across all service requests with a confirmed willingness to offer	Time [working days]	See benchmark 5 in section 4.1.5.8.1. *Quality of the service delivery*
	6	Efficiency of finalisation of contractual arrangements	Quarterly average across all service requests with a confirmed willingness to offer	Time [working days]	See benchmark 6 in section 4.1.5.8.1. *Quality of the service delivery*
	7	Compliance with notice period	Quarterly average across all resources	Y/N	See benchmark 7 in section 4.1.5.8.1. *Quality of the service delivery*
	8	Audit success	Every quarter across all audit requests	Y/N	See benchmark 8 in section 4.1.5.8.1. *Quality of the service delivery*
Quality of the work delivered by time and materials resources	9	Quality of the provided resources	Quarterly average across all resources	Number	See benchmark 9 in section 4.1.5.8.2. Quality of the work delivered by time and materials resources
	10	Turnover	Quarterly average across all resources	Quarterly average across all resources	See benchmark 10 in section 4.1.5.8.2. *Quality of the work delivered by time and materials resources*

4.1.5.13. Use of the cascade

For ease of reference, this section repeats the cases and the mechanisms by which the cascade will be invoked and the duration or number of requests.

The Agency can decide to invoke the cascade:

- When the criteria for quality or timeliness as described in section 4.1.5.4. Process for ordering services, are not met for a particular request for services
- When the benchmarks as described in section 4.1.5.8. Quality monitoring, are not met for the duration or number of requests as specified in section 4.1.5.9. Measures in cases of underperformance.

5. Information visit

Information visits are not foreseen for this tender.

6. Participation in the tender

6.1. Multilateral agreement on public procurement

Participation in this tendering procedure shall be 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 the European Union in the field of public procurement under the conditions laid down in that agreement.

Where the Multilateral Agreement on Public Procurement concluded within the World Trade Organisation applies, the tendering procedure shall also be open to nationals of the countries which have ratified this agreement, under the conditions laid down in that Agreement. In that connection, it should be noted that the services under Annex II-B to Directive DIR/2004/18/EC and the R&D services listed in category 8 of Annex II-A to that Directive are not covered by the Agreement.

6.2. Subcontracting

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

(i) A document signed by the tenderer stating clearly the identity, roles, activities and responsibilities of subcontractor(s) and specifying the volume/proportion of the work to be undertaken by each subcontractor (see sheet 04.05 List of Subcontractors in **Annex 2 Response Questionnaire**).

(ii) A letter of intent by each subcontractor stating its unambiguous undertaking to collaborate with the tenderer if it wins the contract and the extent of the resources that it will put at the tenderer's disposal for the performance of the contract (see sheet 04.05 List of Subcontractors in **Annex 2 Response Questionnaire**).

(iii) As requested under points 13, 14 and 15 all documents regarding the exclusion and/or selection criteria for any subcontractors.

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

Subcontracting is permitted to subcontractors proposed in the offers submitted in reply to the call for tenders. Additional subcontracting to other than one-person companies (or freelancers) during the execution of the contract will only be accepted with the prior written consent of the Agency.

One-person companies (or freelancers) may be authorised as subcontractors and added to the list of subcontractors at any time during the execution of the contract. Please note that the documents required under points (i), (ii) and (iii) above are not required for one-person companies but tenderers should include the names and addresses of one-person companies in sheet 04.05 List of Subcontractors in **Annex 2, Response Questionnaire**.

The Contractor may subcontract to another contractor but no further levels of subcontracting will be permitted.

Where joint tenders are envisaged, the following documents must be provided with the tender submission:

(i) A document signed by the tenderer stating clearly the identity, roles, activities and responsibilities of each member of the joint tender group, including subcontractors (but not one-person companies) and specifying the volume/proportion of the work to be undertaken by each joint member.

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

iii) As requested under points 13, 14 and 15 of this Invitation to Tender, all documents regarding the exclusion and selection criteria for each company individually, including joint tenderers.

7. Additional documentation available to tenderers

We strongly recommend that Tenderers read the Agency's 'Guidebook for Tenderers', which can be downloaded from:

- http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/01/WC500057107.pdf

Further information about the work of the Agency can be obtained from its website:

- http://www.ema.europa.eu

Further information on EU Telematics is available at:

- http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000116.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028c2b

Further information on various projects can be found on the following websites:

- EudraVigilance
  - http://eudravigilance.ema.europa.eu
  - http://eudravigilance.ema.europa.eu/veterinary
- Electronic submissions:
  - http://esubmission.ema.europa.eu
- EudraPharm :
  - http://eudrapharm.eu/eudrapharm/
- EudraCT :
  - http://eudract.ema.europa.eu/
- EudraGMP:
  - http://eudragmp.ema.europa.eu
- ENCePP:
  - http://www.encepp.eu

Information on standards agreed at the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is available in the section of the

ICH website (www.ich.org) devoted to the work of the second multidisciplinary group (M2) dealing with Electronic Standards for Transmission of Regulatory Information (ESTRI).

Publicly available information with regard to earlier tenders in the field of information technology may be consulted through the Calls for Tender section of the Agency's website at:

- http://www.ema.europa.eu/htms/general/admin/tenders/contracts.htm

8. Variants

Not applicable.

9. Estimated contract volume

The Agency estimates, without this being binding, that the volume of services required under the contract over a four year period is as shown in the table below.

Number of person-days					
Period:	2012	2013	2014	2015	2012-2015
Profile:					
Database Administrator	480	480	720	720	**2400**
Middleware Administrator	240	240	240	240	**960**
Business Intelligence Administrator	240	240	240	240	**960**
Total:	**960**	**960**	**1200**	**1200**	**4320**

10. Price

10.1. Currency of tender

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

10.2. All-inclusive Prices

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

10.3. Price Revision

Prices submitted in response to this tender shall be fixed and not subject to revision for Specific Contracts concluded during the first year of performance of the contract.

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

This revision shall be determined by the trend in the European Index of Consumer Prices (EICP) published by the Statistical Office of the European Communities 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:

$$A_r = A_o \frac{I_r}{I_o}$$

Where

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

10.4. Costs involved in preparing and submitting a tender

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

10.5. Period of validity of the tender

Tenderers must enclose a confirmation that the prices, conditions and stipulations contained within the response to the Invitation to Tender (ITT) are valid for twelve months from the date of submission of the tender.

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

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

11. Payment arrangements

Payment shall be made on completion of the services subject to certification by an authorised staff member of the Agency that the services have been satisfactorily performed and submission of any reports required in line with the Specific Contract, on the basis of an invoice to be established by the Contractor, giving a breakdown of the fees, and verified by the Agency, by bank transfer to the Contractor's bank account.

Payments shall be made within 45 days of receipt of the request for payment and shall be deemed to have been made on the date on which they are debited to the Agency's account. The Agency may, however, after giving notice to the Contractor, defer payment if the products or services covered by the request for payment are contested by the Agency or if the vouchers in support of the request are incomplete. Where payment is so deferred, the Agency shall not be liable to pay interest or indemnities of any kind. All requests for payment and any complaints shall be sent to the following address:

European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

The Agency shall be bound to comply with payment periods only if requests for payment are properly presented at the above address.

The Contractor is required to give the following information on all invoices:

- The breakdown of fees or quantities of goods supplied, the contract price and the amount of VAT applied, if any, or, whenever appropriate, a note that the services rendered under the contract are exempted from VAT in accordance with the national tax law by which the Contractor is governed.
- A reference to the tender number as shown on the first page of the Invitation to Tender.
- A reference to the framework contract number and specific contract number.
- A reference to the Agency's purchase order number.

12. Contractual details

A draft Framework Contract, with a draft Specific Contract in annex, is attached to these Technical Specifications as ***Annex 7: Draft Framework Contract, including draft Specific Contract***. Tenderers must confirm acceptance of these draft contracts and terms and conditions of the tender as part of their tender response.

The Agency wishes to conclude multiple framework contracts to provide the services as described, as and when required, for an initial period of two years, with the possibility of two renewals each of one year. A framework contract will establish the terms governing specific contracts to be awarded during a given period, in particular with regard to price.

Signature of the framework contract imposes no obligation on the Agency to order services. Only the implementation of the framework contract through specific contracts is binding for the Agency.

Each specific contract will contain details of deliverables and timelines for particular services to be provided.

12.1. Confidentiality Undertakings

At the time of signature of the contract, Contractors will be required to sign the Agency's confidentiality undertaking for Contractors (see ***Annex 9: Confidentiality Statement*).**

In addition, prior to commencing work, each individual allocated by the Contractor to work on a project will be required to sign the confidentiality undertaking set out in ***Annex 9: Confidentiality Statement***.

13. Exclusion criteria

Tenderers should provide the information requested in this section by using the questionnaire provided in *Annex 2: Response Questionnaire*.

Tenderers shall be excluded from participation in this procurement procedure if:

1. they are insolvent (or the subject of bankruptcy proceedings if an individual) or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
2. they have been convicted of an offence (if an individual) or judgment has been made against them concerning their professional conduct by a judgment which has the force of *res judicata*;
3. they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;
4. they have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed;
5. they have been the subject of a judgment which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the European Union's financial interests;
6. following another procurement procedure or grant award procedure financed by the European Union budget, they have been declared to be in serious breach of contract for failure to comply with their contractual obligations.
7. Contracts may not be awarded to candidates or tenderers who, during the procurement procedure:
8. are subject to a conflict of interest;
9. are guilty, either knowingly or negligently, of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the contract procedure or fail to supply this information.

Tenderers must complete, date and sign the declaration in the response questionnaire in ***Annex 2: Response Questionnaire*** in relation to Exclusion Criteria. For joint applicants, the declaration must be signed and dated by each company, including subcontractors, and will be assessed individually.

Only the successful tenderer, including joint applicants and subcontractors (excluding one-person companies (or freelancers)), will be required to provide all the supporting documentation indicated below at a later stage prior to contract signature.

Successful tenderers to which a contract is to be awarded will, in addition to the signed statement and original declaration(s) submitted, be required to show that they are not in one or more of the situations listed above by providing evidence in relation to these items within a time limit to be defined by the Agency and prior to the signature of any contract. For joint applicants, the documentation is required for each member of the group, including subcontractors.

The evidence which may be required from the successful Tenderers is as follows:

- In relation to points 1, 2 and 5 above, relevant extract(s) from the judicial record or, failing that, equivalent documentation issued by a judicial or administrative authority in the country where the tenderer is established. The extract(s) or equivalent documentation must be the most recent reasonably available. Depending on the national legislation of the country in which the tenderer is established, these documents must relate to entities with legal personality and/or natural persons; in the latter case, they must relate to the person(s) empowered to represent the tenderer and sign the contract if the tender is successful.

- In relation to point 4 above, the most recent certificates issued by the competent social security and tax authorities of the country where the tenderer is established.

  Where no such document or certificate is issued in a particular country, this can be replaced by a sworn and solemn statement made before a judicial or administrative authority, a notary or a qualified professional body of the country in which the tenderer is established. The statement provided must be dated less than four months before the final date for submission of tenders. Depending on the national legislation of the country in which the tenderer is established, these documents must relate to entities with legal personality and/or natural persons; in the latter case, they shall relate to the person(s) empowered to represent the tenderer and sign the contract if the tender is successful.

- In relation to points 3, 6, 7 and 8 above, a sworn and solemn statement made before a judicial or administrative authority, a notary or a qualified professional body of the country in which tenderers are established stating that:

  - The Tenderer has not been found liable for any professional misconduct
  - The Tenderer has not been declared in serious breach of contract following a procurement procedure or grant award financed by the Community budget
  - As far as is known, the Tenderer is not subject to a conflict of interest
  - The Tenderer is supplying all the information required for the procurement procedure in good faith and without misrepresentation either knowingly or negligently.

  This sworn or solemn statement should be signed by the person(s) empowered to represent the Tenderer and sign the contract if the tender is successful and should be dated less than four months before the final date for submission of tenders.

The Agency may waive the obligation of a Tenderer to submit the documentary evidence referred to in the bulleted list above if such evidence has already been submitted for the purposes of another Agency procurement procedure and provided that the issue date of the documents is within 12 months of the date of submission of this tender and that they remain valid. In such a case, Tenderers must declare on their honour that the documentary evidence has already been provided in a previous procurement procedure and must confirm that no changes in their situation have occurred.

14. Selection criteria: financial and economic capacity

Tenderers should provide the information requested in this section by using the questionnaire provided in *Annex 2: Response Questionnaire*.

Tenderers are requested to provide the following documentation to enable an assessment of their financial and economic capacity.

The minimum financial turnover requirement for tenderers is:

Euro 3,000,000 per annum for each of the last three financial years.

For joint tenderers, including subcontractors, the same documentation must be provided for each company individually. A consolidated assessment of the economic and financial capacity of all members of the joint application, including subcontractors, will be carried out.

If the tenderer is a company and is otherwise required under the law of the State in which it is established to publish its accounts, the following information is requested:

1. A copy of the most recent audited accounts that cover the last three years of trading or for the period that is available if trading for less than three years.
2. A statement of the company's 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 point 1 above.
3. Where documents mentioned under point 2 cannot be provided, please provide a statement of the company's cash flow forecast for the current year and a bank letter outlining the current cash and credit facility position.
4. If the organisation is a member of a group of companies, documents under points 1, 2 and 3 are required for both the tenderer and its ultimate holding company. Where a consortium or association is proposed, the information is requested for each member company.
5. Please enclose a separate statement of the tenderer's turnover that relates directly to the requirements of the Agency for the past three years, or for the period the tenderer has been trading (if less than three years).
6. Evidence of professional risk indemnity insurance.
7. If the tenderer is not obliged to publish its Accounts under the law of the state in which it is established, please supply copies of such accounting information as the tenderer is willing to provide relating to the last three financial years or any period since the end of the last financial year.

The documentation supplied in response to this section will be reviewed to assess the general financial health of the tenderer (or all tenderers in the case of joint applications) and parent companies where the parent company is providing a guarantee. In addition to verifying that the financial turnover meets the required minimum amounts, as listed above and in the Official Journal notice, the level of trade debtors, net current assets/liabilities and net assets of the applicant will also be assessed.

Tenderers and subcontractors (excluding one-person companies (or freelancers)) must complete the sheets entitled "03a – Selection Financial" and "03b – Selection Financial" in the Response Questionnaire in ***Annex 2: Response Questionnaire*** and reference the documentation requested above in those sheets.

15. Selection criteria: technical and professional capacity

Tenderers should provide the information requested in this section by using the questionnaire provided in *Annex 2: Response Questionnaire*.

Tenderers are requested to provide the following documentation to enable an assessment of their technical and professional capacity. For joint applications, the capacities of all members of the joint application, including subcontractors, should be taken into account in the responses to the questions below. In relation to professional and technical capacity for joint applications, the combined capacities of all members, including subcontractors, will be assessed.

The Tenderer's professional and technical capacity will be evaluated on the basis of:

1. Proof of authorisation to perform the contract under national law, as evidenced by inclusion in a trade or professional register, or a sworn declaration or certificate, membership of a specific organisation, express authorisation, or entry in the VAT register.

2. Details of staff turnover during the last financial year: total staff turnover and percentage of staff that have worked within the relevant business area for over 3 years.

3. Curricula Vitae, clearly showing the qualifications and professional experience, of the Contractor personnel within the relevant business area. To that end, the Tenderer will provide:

   3.1. Two CVs per profile described in section 4.1.3. Detailed specifications of the profiles required;

   3.2. The CVs of the individuals proposed to manage the account evidencing their expertise in this area. The CVs of key individuals responsible for the day-to-day management of the account are required. It is up to tenderers to decide which are the key individuals and how many CVs they wish to present. There is no minimum or maximum requirement with regard to the number of CVs to be supplied.

   Where CVs are submitted, the name of the person must not appear on the CV. Each CV should be given a unique identifier, which should then be cross-referenced to a list of names, which should be submitted in a separate, sealed envelope, clearly marked.

4. Details of 3 major contracts awarded to the tenderer:

   The contracts referenced must have the following characteristics:

   - Relevant to the contract required by the Agency
   - In respect of which professional IT staff were supplied
   - Each contract must have been undertaken for a different client (departments, divisions, directorates etc. are regarded as the same client)
   - Contracts must have been undertaken over the last three years
   - Provision of evidence that the Tenderer has in the recent past provided resources of the type (See section 4.1.3.) and in the quantities (See section 9.) requested in this ITT.

   The following information is to be provided:

   - Customer name and address
   - Contact name and telephone number
   - Contract reference (e.g. number of the invitation to tender or of the framework contract or of the specific contracts) and date of signature of the first contract
   - Brief description of service undertaken
   - A brief description of how this contract is relevant to the Agency
   - Name(s) of sub-contractors and/or consortium members and their role
   - Start- and end-date of the service contract
   - Financial volume of the contract effectively delivered (i.e. total amount effectively invoiced to the customer) during the complete duration of the contract.
   - Total number of person-months delivered across all profiles (e.g. Project Manager: xyz person months; Software Architect: xyz person-months; …) during the complete duration of the contract.

The Agency may elect to contact any of the above companies for a reference. The Tenderer is required to make arrangements so that the Agency can contact the references at any time during the evaluation period without contacting the tenderer.

5. A statement of the Tenderer's policy on the use of subcontractors, and of the means of ensuring quality when subcontractors are used. A confirmation whether or not subcontractors will be used for this contract and if so the full name and address of the subcontractor(s). The role, activities and responsibilities of each subcontractor should be described and an estimate given of the volume/proportion of the contract to be subcontracted. A letter of intent must also be provided by each subcontractor, confirming its intention to collaborate if the Tenderer wins the contract.
6. Details of any quality assurance accreditation that the tenderer holds. Copies of accreditation certificates should be provided. If no accreditation held, please provide an outline of any quality assurance policy. Please also provide details of any quality assurance accreditations for which you have applied.
7. The Tenderer's Skills List to be completed by the Tenderer.
8. An outline of the range of business activities and services provided by the tenderer which are relevant to this tender.

In addition, the Agency reserves the right to use any other information from public or specialist sources to assist with the verification of selection criteria.

16. Award criteria

16.1. Award criteria

16.1.1. Overview of the award criteria

Tenderers should provide the information requested in this section by completing the sheet "05 Award Criteria" in Annex 2: Response Questionnaires and sheet "01 Price" in Annex 3: Response Questionnaire - Financial.

Having established the capacity of the Tenderer to provide the service (i.e. provision of resources) during the selection phase, the award phase will establish the most economically advantageous offers to which contracts may be awarded. The award criteria will be considered in relation to the tender as a whole.

The award criteria which will apply to this tender are as follows:

Award Criteria	Points
1. Resource Selection Methodology	15
2. Personnel Management	15
3. Account Management	10
4. Skills Assurance	10
5. Quality of the technological proposal	10

Award Criteria	Points
6. Price	40
Total:	100
7. Presentation at the Agency	10
Grand total:	110

The technical evaluation will consist of an initial assessment against the technical award criteria.

Tenders not meeting the minimum score of 60% overall in the technical award criteria numbered 1-5 will be excluded.

16.1.2. Description of the award criteria

The information given in the response questionnaire in **Annex 2: Response Questionnaires** and in supporting documents will be used to evaluate the technical award criteria.

16.1.2.1. Resource Selection Methodology

This criterion will be used to evaluate the efficiency and effectiveness of the methodology used by the Tenderer to select and propose personnel suitable for the profiles described in section 4.1.3. Detailed specifications of the profiles required. To that end, the Tenderer will provide a description of the methodology used.

The description should address, *inter alia*, elements such as:

- How does the Tenderer propose to evaluate the requirements from the Agency, based on the service request (see section 4.1.5.1. Overview of the operation of the contract) and the profile description(s) (See section 4.1.3. Detailed specifications of the profiles required at entry level)?
- What database(s) or other mechanism does the Tenderer use to keep track of the skills of its potential candidates and find the candidate that best matches the Agency's requirements?
- How does the Tenderer select the best suited candidate?
- How does the Tenderer propose to present the candidate(s) to the Agency?
- What would be the methodology for *ad hoc* timely recruitment when a service request cannot be fulfilled from the Tenderer's existing pool of potential candidates?
- What is the Tenderer's policy on proactive recruitment?
- Evidence of active application of this in recent contracts

16.1.2.2. Personnel Management

This criterion will be used to evaluate the efficacy and efficiency of the methodology used to manage personnel fulfilling the service that is the subject of this ITT. To that end, the Tenderer will provide a description of the methodology used.

The description should address, *inter alia*, elements such as:

- How does the Tenderer ensure continued motivation of its personnel (full-time staff and freelancers) fulfilling the service that is the subject of this ITT?
- How does the Tenderer stay informed of the day-to-day activities, issues and concerns of its personnel (full-time staff and freelancers)?
- What process does the Tenderer have in place to deal with issues raised by its personnel (full-time staff and freelancers)?
- What is the human resources policy of the Tenderer?
- What is the Tenderer's policy for internal promotion (in terms of responsibility and financial) of its personnel (full-time staff and freelancers)?
- What is the Tenderer's policy in dealing with freelancers (including one-person companies)?
- Evidence of effective application of this in recent contracts.

16.1.2.3. Account Management

This criterion will be used to evaluate the efficacy and efficiency of the methodology used to manage the contract that would be put in place at the conclusion of this procurement procedure. To that end, the Tenderer will provide a description of the structures and mechanisms envisaged to be put in place.

The description should address, inter alia, elements such as:

- How does the Tenderer propose to manage this account?
- What would be the proposed communication model?

  Including: what are the proposals for reporting and what does the Tenderer propose to report upon?
- What governance structure would the Tenderer put in place to manage this contract?
- What would be the escalation mechanism?
- Evidence of effective application of this in recent contracts

Tenderers should note that section 4.1.5. contains some mandatory requirements in this area.

16.1.2.4. Skills Assurance

This criterion will evaluate how the Tenderer:

- Ensures that its personnel has the appropriate skills to provide the service prior to starting work at the Agency
- Ensures that the skills levels of personnel assigned to Agency projects are maintained throughout the period that they are working at the Agency

The Tenderer will be required to ensure that the skills levels of personnel assigned to the Agency's projects are maintained throughout the period that they are working at the Agency. The Agency may require the Tenderer to provide for the maintenance or enhancement of such skills levels for the individuals allocated to Agency activities through formal training at the cost of the Tenderer. Such training is likely to require an average of 5 man-days per person per annum. The Tenderer will be

expected to clear any proposed training with the Agency prior to commencement and to agree timings with the individual and with the individual's Project Manager before proceeding.

The Agency will provide, at the Agency's expense, any relevant introductory training at its premises for the Tenderer's personnel with regard to the details of the project on which they will be working and with regard to generally relevant topics, such as general ICT systems in use in the Agency, health and safety, business continuity, emergency procedures and so on. An exception to this is the case described in section 4.1.5.5. Replacement of Contractor personnel not initiated by the Agency, where the project-related training is part of the handover.

The Tenderer will provide in his response to this ITT a description of the skills assurance methodology including evidence of effective application of this in recent contracts.

16.1.2.5. Quality of the technological proposal

Taking into account the description of the services and the profiles described in section 4.1.3. , the Tenderer will provide in its response to this ITT:

- Its global analysis of the perspectives and evolutions during the next 4 years on the following points:
  - Oracle high-availability OLTP and Data Warehouse database solutions
  - the role of Oracle middleware in multi-tier applications
  - technologies and tools used (See **Annex 6, EMA ICT Standards**)
  - the technical skills of the profiles with required expertise for this lot
- In order of priority, what the Tenderer considers to be the 10 most important technological points that will influence these services in the next 4 years and an explanation of how each of those points is taken into account in its offer of services for this tender.

16.1.2.6. Price

Evaluation of price will be conducted according to the following formula using the total price of the scenarios (*intra muros*) indicated in the worksheets:

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

Prices to be evaluated will be based on the pricing and expenses scenario worksheets (See ***Annex 3: Response Questionnaire - Financial***). The formula indicated above will be applied to the grand total of the *intra muros* prices in the pricing scenario worksheet. Tenderers will be ranked according to the outcome of the initial evaluation of the award criteria, including price.

16.1.2.7. Presentation at the Agency

Tenderers should be prepared to complement the written response with a visit to the Agency in order to present their expertise, to provide answers to additional questions that the Agency's Evaluation Committee may have as part of the evaluation process.

It is anticipated that the meetings, if required, will take place in June 2012. Tenderers will be given a minimum of 4 working days' notice if they are required to attend such a meeting.

If such presentations are required, an additional 10 points will be allocated for this part of the evaluation and the final total will be out of 110. If presentations are not required, the final total will be out of 100.

Tenderers should note that this meeting is a mandatory part of the evaluation process and that refusal of an invitation shall result in the exclusion of the Tenderer from any further part in the procurement procedure.

17. Tender to be submitted

Letter of Invitation to Tender

The letter of invitation to tender, to which this technical specifications document is attached, contains further information on:

- How to submit a response to the tender
- How to obtain additional information for the purpose of clarifying the nature of the contract

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

- A letter enclosing the tender on the official letter headed paper of the tenderer and signed by an authorised representative of the tenderer.
- An information sheet on the tenderer indicating the information listed here below. Tenderers must use the sheets entitled "01a – Identification" and "01b – Joint applicants" in the Response Questionnaire in ***Annex 2: Response Questionnaire***.
- A completed ***Annex 2, Response Questionnaire***
- A completed ***Annex 3, Response Questionnaire - Financial***
- Documentation requested to enable assessment of Selection Criteria (sections 14 and 15 above).
- Documentation requested to enable assessment of Award Criteria (section 16 above).
- A statement to confirm that information provided in response to this tender is accurate and complete as at the date of submission and acknowledgement that the provision of false information, either knowingly or negligently, in response to this tender could result in the tenderer being excluded from future tenders for contracts with the Agency.
- Confirmation of acceptance of the draft contract and terms and conditions of tender.
- An undertaking to inform the Agency promptly following any matter which would alter or add to any of the information given in response to this tender.
- Documents as requested in relation to proposed subcontracting.
- Tenders submitted by consortia or by groups of service providers must indicate the role, title and experience of each member or of the group.
- **To be submitted in separate binders or folders, which must be clearly labelled**, a detailed financial tender using the Response Questionnaire - Financial attached in ***Annex 3***, and exclusive of VAT, signed by an authorised representative of the tenderer.

Tenderers are requested to make use of the checklist given in ***Annex 1: Summary Checklist*** to ensure that no enclosure has been omitted in their tender.

Format of Replies

It is important that all replies follow the guidance set out below and in sections 13. 14. 15. and 16. in order to facilitate a fair and consistent assessment. Failure to comply may impair the Agency's ability to judge the completeness or competitiveness of a tender offer.

Tenderers must

- draw up their offer using the Agency's questionnaires as contained in these tender specifications. The response questionnaires (***Annex 2: Response Questionnaire and Annex 3: Response Questionnaire - Financial***) include instructions in the first tab, entitled "Instructions", for completion of the questionnaires;
- give a YES answer to a MANDATORY requirement. Failure in this respect will result in elimination of the offer;
- provide complete information; any lack of an answer or a supporting document may be considered as a negative answer;
- where possible, responses should be given in the space provided. If more space is required, the response should be made separately and annexed to the questionnaire. Such a response should be clearly referenced or identified and this reference should be noted on the questionnaire in place of the actual response. In addition to completing the questionnaire, the Tenderer may also include any other information which he considers relevant;
- where CVs are submitted, exclude the name of the individual from the CV form. A unique identifier should be given to each CV and a separate list of names corresponding to these identifiers should be included in the tender in a separate sealed envelope, clearly marked.

A tender may be drawn up in any of the official languages of the European Union. The Agency prefers, however, to receive documentation in English.

The Tenderer warrants that the information contained in the electronic copies of the tender is precisely the same as that submitted on paper.

18. Annexes

Annex 1 is contained in this document. All other annexes are contained in separate files.

Annex 1: Summary Checklist

Annex 2: Response Questionnaire

Annex 3: Response Questionnaire – Financial

Annex 4: Required Skills per Profile

Annex 5: Draft Service Level Agreement

Annex 6: EMA ICT Standards

Annex 7: Draft framework contract, including draft specific contract

Annex 8: Standard timesheet

Annex 9: Confidentiality statement

Annex 10: Standard Profile Specification and Request Form

Annex 11: Financial Identification Form

Annex 1 Summary Checklist

Summary checklist of documents which tenderers must submit

1. Letter enclosing the tender on the official letter headed paper of the tenderer and signed by an authorised representative of the tenderer.
2. Tender in one original paper copy with one copy of all documents on CD-ROM, containing the following elements:

- A completed Response Questionnaire in ***Annex 2***
- A completed Response Questionnaire – Financial in ***Annex 3***
- Documentation requested to enable assessment of Selection Criteria (sections 14 and 15 above).
- Documentation requested to enable assessment of Award Criteria (section 16 above).
- A statement to confirm that information provided in response to this tender is accurate and complete as at the date of submission and acknowledgement that the provision of false information, either knowingly or negligently, in response to this tender could result in the tenderer being excluded from future tenders for contracts with the Agency.
- Confirmation of acceptance of the draft contract and terms and conditions of tender.
- A properly completed, signed and dated Financial Identification Form (see ***Annex 12*****)**, with supporting bank statement header.
- An undertaking to inform the Agency promptly following any matter which would alter or add to any of the information given in response to this tender.
- Documents as requested in relation to proposed subcontracting.
- Tenders submitted by consortia or by groups of service providers must indicate the role, title and experience of each member or of the group.
- **To be submitted in separate binders or folders, which must be clearly labelled**, a detailed financial tender using the costing sheet attached in **Annex 3**, and exclusive of VAT, signed by an authorised representative of the tenderer.