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Technical specifications for open invitation to tender

Procurement Procedure EMA/2012/13/ICT External Service Providers for
Software Applications: provision of resources for online analytical processing
systems– Lots 1 and 2

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1. About this document

This document contains the Technical Specifications for the Open Invitation to Tender no. EMA/2012/13/ICT for external service providers for software applications: on-line analytical processing systems: Lots 1 and 2.

The contract notice for this open tender has been published in the Official Journal of the European Union.

1.1. Glossary

Term	Description
Architecture & Products	These terms are used in this document to describe (a) the structure or structures of a system which comprise software components, the externally visible properties of those components, and the relationships between them; and (b) software that facilitates the accomplishment of a task via development.
ATC	Anatomical Therapeutic Chemical classification system
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 analysis	Business analysis is the discipline of identifying business needs and determining solutions to business problems. Solutions often include a systems development component, but may also consist of process improvement, organizational change or strategic planning and policy development. The person who carries out this task is called a business analyst or BA.
Business process analysis and modelling	Business process modelling (BPM) in systems engineering and hardware engineering is the activity of representing processes of an enterprise, so that the current process may be analysed and improved.
Business domain	The business context in which the system is to be built. 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.

Term	Description
Data warehouse	Please refer to on-line analytical processing systems
DWH	Data warehouse
eCTD	Electronic common technical document
Effort	The amount of work required to complete a task.
Elapsed time	The actual time between starting and ending an activity
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.
EVCTM	EudraVigilance Clinical Trials Module
Fixed price orders	See Order types
FP	Fixed price
Pharmacovigilance	The detection, assessment, understanding and prevention of the adverse effects of medicines
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)
ICSR	Individual case safety report
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.
INN	International non-proprietary name
Mark up	The percentage or amount by which a seller 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.
MicroStrategy	<i>MicroStrategy</i> is the vendor of enterprise business intelligence (BI) application software with the same name.
Multiple Framework Contract (MFC) with reopened competition	This is a Framework Contract that is made up of separate contracts, concluded on the same terms

Term	Description
	with different parties (minimum 3). When Specific Contracts are awarded under an MFC the parties will compete again on the basis of the same and, if necessary, more precisely formulated terms, and, where appropriate, on the basis of other terms referred to in the specification for the framework contract.
OBIEE	Oracle Business Intelligence Enterprise Edition, also known as OBIEE, is Oracle's set of business intelligence tools.
on-line analytical processing systems ("OLAP")	An on-line analytical processing or a data warehouse system is a database used for reporting and analysis. The data stored in this database is uploaded from the operational systems. The data may pass through an operational data store for additional operations before it is used in the DWH for reporting.
Order types	This ITT refers to three types of orders: Time and materials orders, which correspond to the order of a number of days for defined profiles. Fixed-price orders, which correspond to an order for defined work. Quoted time and materials orders, which correspond to the order of a number of days for defined subtasks.
Quoted time and materials orders	See Order types
QTM	Quoted time and materials
Requirements analysis	Requirements analysis in systems engineering and software engineering encompasses those tasks that go into determining the needs or conditions to be met for a new or altered product, taking account of the possibly conflicting requirements of the various stakeholders, such as beneficiaries or users.
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.
Systems Analysis	In the context of this ITT: Requirements analysis. The latter is the preferred term
Tenderer	An economic operator or group of economic operators which is submitting a response to this ITT.
Time and materials orders	See Order types

Term	Description
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 the contractor and subcontractor. The difference between the selling price and the price charged by the subcontractor.
Tracking system	Systems that record the status of transactions at pre-defined points in a process.
UAT	User acceptance testing.

2. Executive summary

This tender aims to put into place contractual arrangements, on a time and materials, quoted time and materials or fixed price 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 design, construction, implementation and maintenance of applications developed or implemented in house.

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 economic operators for the provision of services, on a time and materials basis (Lot 1) and quoted time and materials or fixed price basis (Lot 2), that will enable the Agency to acquire resources not employed directly by the Agency in the domain of the development and maintenance of on-line analytical processing information systems. These resources will contribute expertise directly to the design, construction, implementation and maintenance of mainly internally developed applications.
Tender	External Service Providers (ESP) for Software Applications – on-line analytical processing systems
Contracts	<u>For Lot 1</u>, 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 framework 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 both on the contractor's and/or the Agency's premises as appropriate) of the personnel to be used to undertake the services

Item	Summary
	provided as described in this ITT. Based on these costs, Specific Contracts may be concluded according to the Terms and Conditions of this ITT and of the corresponding financial proposal of the contractor. Tenderers should be aware that the incumbent suppliers of the services which are the subject of Lot 1 currently employ ten resources <i>in situ</i> at the Agency's premises which includes six of the supplier's employees, the rest being consultants (who are either freelance or contracted via agencies), all of who are carrying out exclusive functions for the Agency, all on a full-time basis. Any change of service provider may, therefore, be subject to the Transfer of Undertakings (Protection of Employment) Regulations 2006 (sometimes known as "TUPE") which apply in the UK. The attention of tenderers is therefore specifically drawn to these Regulations, as a successful tender may result in them becoming a potential transferee for the purposes of TUPE, and they are recommended to seek legal advice as to the extent to which TUPE will apply to the proposed contract and to reflect the legal and financial implications of such a transfer in their tender if they so wish. Tenderers should ensure that they read the full details in 5.2.4.2. General description of framework contracts. <u>For Lot 2</u>, the Agency intends to sign a maximum of 5 multiple framework contracts under which competition can be re-opened. The framework contracts in this instance lay down the administrative provisions governing the relations between the Agency and the contractor during their period of validity. These framework contracts will not lay down all the terms and conditions and a system of priority will not be established. In this case, the Agency will re-open competition and, when a specific contract is required, ask the parties to compete on the basis of more precisely formulated terms. The Agency will consult the contractors in writing, fixing a time limit which is sufficiently long to allow tenders to be submitted in writing. The Agency will then award each Specific Contract to the contractor which has submitted the most economically advantageous tender on the basis of and following a further evaluation against award criteria set out in the specifications for each Specific Contract. See <i>Annex 7 Draft Framework Contracts, including draft Specific Contracts.</i>
Duration of framework contracts	Two years with two possible extensions of one year each. Maximum possible duration: Four years.
Place of delivery	Mainly at the Agency's premises at 7 Westferry Circus, Canary Wharf, London E14 4HB, United Kingdom and/or the Contractor's premises.
Particulars of delivery	Delivery of services must be in conformity with the placed orders, which will be time and materials based Specific Contracts (Lot 1) or quoted time and materials or fixed price Specific Contracts (Lot 2).

Item	Summary
	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 <i>Annex 5, Draft Service Level Agreement.</i>
Volume (indicative)	Lot 1: The resulting framework contracts will replace existing framework contracts in respect of which the financial envelope has been exhausted. The Agency estimates, without this being binding, that the total requirement for time and materials services is expected to represent approximately 16472 person-days. Lot 2: The Agency estimates, without this being binding, that the total value of Specific Contracts to be let will be in the region of €5 million.
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 ITT. For details see Section 7.2. Subcontracting.
Closing Date for receipt of Tenders	12.00 GMT, Wednesday 20th February 2013
Opening of Tenders	European Medicines Agency, London, 14.30 GMT, Monday 25th February 2013
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>

Item	Summary
	This phase consists of two sections; • Technical evaluation of the offer • Financial evaluation of the offer The purpose of this phase is to choose the most economically advantageous offers of those submitted by tenderers which are not excluded and which meet the selection criteria. <u>Signature of the Contract(s)</u>

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 Agency¹ ("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, 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.

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

Principal activities

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

- 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 on-going professional development of every member of the Agency.

Central Authorisation Procedure

This procedure results in a single marketing authorisation that is valid across the European Union, as well as in Iceland, Liechtenstein and Norway.

The centralised procedure is **compulsory** for:

- human medicines for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases;

- veterinary medicines for use as growth or yield enhancers;
- medicines derived from biotechnology processes, such as genetic engineering;
- advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;
- officially designated 'orphan medicines' (medicines used for rare human 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 EU 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 an EU 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/>

4. Introduction to ICT systems at the Agency

This section describes most ICT systems currently in use at or being developed by the Agency. Note that this section merely aims to provide an overview of the ICT application landscape at the Agency and does not have as its purpose to list the systems or projects that are the subject of this ITT.

Examples of the complexity of some of our projects/systems:

	System A	System B	System C
Total Cyclomatic Complexity (Num of decision points)	27509	49216	35469
kLocs	78	366	107
Classes	1003	343	1672

4.1. 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.

4.1.1. 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:

4.1.1.1. SIAMED (*Sistema de informacion Automatizada sobre MEDicamentos*)

SIAMED is a system developed jointly with WHO² for computer assisted medicines registration.

New versions (SIAMED II) of this application are under development and planned, aiming 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;
- communicate with other systems, including - but not limited to - EudraVigilance, EudraPharm, EUTCT³, ECD⁴ and ERP⁵;
- 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, put into production at the end of 2011, supports the business processes covering Marketing Authorisation and Post Authorisation Applications. Release 4.0 will allow the phasing out of SIAMED I

4.1.1.2. Paediatrics Database

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

4.1.1.3. 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

² World Health Organisation

³ EU Telematics Controlled Terms

⁴ Eudra Common Directory

⁵ EMA Resource Planning

- 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 they change.

4.1.1.4. 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

4.1.1.5. 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.

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

4.1.1.6. 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 in October 2011.

4.1.1.7. 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.

4.1.1.8. Experts Database

The Experts Database is a list of European Experts that may participate in the Agency's work. This includes members of the CHMP⁶, CVMP⁷, COMP⁸, HMPC⁹, PDCO¹⁰ and their working parties. It also includes any expert who is taking part in any other scientific activity of the Agency.

4.1.1.9. 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.

4.1.1.10. 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.

4.1.1.11. 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.

4.1.1.12. 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.

4.1.1.13. Electronic Signatures

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

4.1.1.14. Electronic Declaration of Interest Form

This project provides an electronic format of the Declaration of Interests form for Experts that :

- Is integrated into the Agency's Expert Database
- publishes the Declaration of Interest on-line

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

4.1.1.15. 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>)

4.1.1.16. 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.

4.1.1.17. 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.

4.1.2. 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.

4.1.2.1. 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.

4.1.2.2. 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.

4.1.2.3. 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 ICH¹¹. Reports are received via a gateway similar to the eSubmission Gateway described elsewhere in this document.

EudraVigilance supports in particular the:

- 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 EEA¹²;
- 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/>

4.1.2.4. 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

4.1.2.5. 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 on-going 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

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

¹² European Economic Area

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).

4.1.2.6. EudraGMP

EudraGMP is a system that

- 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>

4.1.2.7. 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 eCTD¹³ 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.

4.1.2.8. Eudra Data Warehouses

These 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 provide users with reporting and data analysis functionalities on EudraVigilance systems (human and veterinary), clinical trials and paediatrics.

¹³ Electronic Common Technical Document, a guideline issued by the International Conference on Harmonisation (www.ich.org)

4.1.2.9. 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 MedDRA¹⁴ 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);
- 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.

4.1.2.10. 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.

4.1.2.11. Central Repository

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

4.1.2.12. eSubmission Gateway

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

4.1.2.13. 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.

¹⁴ Medical Dictionary for Drug Regulatory Activities

4.1.2.14. 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/>.

4.2. ICT Standards

4.2.1. 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.

4.2.2. Reference Data Model

The reference data model is designed to be used as a prescription for the definition of the concepts for modelling of data during the design of new or old systems and to generate required exchange standards between systems and institutions. It:

- Defines the concepts that underlie the meaning of
 - Individual data elements; and
 - Constructs built up through the structured linking of individual elements;
- Sets out the parameters that constrain the way in which each element is used;
- Describes the relationships between elements to form the required constructs; and thus
 - Provides pre-defined elements and constructs for systems within the European Medicines Regulatory Network;
 - In a manner that supports the information needs and processes of the business of regulation of medicinal products in the EEA.
- For EU Telematics, it is being established in the form of:
 - A conceptual data model that includes information elements used in relation to all aspects of regulatory activity throughout the lifecycle of a medicinal product;
 - A physical implementation of the conceptual data model that defines the individual information elements in sufficient detail to ensure that any information system built to deal with any aspect of regulatory activity at any stage of a medicinal product's lifecycle would be able to draw the definitions of the elements, and the relationships between them, from the reference data model;
 - A physical implementation of the conceptual data model that includes the controlled terms, appropriately used in each context;

- A physical implementation of the conceptual data model that is compatible with international standards agreed for implementation in the European Medicines Regulatory Network and
- Confirmation from all stakeholders that the reference data model is the reference point for systems and exchange standards used in the European Medicines Regulatory Network.

5. Subject of the tender

5.1. Description of the Lots

The services required are divided into two lots:

Lot	Description
1	Provision of resources on a time and materials basis for on-line analytical processing systems
2	Provision of on-line analytical processing systems on a quoted time and materials basis or a fixed price basis

Tenderers may apply for both lots or for one individual lot. Tenderers must clearly indicate in their covering letter and also in their response to the tender for which lot(s) they are applying. Each lot will be evaluated as a separate entity.

5.2. Lot 1 - Provision of services on a time and materials basis

The services to be provided under Lot 1 consist of the provision of appropriately skilled individuals to participate in the teams further developing and/or maintaining the OLAP aspects of the systems listed in sections 4.1.1. and 4.1.2. , including the data design and database related aspects of this. Tenderers should note, however, that the above list represents only currently on-going projects and a sample of current systems. New systems are anticipated. Where new systems are introduced the services will include the provision of appropriately skilled individuals to participate in systems development project teams. The services may be provided either at the Contractor's premises or at premises designated by the Agency, being normally 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 Contracts, including draft specific contracts.**

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 5.2.3. 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)

5.2.1. On-line analytical processing systems

The services to be provided are in connection with the on-line analytical processing aspects of the systems:

- Listed in section 4.1.1. The Agency's administrative and business projects and systems,
- Listed in section 4.1.2. The EU Telematics Systems and Projects,
- Other systems yet to be specified.

5.2.2. Overview of the Profiles Required

A list of the various profiles required in order to carry out the services in Lot 1 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.

Due to the nature of the Agency, experience in the following business domains is desirable:

- Medicines information
- Pharmacovigilance
- Regulatory environment.

In addition, experience in a multicultural organisation and public sector would be desirable.

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

Profile	Experience in IT [minimum number of years]	Experience in Application Domain (OLAP) [minimum number of years]	Experience in Role [minimum number of years]
Project Manager (PM)	10	6	6
Business Analyst (BA)	n.a.	n.a.	5
Software Data Architect (SWDA)	7	4	3
System Analyst (SA)	7	4	2
Senior System Analyst (SSA)	9	4	5
Developer (DEV)	5	3	2
Senior Developer (SDEV)	7	3	5
Testing Manager (TM)	7	6	5
Testing Engineer (TE)	3	3	2
Trainer (TR)	2	1	3
Technical Writer (TW)	2	2	2
Lead consultant (LC)	10	7	3
Technical Consultant (TC)	6	-	-
Project Officer (PO)	3	-	2

NB Language requirements: standards must be equivalent to the levels outlined in the Common European Framework of Reference for Languages

5.2.3. Detailed specifications of the profiles required at entry level

5.2.3.1. Project Manager

5.2.3.1.1. Languages: English is mandatory at a minimum of level B2

5.2.3.1.2. Education

- Bachelor's Degree in Computer Science, Information Systems, Business Administration or other related field or equivalent work experience.

5.2.3.1.3. Relevant Professional Qualifications

- Relevant professional qualifications (e.g. PMI PMP; Prince 2 Practitioner) are very desirable

5.2.3.1.4. Specific knowledge

- Expertise per list
 - Ability to use the project management tools and methodologies as specified in **Annex 4: Required Skills per Profile.**

5.2.3.1.5. Experience

- 10 years of relevant IT experience, including six years of project management experience, with a strong focus on the application domain of online analytical processing system
 - Demonstrable experience of projects meeting visions similar to those set out in sections 4.1.1.
 - Demonstration that the execution of projects and/or the outcome of projects have been of a complexity similar to that set out in sections 4.1.1.

5.2.3.1.6. General characteristics

Competences in the role

- Demonstrable competences in the role are very desirable. These include:
 - Planning;
 - Definition of tasks and deliverables;
 - Review of project deliverables;
 - Quality control;
 - Risk assessment and management;
 - Status and problem reporting;
 - Follow-up of decisions and activities;
 - Organisation of teams and work;
 - Human resource management;
 - Prepare and maintain quality plans;
 - Estimation of costs, timescales and resource requirements;

- Management of execution of projects against time, quality and cost criteria;
- Management of the change control process gaining agreement for revisions to the project from project owners;
- Ability to give presentations at all levels (from team members to executive level);
- Capability of integration in an international/multi-cultural environment, rapid self-starting capability and experience in team working, understanding the needs, objectives and constraints of those in other disciplines and functions;
- Management of conflicts;
- Ability to reach common understanding and agreement from all stakeholders;
- Negotiations skills.
- Communication abilities are very desirable. These include
 - Receive and understand instructions
 - Deliver messages clearly
 - Report the right information at the right level
 - Interact at executive and team levels
 - Use both written and oral channels
 - Able to deal diplomatically with sensitive matters
- Time management capabilities are very desirable. These include
 - Ability to manage one's own time, even in the face of stressful situations;
 - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.
- Supervisory and leadership capabilities are very desirable. These include:
 - Demonstrable leadership capabilities.
 - Demonstrable capability to manage change.

5.2.3.2. Business analyst

5.2.3.2.1. Languages: English is mandatory at a minimum of Level B2

5.2.3.2.2. Education:

- Bachelor's Degree in Computer Science, Information Systems, Business Administration or other related field or equivalent work experience.

5.2.3.2.3. Relevant professional qualifications

- Relevant professional qualifications are very desirable.
- Relevant qualifications in the area of business analysis and/or business process analysis and modelling (e.g. OMG Certified Expert in BPM, Six Sigma Black Belt or higher, BABoK) are very desirable.

5.2.3.2.4. Specific Knowledge

- Expertise per list
 - Ability to use the business analysis tools and methodologies as specified in **Annex 4: Required Skills per Profile**

5.2.3.2.5. Experience

- 5 Years of Business Analysis experience with a strong focus on the application domain of on-line analytical processing systems. Demonstrable experience of projects meeting visions similar to those set out in sections 4.1.1.
- Demonstration that the analysis of projects and/or the outcome of projects have been of a complexity similar to that set out in sections 4.1.1.

5.2.3.2.6. General characteristics

Competences in the role

- Demonstrable competences in the role are very desirable. These include:
 - Proven business analysis skills, result oriented ideally within a challenging international environment;
 - Experience in leading similar large scale business analysis;
 - Ability to understand regulatory requirements and how they can be translated into workable, efficient operational procedures;
 - Ability to understand, analyse and re-engineer complex administrative procedures in support of scientific assessments for which a proven track record of interaction with scientific experts
 - Analytical approach and must be extremely organised and able to handle and prioritise multiple tasks;
 - A thorough understanding of working in a fast-paced and complex business environment;
 - Problem identification and solving skills: ability to constructively challenge assumptions, identify key issues and escalate as appropriate;

- Strong experience in defining the business analysis strategy and plan and undertaking the tasks through the entire project until its successful implementation;
- Strong experience in facilitation and animation of business workshops and similar types of meetings as required
- Ability to provide effective co-ordination for the business team ensuring that team members are motivated and constantly developing their skills and experience;
- Experience in PRINCE2, PMBOK and DMAIC or business process management, lean and six sigma would be considered an advantage
- Ensure integrity and professionalism;
- Ability to define business architectures;
- Definition of business use cases and actors and how they interact;
- Strong experience and proven track-record in business process analysis and definition;
- Gathering of user requirements;
- Critical review of user requirements;
- Documentation of user requirements;
- Expertise in integration of information systems into the business environment;
- Ability to achieve consensus or optimal solution in the face of conflicting requirements and objectives;
- Formal business analysis methods and techniques;
- Willingness to understand and learn the business aspects that are unique to the Agency, and also to communicate the constraints of IT (within budget) to the users;
- Willingness to use the Agency's requirements management tool and work within the Agency's project management methodology;
- Flexibility/adaptability: ability to anticipate goals and priority shifts in a changing environment;
- Passion for achievement: must demonstrate full accountability;
- Ability to manage conflicts;
- Business acumen: application of deep understanding of external and internal environmental factors to drive Agency improvements;
- Ability to share knowledge with the Agency;
- Agency focus and commitment: develop long term relationship with the Agency and commit to successful project delivery
- Communication abilities are very desirable. These include:
 - Good interpersonal skills both one to one and in small and large committees
 - Ability to link non-IT users and IT technical staff in a way that both clearly understand;
 - Outstanding management skills especially in upward management; will need to demonstrate skills of gaining buy in from senior individuals;
 - Strong interpersonal and relationship building skills;

- Ability to link non-IT users and IT technical staff in a way that both clearly understand;
- Ability to interact professionally with a diverse group, including executives, managers, operational staff and subject matter experts in the scientific, legal and regulatory areas;
- Ability to develop and maintain good working relationships across an international organisation;
- Excellent verbal and written communication skills;
- Receive and understand instructions;
- Deliver messages clearly, including via formal presentations;
- Interact at executive and team levels;
- Use both written and oral channels;
- Ability to listen.
- Time management capabilities are very desirable. These include:
 - Ability to manage one's own time, even in the face of stressful situations;
 - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.
- Supervisory and leadership capabilities are very desirable. These include:
 - Demonstrable leadership capabilities.
 - Demonstrable capability to manage change.

5.2.3.3. Software Data architect

5.2.3.3.1. Languages: English is mandatory at a minimum of level B2

5.2.3.3.2. Education:

- Bachelor's Degree in Computer Science, Information Systems or other related field, or equivalent work experience.

5.2.3.3.3. Relevant Professional Qualifications

- Relevant professional qualifications (e.g. Data Warehouse Certifications, OBIEE Certified Professional, MicroStrategy Architect Certification, Oracle Database Certification) are desirable.

5.2.3.3.4. Specific knowledge

- Expertise per list
 - Ability to use the software architecture tools and methodologies as specified in **Annex 4: Required Skills per Profile.**
 - Five years of programming experience in the programming technologies currently used at the Agency
 - Experience with CASE tools (e.g. IBM Rational Rose)

5.2.3.3.5. Experience

- 7 years of IT experience with a minimum of 4 years in the application domain of on-line analytical processing systems, of which 3 in the requested role.
 - Excellent team and collaboration skills are desirable.
 - Strong attention to detail is desirable.
 - Highly organised and motivated individual is desirable.
 - Demonstrable experience of projects meeting visions similar to those set out in sections 4.1.1.
 - Demonstration that the analysis of projects and/or the outcome of projects have been of a complexity similar to that set out in sections 4.1.1.

5.2.3.3.6. General characteristics

- Competences in the role: Demonstrable competences in the role are very desirable. These include:
 - Architectural analysis, including definition of a candidate architecture for the system and of the architectural patterns, key mechanisms and modelling conventions of the system in line with the Agency's Information and Communication Technology Standards
 - Analysis of reporting needs:
 - Able to distinguish between transactional and analytical reports
 - Identify the measures and analytical dimensions and hierarchies needed for reporting
 - Identify the data transformation needs and assess the availability of data at the right granularity

- Definition of a software architecture satisfying quality attributes complying with enterprise standards;
- Design and conduct architectural proofs-of-concept and prototypes;
- Define the ETL integration method with the transactional systems
- Define the reporting architecture
- Define the ETL architecture and processes
- Coaching and technical guidance for developers
- Design the data model – Normal Form 3 (NF3) or dimensional model (star schemas, OLAP cubes)
- Tune the ETL code / Reporting queries
- Optimise DDL and DML Codes.
- Conduct architecture and code reviews;
- Production of the relevant technical documentation, such as system designs, data model designs etc and documentation for the support team;
- Capacity to assist the support team in training the users of the system;
- Capacity to assist with the evaluation and testing of products delivered by external system suppliers to ensure that they conform to requirements and technical standards;
- Estimation and prioritisation of work packages and project plans;
- Definition and maintenance of a software development methodology including standards and quality aspects.
- Communication abilities are very desirable. These include:
 - Able to summarise and present successfully key technical issues to the relevant stakeholders (developers, analysts, peers, management and business users) taking into consideration the background of the audience
 - Able to communicate in a succinct, clear and understandable manner
 - Prepare and deliver formal presentations to the relevant stakeholders
 - Interact at executive, team and business levels
 - Liaise with different technical teams, such as system administrators, testers and support, understanding their requirements.
 - Excellent written and verbal communication skills
- Time management capabilities are very desirable. These include:
 - Ability to manage one's own time, even in the face of stressful situations;
 - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.
- Supervisory experience is very desirable. These include:
 - Number of years: 2 years minimum

- Able to define tasks and assign them to developers according to the nature of the task and the developer's skills
- Leadership capabilities are very desirable. These include:
 - Demonstrable leadership capabilities.
 - Experience in coaching developers in new technologies
 - Experience in managing interactions between the development team and other stakeholders (e.g. system administration, testers, support, analysts, management, business)

5.2.3.4. System analyst

5.2.3.4.1. Languages: English is mandatory at a minimum level of B2.

5.2.3.4.2. Education:

- Bachelor's Degree in Computer Science, Information Systems or other related field, or equivalent work experience.

5.2.3.4.3. Relevant Professional Qualifications

- Relevant professional qualifications or recognised training courses are very desirable

5.2.3.4.4. Specific knowledge

- Expertise per list
 - Ability to use the system analysis tools and methodologies as specified in **Annex 4: Required Skills per Profile**.

5.2.3.4.5. Experience

- A minimum of 7 years relevant IT experience, including a minimum 4 years in the application domain of on-line analytical processing systems and 2 years in the requested role.
 - Excellent team and collaboration skills are desirable.
 - Strong attention to detail is desirable.
 - Highly organised and motivated individual is desirable.
 - Demonstrable experience of projects meeting visions similar to those set out in sections 4.1.1.
 - Demonstration that the analysis of projects and/or the outcome of projects have been of a complexity similar to that set out in sections 4.1.1.

5.2.3.4.6. General characteristics

Competences in the role

- Demonstrable competences in the role are very desirable. These include:
 - Tailored implementation of the Agency's requirements management plan;
 - Requirements gathering, including the organisation and conduct of workshops;
 - Management of diverse business stakeholders groups with differing expectations;
 - Documentation of stakeholder requests, functional and non-functional requirements;
 - Development of Vision documents;
 - Analysis of requirements and creation of analysis artefacts, such as logical data models
 - Management of artefacts supporting the elicitation of user requirements, such as screen mock-ups;
 - Definition of actors and use cases, at the appropriate detail level for either in house development or outsourcing;
 - Creation and structuring of use case models;

- Cost/benefit analysis;
- Experience in the change control process of requirements and enhancements;
- Ability to link non-IT users and IT technical staff in a way that both clearly understand;
- Willingness to understand and learn the business aspects that are unique to the Agency, and also to communicate the constraints of IT (within budget) to the users;
- Willingness to use the Agency's requirements management tools and work within the Agency's project management methodology.
- Communication abilities are very desirable. These include:
 - Excellent written and verbal communication skills
 - Able to communicate in a succinct, clear and understandable manner
 - Prepare and deliver formal presentations to the relevant stakeholders
 - Interact at executive, development team and business levels
 - Liaise with different technical teams, such as developers, architects and testers 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 prioritise between competing tasks on a rational basis and in a decisive manner.
- Supervisory and leadership capabilities are very desirable. These include:
 - Demonstrable leadership capabilities.
 - Demonstrable capability to manage change.

5.2.3.5. Senior System Analyst

5.2.3.5.1. Languages: English is mandatory at a minimum of level B2.

5.2.3.5.2. Education:

- Bachelor's Degree in Computer Science, Information Systems or other related field, or equivalent work experience.

5.2.3.5.3. Relevant professional qualifications

- Relevant professional qualifications or recognised training courses are very desirable

5.2.3.5.4. Experience

- A minimum of 9 years' relevant IT experience, including a minimum 4 years in the application domain of on-line analytical processing systems and 5 years in the requested role.
 - Excellent team and collaboration skills are desirable.
 - Strong attention to detail is desirable.
 - Highly organised and motivated individual is desirable.
 - Demonstrable experience of projects meeting visions similar to those set out in sections 4.1.1.
 - Demonstration that the analysis of projects and/or the outcome of projects have been of a complexity similar to that set out in sections 4.1.1.

5.2.3.5.5. General characteristics

Competences in the role

- Demonstrable competences in the role are very desirable. These include:
 - Tailored implementation of the Agency's requirements management plan;
 - Requirements gathering, including the organisation and conduct of workshops;
 - Management of diverse business stakeholders groups with differing expectations;
 - Documentation of stakeholder requests, functional and non-functional requirements;
 - Development of Vision documents;
 - Analysis of requirements and creation of analysis artefacts, such as logical data models
 - Management of artefacts supporting the elicitation of user requirements, such as screen mock-ups;
 - Definition of actors and use cases, at the appropriate detail level for either in house development or outsourcing;
 - Creation and structuring of use case models;
 - Cost/benefit analysis;
 - Experience in the change control process of requirements and enhancements;
 - Ability to link non-IT users and IT technical staff in a way that both clearly understand;

- Willingness to understand and learn the business aspects that are unique to the Agency, and also to communicate the constraints of IT (within budget) to the users;
 - Willingness to use the Agency's requirements management tools and work within the Agency's project management methodology.
- Communication abilities are very desirable. These include:
 - Excellent written and verbal communication skills
 - Able to communicate in a succinct, clear and understandable manner
 - Prepare and deliver formal presentations to the relevant stakeholders
 - Interact at executive, development team and business levels
 - Liaise with different technical teams, such as developers, architects and testers 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 prioritise between competing tasks on a rational basis and in a decisive manner.
- Supervisory and leadership capabilities are very desirable. These include:
 - Demonstrable leadership capabilities.
 - Demonstrable capability to manage change.

5.2.3.6. Developer

5.2.3.6.1. Languages: English is mandatory at a minimum of level B2.

5.2.3.6.2. Education:

- Bachelor's Degree in Computer Science, Information Systems or other related field, or equivalent work experience.

5.2.3.6.3. Relevant Professional Qualifications

- Relevant professional qualifications are very desirable.

5.2.3.6.4. Specific knowledge

- Expertise per software Individual Skills List
 - Ability to use the development tools and methodologies as specified in **Annex 4: Required Skills per Profile**.
 - Two years of programming experience in the programming technologies currently used at the Agency

5.2.3.6.5. Experience

- A minimum of 5 years relevant IT experience of which at least 2 years in the requested role with a strong focus on the application domain of on-line analytical processing systems.
 - Excellent team and collaboration skills are desirable.
 - Strong attention to detail is desirable.
 - Highly organised and motivated individual is desirable.
 - Demonstrable experience of projects meeting visions similar to those set out in sections 4.1.1.
 - Demonstration that the development of projects and/or the outcome of projects have been of a complexity similar to that set out in sections 4.1.1.

5.2.3.6.6. General characteristics

Competences in the role

- Demonstrable competences in the role are very desirable. These include:
 - For ETL Developer Only:
 - Writing, maintenance and unit testing of ETL routines which reflect the specifications derived from user reporting requirements or from system integration needs.
 - Optimisation of ETL routines
 - Preparation of scripts for database migrations;
 - Preparation of scripts for ETL migration on test and production environments
 - Development and Execution of DML (Data Manipulation Language) scripts.
 - For BI developer only:

- Develop, maintain and unit testing of BI templates and reports which reflect the specifications derived from user reporting requirements or from system integration needs
- Develop Development and Execution of DML (Data Manipulation Language) scripts.
- Optimisation of reports;
- Develop and enhance the BI Repository to support the underline data model
- Preparation of scripts for report migrations;
- Preparation of scripts for reports metadata migration on test and production environments
- Assistance with the testing of ETL routines, reporting modules
- Assistance with design activities;
- Prototyping;
- Production of relevant technical documentation and documentation for the support team;
- Experience in working in an environment with technical teams comprised of testers, analysts and system administrators;
- Capacity to assist the support team in training the users of the system;
- Assistance with operational support of programs produced;
- Capacity to assist with evaluation and testing of products delivered by external system suppliers to ensure that they conform to Agency requirements and methodology.
- 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
 - Prepare and deliver formal presentations to the relevant stakeholders
 - Interact at executive, team and business levels
 - Liaise with different technical teams, such as system administrators, testers and 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 monitor progress against plan;
 - 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.

5.2.3.7. Senior Developer

5.2.3.7.1. Languages: English is mandatory at a minimum of level B2.

5.2.3.7.2. Education:

- Bachelor's Degree in Computer Science, Information Systems or other related field, or equivalent work experience.

5.2.3.7.3. Relevant Professional Qualifications

- Relevant professional qualifications are very desirable

5.2.3.7.4. Specific knowledge

- Expertise per software Individual Skills List
 - Ability to use the development tools and methodologies as specified in Annex 4: Required Skills per Profile.
 - Two years of programming experience in the programming technologies currently used at the Agency.

5.2.3.7.5. Experience

- A minimum of 7 years relevant IT experience of which at least 5 years in the requested role with a strong focus on the application domain of on-line analytical processing systems.
 - Excellent team and collaboration skills are desirable.
 - Strong attention to detail is desirable.
 - Highly organised and motivated individual is desirable.

5.2.3.7.6. General characteristics

Competences in the role

- Demonstrable competences in the role are very desirable. These include:
 - For ETL Developer Only:
 - Writing, maintenance and unit testing of ETL routines which reflect the specifications derived from user reporting requirements or from system integration needs
 - Optimisation of ETL routines;
 - Preparation of scripts for database migrations;
 - Preparation of scripts for ETL migration on test and production environments
 - Development and Execution of DML (Data Manipulation Language) scripts.
 - For BI developer only:
 - Develop, maintain and unit testing of BI templates and reports which reflect the specifications derived from user reporting requirements or from system integration needs
 - Development and Execution of DML (Data Manipulation Language) scripts.

- Optimisation of reports;
- Develop and enhance the BI Repository to support the underline data model
- Preparation of scripts for report migrations;
- Preparation of scripts for reports metadata migration on test and production environments
- Assistance with the testing of ETL routines, reporting modules
- Assistance with design activities;
- Prototyping;
- Production of relevant technical documentation and documentation for the support team;
- Experience in working in an environment with technical teams comprised of testers, analysts and system administrators;
- Capacity to assist the support team in training the users of the system;
- Assistance with operational support of programs produced;
- Capacity to assist with evaluation and testing of products delivered by external system suppliers to ensure that they conform to Agency requirements and methodology.
- 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
 - Prepare and deliver formal presentations to the relevant stakeholders
 - Interact at executive, team and business levels
 - Liaise with different technical teams, such as system administrators, testers and 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 monitor progress against plan;
 - 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.

5.2.3.8. Testing Manager

5.2.3.8.1. Languages: English is mandatory at a minimum of level B2

5.2.3.8.2. : Education:

- Bachelor's Degree in Computer Science, Information Systems or other related field, or equivalent work experience.

5.2.3.8.3. Relevant Professional Qualifications

- Relevant professional qualifications (e.g. ISTQB Certified Advanced or Expert Tester) are desirable.

5.2.3.8.4. Specific knowledge

- Expertise per software Individual Skills List
 - Ability to use the testing tools and methodologies as specified in **Annex 4: Required Skills per Profile.**
 - 5 years of testing experience in the technologies currently used at the Agency
 - Experience with CASE tools

5.2.3.8.5. Experience

- A minimum of 7 years relevant IT experience, including a 6 years minimum experience in the application domain of on-line analytical processing systems. 2 years' experience in the relevant business domain would be an advantage.
 - Demonstrable experience of projects meeting visions similar to those set out in sections 4.1.1.
 - Demonstration that the testing aspects and/or the outcome of projects have been of a complexity similar to that set out in sections 4.1.1.

5.2.3.8.6. General characteristics

Competences in the role:

- Demonstrable competences in the role are very desirable. These include:
 - Definition of the test approach and ensuring its successful implementation;
 - Identification and definition of the required tests;
 - Monitoring of detailed testing progress and results in each test cycle;
 - Evaluation of the overall quality experienced as a result of testing activities;
 - Identification of the appropriate techniques, tools and guidelines to implement the required tests;
 - Provision of guidance on the corresponding resource requirements for the test effort;
 - Creation of the verification and validation plan;
 - Creation of the test plan (including estimating and resource scheduling);
 - Creation of the test scripts;
 - Implementation of tests;

- Automation of tests;
 - Execution of tests;
 - Management of issue workflow;
 - Analysis of test failure;
 - Preparation of test reports;
 - Preparation of validation reports;
 - Assist in identifying suitable test resource requirements.
- Communication abilities are very desirable. These include:
 - Receive and understand instructions
 - Deliver messages clearly, including via formal presentations
 - Interact at executive and team levels
 - Use both written and oral channels
- Time management capabilities are very desirable. These include:
 - Ability to manage one's own time, even in the face of stressful situations;
 - Ability to monitor progress against plan;
 - 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 is very desirable. These include:
 - Number of years: 2 years.
- Leadership capabilities are very desirable. These include:
 - Demonstrable leadership capabilities.

5.2.3.9. Testing engineer

5.2.3.9.1. Languages: English is mandatory at a minimum of level B2.

5.2.3.9.2. Education:

- Bachelor's Degree in Computer Science, Information Systems or other related field, or equivalent work experience.

5.2.3.9.3. Relevant Professional Qualifications

- Relevant professional qualifications or recognised training courses are desirable.

5.2.3.9.4. Specific knowledge

- Expertise per list
 - Ability to use the testing tools and methodologies as specified in **Annex 4: Required Skills per Profile**.
 - One year of testing experience in the technologies currently used at the Agency
 - Experience with CASE tools is desirable

5.2.3.9.5. Experience

- A minimum 3 years of relevant IT experience, focusing on the application domain of on-line analytical processing systems. 2 years' experience in the selected business domains would be an advantage. Demonstrable experience of projects meeting visions similar to those set out in section 4.1.1.
 - Demonstration that the testing aspects and/or the outcome of projects have been of a complexity similar to that set out in sections 4.1.1.

5.2.3.9.6. General characteristics

Competences in the role

- Demonstrable competences in the role are very desirable. These include:
 - Assistance in the creation of the validation plan;
 - Assistance in the creation of the test plan;
 - Creation of test scripts;
 - Creation and management of test data;
 - Implementation of tests;
 - Automation of tests;
 - Execution of tests;
 - Manage issue workflow;
 - Analysis of test failure;
 - Preparation of test reports;

- Assistance in the evaluation of the overall quality experienced as a result of the testing activities;
 - Preparation of validation reports.
- Communication abilities are very desirable. These include:
 - Receive and understand instructions
 - Deliver messages clearly
 - Interact at team level
 - Use both written and oral channels
- Time management capabilities are very desirable. These include:
 - Ability to manage one's own time, even in the face of stressful situations;
 - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.
- Supervisory and leadership capabilities are very desirable. These include:
 - Demonstrable leadership capabilities.
 - Demonstrable capability to manage change.

5.2.3.10. Trainer

5.2.3.10.1. Languages: English is mandatory at a minimum level of C1.

5.2.3.10.2. Education:

- Secondary education attested by a diploma, preferably in the areas of Computer Science, Information Systems or Communication, or equivalent work experience.

5.2.3.10.3. Relevant Professional Qualifications

- Relevant professional qualifications in the training subject and in teaching are desirable.

5.2.3.10.4. Specific knowledge

- Expertise per list
 - Ability to use the training tools and methodologies as specified in **Annex 4: Required Skills per Profile**.

5.2.3.10.5. Experience

- Years of relevant IT literacy: Minimum of 2 years mandatory
- 3 years of experience as a trainer, including 2 years of IT training, with a strong focus on the application domain of online analytical processing system. 2 years' experience in the selected business domain would be an advantage.
 - Demonstrable experience of training courses related to systems similar to those set out in sections 4.1.1.
 - Demonstration that the training aspects and/or the outcome of projects have been of a complexity similar to that set out in sections 4.1.1.

5.2.3.10.6. General characteristics

Competences in the role

- Demonstrable competences in the role are very desirable. These include:
 - Assistance in the creation and maintenance of suitable training materials;
 - Ability to clearly explain potentially difficult and complex technical and scientific concepts;
 - Ability to cope with a multi-cultural and multi-lingual audience;
 - Training sessions for internal personnel and external stakeholders;
 - Follow-up on outstanding issues from training courses;
 - Set up a training feedback process and integrate the lessons learned into the training course and material;
 - Preparation of training reports, as required.
- Communication abilities are very desirable. These include:
 - Receive and understand instructions;

- Deliver messages clearly, including via formal presentations;
- Interact at executive and team levels;
- Explain and impart information at a level and in a manner easily comprehended by an interlocutor;
- Use both written and oral channels.
- Time management capabilities are very desirable. These include:
 - Ability to manage one's own time, even in the face of stressful situations;
 - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.
- Supervisory and leadership capabilities are very desirable. These include:
 - Demonstrable leadership capabilities.
 - Demonstrable capability to manage change.

5.2.3.11. Technical writer

5.2.3.11.1. Languages: English is mandatory at a minimum of level C1

5.2.3.11.2. Education:

- Secondary education attested by a diploma, preferably in the areas of Computer Science, Information Systems, Communication or English Studies, or equivalent work experience.

5.2.3.11.3. Relevant Professional Qualifications

- Relevant professional qualifications (e.g. Cambridge Certificates of English.) are desirable.

5.2.3.11.4. Specific knowledge

- Expertise per list
 - Ability to use the office automation and document management tools and methodologies as specified in **Annex 4: Required Skills per Profile.**
 - Ability to use a help-authoring tool.

5.2.3.11.5. Experience

- 2 years of experience as a technical writer, with a strong focus on the application domain of online analytical processing system, of which 1 year of technical documentation authoring and 1 year of experience with the office automation tools used in the Agency.
 - Demonstrable experience of projects meeting visions similar to those set out in sections 4.1.1.

5.2.3.11.6. General characteristics

Competences in the role:

- Demonstrable competences in the role are very desirable. These include:
 - Production of end-user support and training material, such as user guides, help texts, release notes and so on;
 - Writing of end-user support and training documentation regarding information systems;
 - Preparation of reference and maintenance manuals and other technical documentation in consultation with developers, system architects and software architects.
- Communication abilities are very desirable. These include:
 - Receive and understand instructions
 - Deliver messages clearly, including via formal presentations
 - Interact at executive and team levels
 - Use both written and oral channels
 - Written communication must be clear, concise, unambiguous and easy to read.
- Time management capabilities are very desirable. These include:
 - Ability to manage one's own time, even in the face of stressful situations;
 - 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.

5.2.3.12. Lead consultant

5.2.3.12.1. Languages: English is mandatory at a minimum of level C1.

5.2.3.12.2. Education:

- Bachelor's Degree in Computer Science, Information Systems, Business Administration or other related field or equivalent work experience

5.2.3.12.3. Relevant Professional Qualifications

- Relevant professional qualifications are desirable.

5.2.3.12.4. Specific knowledge

- Expertise per list
 - Ability to use the relevant tools and methodologies that will be specified in the request for services.

5.2.3.12.5. Experience

- 10 years of relevant IT experience, including 7 years in the application domain of on-line analytical processing systems and 3 years as a Lead Consultant.
- Experience sought under this profile is at the Partner/Consultant level
 - Demonstrable successful experience of projects meeting visions similar to those set out in sections 4.1.1.

5.2.3.12.6. General characteristics

Competences in the role

- Demonstrable competences in the role are very desirable. These include:
 - Rapid assimilation of facts and capacity to comprehend complex circumstances, as this profile would typically be used for very specific short-term assignments;
 - Provision of tailored and relevant advice based on a complete understanding of the circumstances and an extensive and detailed knowledge of both the business and application domains;
 - Widely recognised high level expertise in aspects of the application domain to be specified at the time of conclusion of the relevant Specific Contract;
- Communication abilities are very desirable. These include:
 - Receive and understand instructions
 - Deliver messages clearly, including via formal presentations
 - Interact at executive and team levels
 - Use both written and oral channels
- Time management capabilities are very desirable. These include:
 - Ability to manage one's own time, even in the face of stressful situations;
 - 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 desirable.

5.2.3.13. Technical consultant

5.2.3.13.1. Languages: English is mandatory at a minimum of level B2

5.2.3.13.2. Education:

- Bachelor's Degree in Computer Science, Information Systems, Business Administration or other related field or equivalent work experience

5.2.3.13.3. Relevant Professional Qualifications

- Relevant professional qualifications are desirable.

5.2.3.13.4. Specific knowledge

- Expertise per list
 - Ability to use the relevant tools and methodologies that will be specified in the request for services.

5.2.3.13.5. Experience

- 6 years of relevant IT experience, with a strong focus on application domain of on-line analytical processing systems.
 - Demonstrable successful experience of projects meeting visions similar to those set out in sections 4.1.1.

5.2.3.13.6. General characteristics

Competences in the role

- Demonstrable competences in the role are very desirable. These include:
 - Rapid assimilation of facts and capacity to comprehend complex circumstances, as this profile would typically be used for very specific short-term assignments;
 - Provision of tailored and relevant advice based on an understanding of the circumstances and excellent technical expertise, typically in a very specific area (e.g. Enterprise Information Architecture or specific niche products);
 - In depth expertise in aspects of the application domain to be specified at the time of conclusion of the relevant Specific Contract.
- Communication abilities are very desirable. These include:
 - Receive and understand instructions
 - Deliver messages clearly, including via formal presentations
 - Interact at executive, team and technical levels
 - Use both written and oral channels
- Time management capabilities are very desirable. These include:
 - Ability to manage one's own time, even in the face of stressful situations;
 - Ability to prioritise between competing tasks on a rational basis and in a decisive manner.

5.2.3.14. Project Officer

5.2.3.14.1. Languages: English is mandatory at a minimum level of B2

5.2.3.14.2. Education:

- Secondary education attested by a diploma, preferably in the areas of Computer Science, Information Systems or Administration, or equivalent work experience.

5.2.3.14.3. Relevant professional qualifications

- Relevant professional qualifications (e.g. Secretarial/Office Skills or Project Management Basics etc.) are desirable.

5.2.3.14.4. Specific knowledge

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

5.2.3.14.5. Experience

- 3 years of relevant IT experience, including 2 years of relevant Project Management Support.
 - Demonstration that the support activities carried out have been on projects of a similar complexity to those described in sections 4.1.1.

5.2.3.14.6. General characteristics

- Demonstrable competences in the role are very desirable. These include:
 - Ability to take minutes of meetings
 - Ability to use recognised project planning tools
 - Ability to monitor and report against pre-defined criteria
 - Fast
 - Efficient
 - Stress-resistant
 - Accurate
 - Methodical
 - Pro-active
 - Self-starting
- Communication abilities are very desirable. These include:
 - Receive and understand instructions
 - Deliver messages clearly, including via formal presentations
 - Interact at executive and team levels
 - Use both written and oral channels

- Time management capabilities are very desirable. These include:
 - Ability to manage one's own time, even in the face of stressful situations;
 - 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.

5.2.4. 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 5. Subject of the tender;
- The mechanism by which these contracts will be executed and how performance will be measured

5.2.4.1. Overview of the operation of Lot 1

The objective of the procurement procedure is to put into place contractual arrangements with one or more economic operators for the provision of services, on a time and materials basis (Lot 1), that will enable the Agency to acquire resources not employed directly by the Agency in the domain of the development and maintenance of on-line analytical processing information and communication technology systems. To that end, the Agency intends to sign multiple, cascading framework contracts (see section 5.2.4.2.) in order of priority.

Framework contracts do not constitute orders. Orders are placed through service requests (see section 5.2.4.4.) resulting in specific contracts (see section 5.2.4.3.).

During the execution of a specific contract, the Contractor is required to provide the Agency with reports on its performance (see section 5.2.4.10.).

A specific contract is executed against a Service Level Agreement (SLA) with quality indicators (see section 5.2.4.8.).

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 contractor in the cascade to provide the service initially requested, where the higher placed contractor has failed to meet the terms in the service level agreement.

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

5.2.4.2. 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 framework 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 ITT. 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 Contracts, including draft Specific Contracts.**

Tenderers should be aware that the incumbent supplier of the services which are the subject of Lot 1 currently employ ten resources at the Agency's premises, this number includes six of the supplier's employees, the rest being consultants (who are either freelance or contracted via agencies), all of who are carrying out exclusive functions on a full-time basis. Any change of service provider may, therefore, be subject to the Transfer of Undertakings (Protection of Employment) Regulations 2006 (sometimes known as "TUPE") which apply in the UK. The attention of tenderers is therefore specifically drawn to these Regulations, as a successful tender may result in them becoming a potential transferee for the purposes of TUPE, and they are recommended to seek legal advice as to the extent to which TUPE will apply to the proposed contract and to reflect the legal and financial implications of such a transfer in their tender if they so wish.

Tenderers should note that the Agency will be neither transferee nor transferor for the purposes of TUPE. The legal and financial implications of TUPE are a matter for discussion and consultation between the prospective tenderer, the incumbent supplier and the affected personnel at the appropriate time.

Tenderers should note that they will not be able to renegotiate or make changes to any material terms in either their tender, the tender specifications or the framework or specific contracts as a result of the financial, economic or practical implications of the application of TUPE. Material, in this context, shall be deemed to mean the operational terms of the contract (e.g. price, service levels etc.) whereby any change thereto might:

- Introduce conditions which, had they been part of the tender specifications, would have encouraged tenderers, other than those initially admitted, to submit a tender; or
- Extend the scope of the contract to services not initially advertised; or
- Alter the economic balance of the contract in favour of the tenderer in a manner which was not intended in the terms of the contract as advertised.

5.2.4.3. 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 both at the Contractor's and/or at the Agency's premises as required) of the personnel to be used to undertake the work required in this ITT. 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 ITT 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 Contracts, including draft Specific Contracts**.

5.2.4.4. 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 5.2.3. 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 5.2.4.8.) or is unable to provide the services or has provided services unacceptable to the Agency (as defined in this section and section 5.2.4.8.), 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.

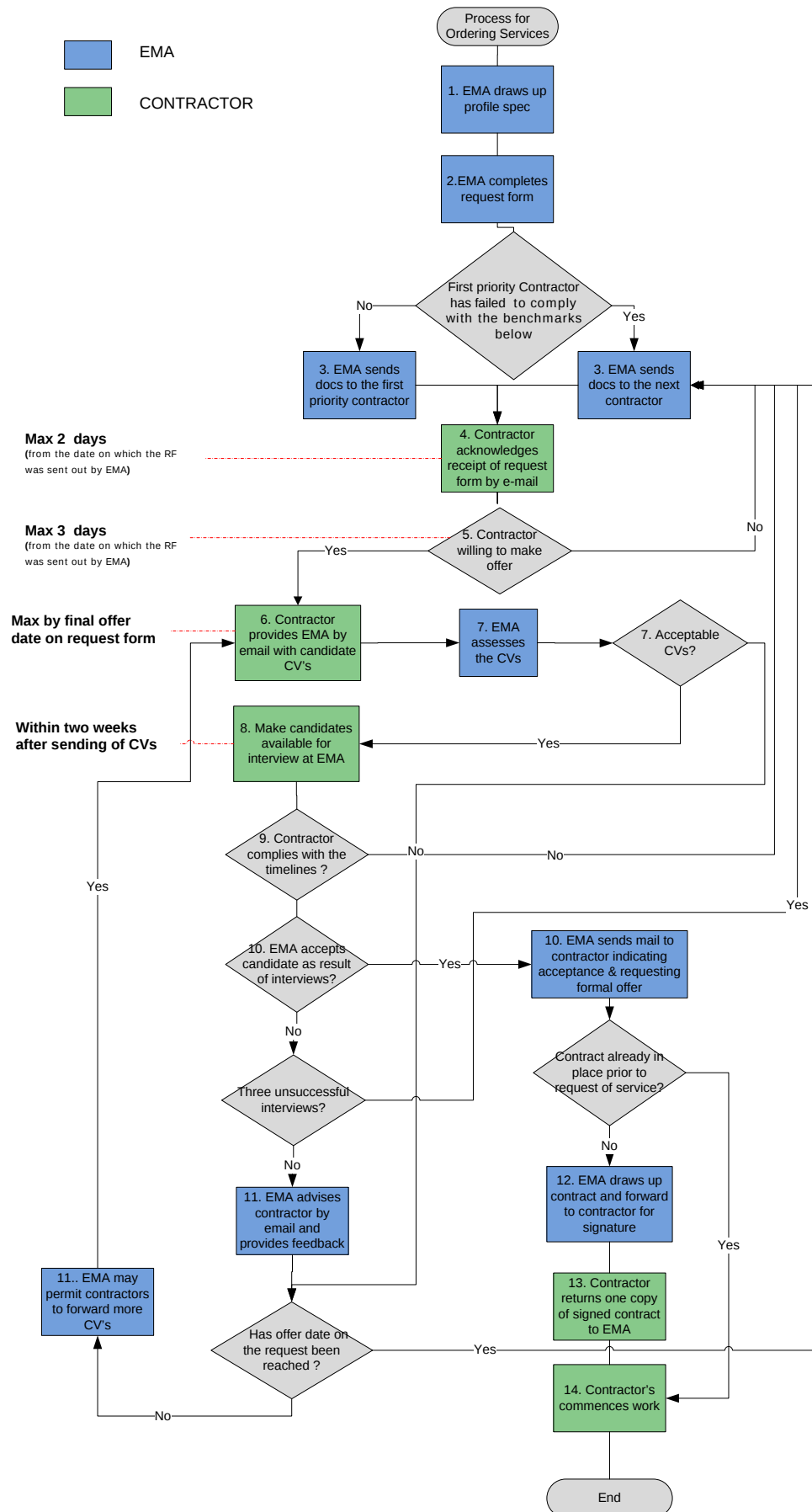


Figure 1: Diagrammatic presentation of the process for ordering services

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

5.2.4.5. 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 5.2.4.4. 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.

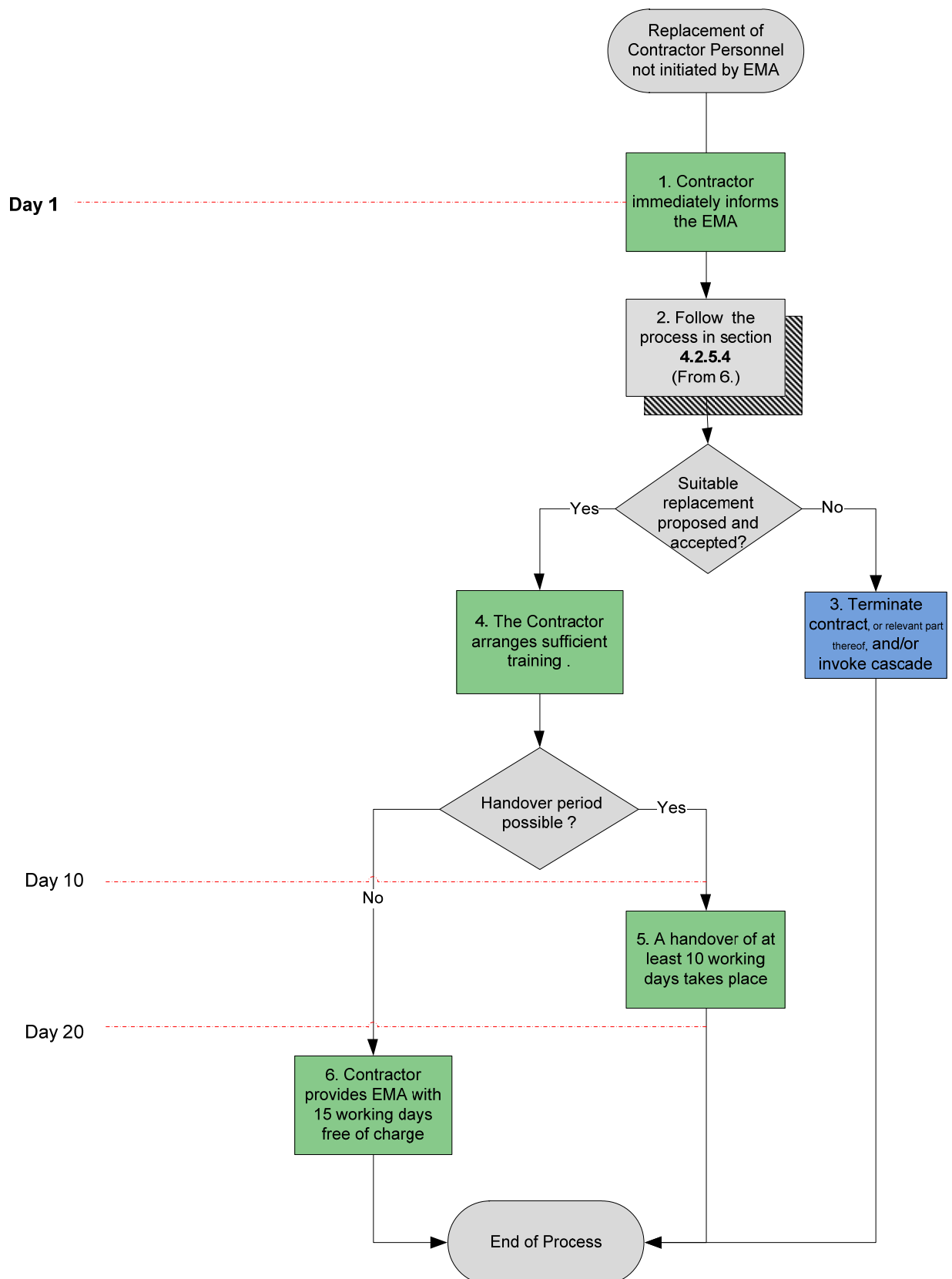


Figure2: Diagrammatic presentation of the process for replacement

5.2.4.6. Languages

The required services must be provided in English.

5.2.4.7. Place of work

Work can be executed on an *intra muros* basis (see below) or *extra muros* (see below). There may be an occasional requirement for meetings outside the European Union (EU) and the European Economic Area (EEA) to be attended by Contractors' staff. The Agency will indicate on all Request Forms where the work has to be undertaken.

5.2.4.7.1. Intra muros

Intra muros work will be undertaken mainly at the Agency's premises at 7 Westferry Circus, Canary Wharf, London E14 4HB, UK. There may be a need for work to be carried out on the premises of the Member States Competent Authorities within the EU and the EEA, or at the premises of one or more of the Agency's industry partners. 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.

5.2.4.7.2. Extra muros

Extra muros work will be performed primarily at the Contractor's premises. Project meetings are typically held at the Agency's premises. Deliverables must be formally delivered at the Agency's premises.

The Contractor must provide all deliverables in the form and format specified in the order and shall guarantee their integration into the target informatics environment. In case of failure or difficulty to integrate the deliverables in the target informatics environment, the Agency may request the Contractor to provide the required corrective action at his own cost.

5.2.4.7.3. Distribution Intra muros - Extra muros

It is expected that up to 5% of the person days referred to in section 10. could be *extra-muros*.

5.2.4.8. 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 5.2.4.12. Service Quality Indicators and Service Quality Benchmarks)

Penalties may be imposed (See section 5.2.4.9.) 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.

5.2.4.8.1. 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 ITT 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
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 5.2.4.4.), 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 5.3.2.8.2. <i>Quality audits</i>

5.2.4.8.2. *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 5.2.4.4.), the service level agreement and the quality of code (*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.

5.2.4.8.3. 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 5.2.4.4. Process for ordering services, 5.2.4.5. Replacement of Contractor personnel not initiated by the Agency, 5.2.4.10. 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.

5.2.4.9. 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 specific 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.

5.2.4.10. 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 5.2.4.4. Process for ordering services and 5.2.4.8. 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.

5.2.4.11. Interfaces, roles and responsibilities

5.2.4.11.1. 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.

5.2.4.11.2. 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.

5.2.4.12. 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 5.2.4.9.) 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 5.2.4.4. Process for ordering services: Step 6	Time [working days]	See Benchmark 1 in section 5.2.4.4. Process for ordering services: Step 6
	2	Compliance with timeline for sending the response	For every service request: Section 5.2.4.4. Process for ordering services: Step 7	Time [working days]	See benchmark 2 in section 5.2.4.4. Process for ordering services: Step 7
	3	Success or failure to provide the requested service	For every service request: Section 5.2.4.4. Process for ordering services: Step 12	Y/N	See benchmark 3 in section 5.2.4.4. Process 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 5.2.4.8.1. 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 5.2.4.8.1. <i>Quality of the service delivery</i>
	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 5.2.4.8.1. <i>Quality of the service delivery</i>
	7	Compliance with notice period	Quarterly average across all resources	Y/N	See benchmark 7 in section 5.2.4.8.1. <i>Quality of the service delivery</i>
	8	Audit success	Every quarter across all audit requests	Y/N	See benchmark 8 in section 5.2.4.8.1. <i>Quality of the service delivery</i>
Quality of the work delivered by time and materials	9	Quality of the provided resources	Quarterly average across all resources	Number	See benchmark 9 in section 5.2.4.8.2. Quality of the work delivered by time

Category	Service Quality Indicators		Reference to usage/point of measurement	Value	Service Quality Benchmarks
resources					and materials resources
	10	Turnover	Quarterly average across all resources	Quarterly average across all resources	See benchmark 10 in section 5.2.4.8.2. <i>Quality of the work delivered by time and materials resources</i>

5.2.4.13. 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 5.2.4.4. Process for ordering services, are not met for a particular request for services
- When the benchmarks as described in section 5.2.4.8. Quality monitoring, are not met for the duration or number of requests as specified in section 5.2.4.9. Measures in cases of underperformance.

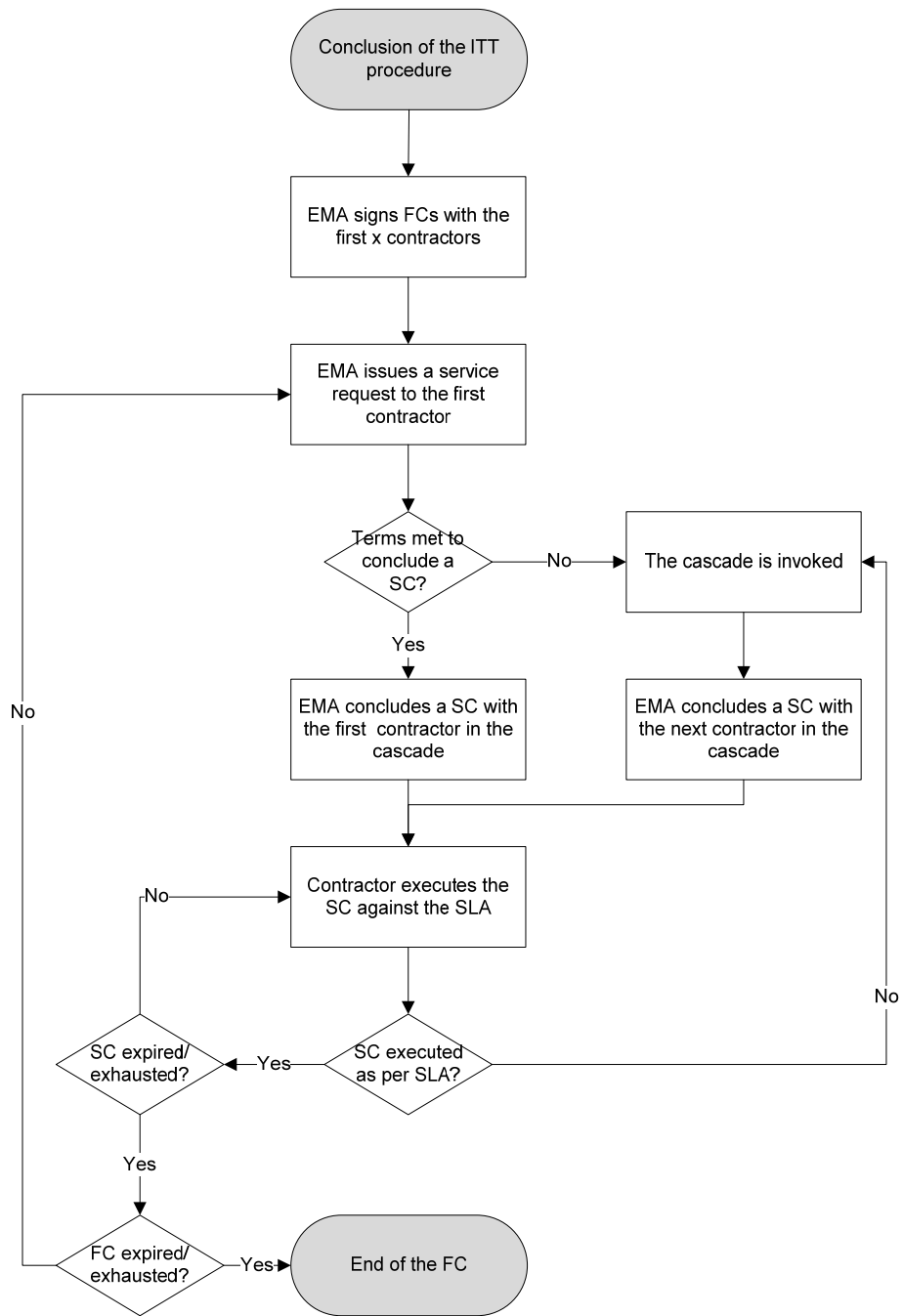


Figure 3: Overview of the operation of Lot 1

5.3. Lot 2 - Provision of ICT artefacts on a fixed price or quoted time and materials basis

5.3.1. Overview of the services required

In certain circumstances the Agency instructs third parties to undertake work on a quoted time and materials (QTM) or fixed price (FP) basis. The Agency describes the deliverables (FP) or tasks (QTM) in Specific Contracts by means of its software development methodology. The Contractor undertakes to deliver as specified for a given price within a given timescale. Specific Contracts can be let in relation to any OLTP system (or related services) which can be developed with the tools listed in the Agency's ICT Standards document in **Annex 6: EMA ICT Standards**.

Examples of ICT artefacts that are envisaged within this lot are:

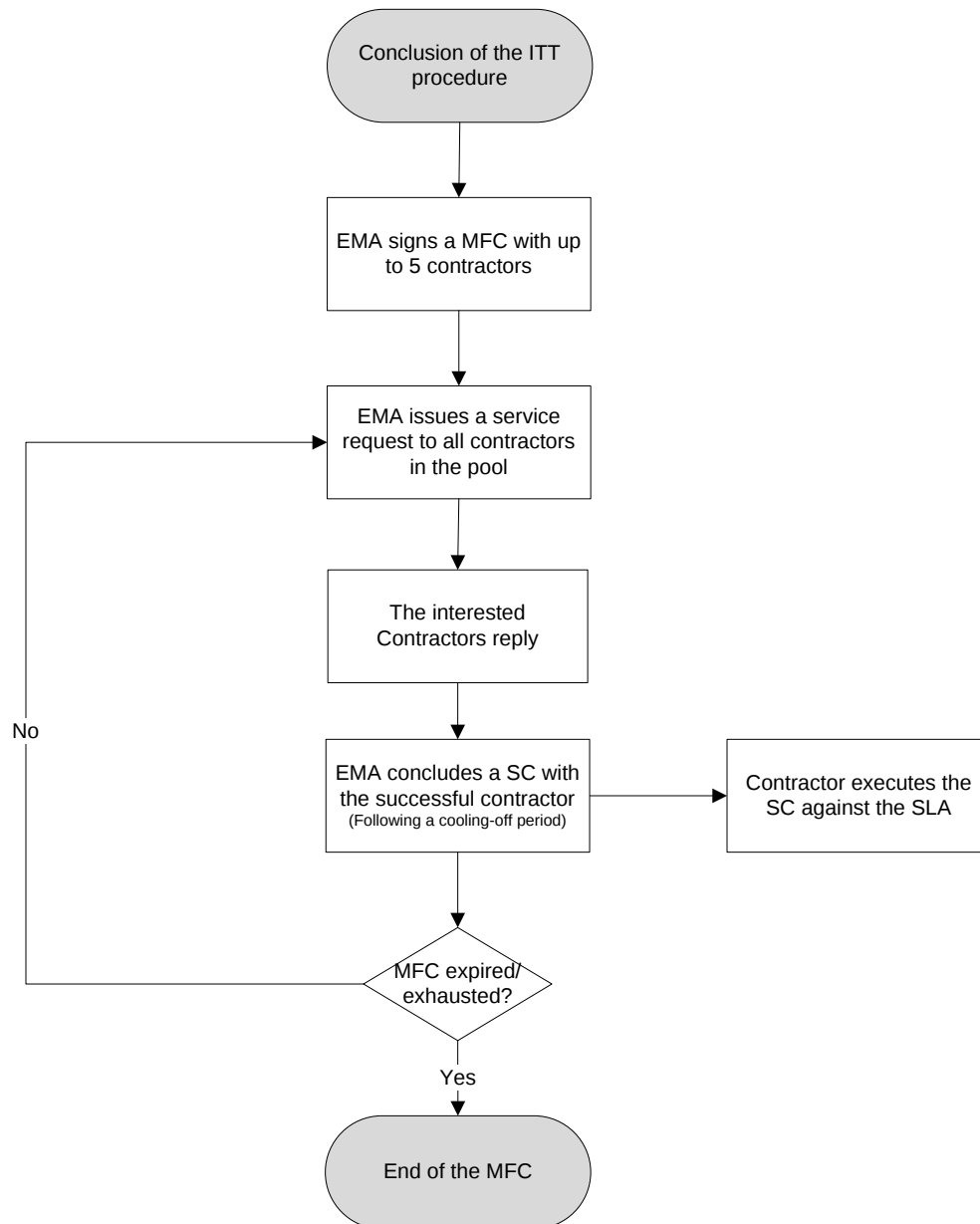
- Feasibility study for a system, consisting of a Vision document, Risk Assessment and a Business Case
- Development and delivery of a complete system on the basis of specifications provided by the Agency
- Development and delivery of a self-contained iteration of a system on the basis of specifications provided by the Agency
- Development of a specific module, technically separate from the main development of the system
- Specific maintenance deliverables for bespoke software
- Training programme in respect of specific systems

It is anticipated that Specific Contracts will be let under this lot according to a consistent rhythm over the period of the framework contract.

Please note that the tenderer is expected to develop in and for an environment that replicates the architecture of the Agency at its own premises. It is understood that tenderers cannot be expected to replicate all elements of the Agency's architecture. However, it is expected that tenderers will take all necessary steps to ensure that the solution developed at the tenderer's premises will be seamlessly integrated into the Agency's test and production environments when deployed in the Agency and that all tests executed at the tenderer's premises are relevant.

5.3.2. Operation of the contract

5.3.2.1. Overview of the operation of Lot 2



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

5.3.2.2. General description of framework contracts

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

It is the Agency's intention to sign multiple framework contracts in a pool arrangement for Lot 2 as a result of this Invitation to Tender. Framework contracts will be awarded to a maximum of 5

contractors each of whom may then be requested to tender on a fixed price or quoted time and materials basis for each Specific Contract to be let.

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 Contracts, including draft Specific Contracts.***

5.3.2.3. 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.

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

5.3.2.4. Process for ordering services

The ordering process for fixed price or quoted time and materials orders is as follows:

1. The Agency draws up a specification of the services required and decides on the timelines for the responses from the Contractors.
2. The Agency sends a mini-call for tender to all Contractors in the pool.
3. The Contractor is required to reply with a tender in response to the mini-call for tender by the deadline indicated in the documentation. If no reply is given, then the Contractor waives his participation in that particular tender procedure.

3.1. For fixed-price orders¹⁵:

- i. The Contractor must present proposals meeting the requirements as specified by the Agency in the Request Forms and associated documents (e.g. specifications, work packages, deliverables, activities, deadlines etc.).
- ii. The offer must include a technical analysis based on the requirements.
- iii. The offer must include a project plan. It has to indicate the proposed activities, the team structure, profiles, roles, responsibilities and workloads.
- iv. A methodology agreed by the Agency has to be used for the calculation of the workload of the different tasks. Based on this, the financial offer must be based on the estimation of the number of days for each activity.
- v. The deliverables must be on time, and conform to the specifications as described in the Specific Contract.
- vi. The invoicing is based on the acceptance of the deliverables by the Agency (and not on the effective workload).

¹⁵ See glossary

- vii. Technical interventions can be foreseen on the Agency's premises for specific tasks like installations, configurations, acceptance tests, technical analysis or maintenance tasks.
- viii. Meetings at the location of delivery with members of the team can be required without any additional cost to the Agency.
- ix. A warranty applies to the deliverables accepted by the Agency.

3.2. For quoted time and materials orders¹⁵:

- i. The Agency specifies the different tasks and sub-tasks to be executed and a total number of days for activities or profiles. When the request corresponds to activities, the Agency indicates the required activities with (or without) individual numbers of days. When the request corresponds to profiles, the Agency may specify (or not) the required profiles and their workload.
 - ii. The Contractor must present proposals meeting the requirements as specified by the Agency in the Request Forms and associated documents (e.g. technical annex with description of tasks, sub-tasks etc.).
 - iii. The offer must include a technical proposal based on the requirements
 - iv. The offer should detail the profiles, roles, activities, responsibilities and workload (activity-days or person-days).
 - v. The financial proposal has to be based on activities or profiles and their total workload.
 - vi. Contractor's staff must match the requested profile description.
 - vii. The work is divided into various sub-tasks performed during the execution of the specific contract. The Agency will provide the Contractor with a detailed description of each sub-task. The contractor will send the Agency a proposal for the execution of each sub-task (including the workload and time schedule) on the basis of a number of activity-days or person-days for the corresponding activities or profiles. The workload must be based on a methodology agreed by the Agency. When agreement with the Agency has been reached, a form is signed by both parties. Only agreed costs for the specified sub-tasks are chargeable, after acceptance by the Agency.
 - viii. Technical interventions can be foreseen on the Agency's premises for specific tasks like installations, configurations, acceptance tests, technical analysis or maintenance tasks.
 - ix. Meetings at the location of delivery with members of the team can be required without any additional cost to the Agency.
 - x. A warranty applies to the sub-tasks accepted by the Agency.
4. The submitted responses are opened and evaluated by an Evaluation Committee according to the award criteria stipulated in the documentation.
 5. The Agency confirms to the successful Contractor by email and letter that the offer is accepted and will form the basis of a Specific Contract.
 6. The Agency will draw up the Specific Contract which will include the details of the services to be provided, the start date, the duration, deliverables, price and any other relevant information. The Specific Contract will be signed in the relevant number of copies by the Agency signatory and then forwarded to the Contractor for signature. The Specific Contract becomes effective from the date of the last signature. The Contractor will retain the relevant number of copies for their files and return one copy to the Agency.

7. The Contractor's personnel will commence work on a mutually convenient date and at the location stipulated in the Request Form. For Fixed Price contracts, this would normally be at the Contractor's own premises.

The Contractor must prepare proposals meeting the requirements as specified in the ITT and associated documents. Deliverables must be on time and conform to the specifications as described in the Specific Contract.

If there is a need for contract extension, the Agency may wish to re-open the competition.

5.3.2.5. *Change management*

Changes to the scope will be reflected in amended requirements (e.g. use cases) supplied by the Agency which will result in agreed amendments to the relevant Specific Contract.

5.3.2.6. *Languages*

The required services must be provided in English.

5.3.2.7. *Place of work*

For fixed price or quoted time and materials orders, the Contractor shall provide all the necessary infrastructure on the Contractor's premises for the successful execution of the work (except for material, licences or products not available on the market, but that can be provided by the Agency during the period of execution). Official acceptance of the work carried out will take place at milestones during and at the end of each order execution, using a procedure agreed to at the beginning of the order. Invoices may be issued only for executed orders and tasks that have been completed and duly accepted.

The Contractor must provide all deliverables in the form and format specified in the order and shall guarantee their integration into the target informatics environment. In case of failure or difficulty to integrate or make operational the deliverables in the target informatics environment as per the specifications included with the specific contract, the Agency may request the Contractor to provide the required corrective action at the cost of the Contractor. The latter will not apply if the Contractor can positively prove that the problem causing non-operation is attributable to the Agency.

5.3.2.8. *Quality monitoring*

5.3.2.8.1. *Quality of the service delivery*

5.3.2.8.1.1. *Quality of the service delivery for fixed price contracts*

Monitoring of the quality of service delivery will measure whether the Contractor is delivering a standard of service in line with expectations.

Where the deliverable from the fixed price specific contract is to be a system or part thereof, the specifications in the specific contract will include at least the vision and system use cases prepared in accordance with the principles of RUP@EMA, as well as the requirements for documentation to be delivered with the system.

The monitoring of the quality of such fixed-price projects for software development will be carried out as follows:

1. At the outset of the project, a detailed software development plan will be drawn up by the Contractor following the principles of the Agency's RUP@EMA software development

methodology. The deliverables of each iteration will be agreed between the Contractor and the Agency in the software development plan. This plan will be used by the Agency to measure the progress and quality of the project.

2. At the end of each iteration specified in the software development plan the Agency will test and approve the deliverables.
3. During the project, the Contractor will be required to provide regular progress reports containing:
 - An executive summary of the status of the project
 - The status of all the milestones.
Where there are delays, the reason(s) for the delay
Where there are delays, a revised end date
 - The risk list, including:
A description of the risk
The probability, severity and consequence of the risk occurring
The mitigation plan for the risk
The current probability, severity and consequence of the risk occurring
 - The list of issues
4. During the project, the system analysis and design documentation using UML must be reviewed and approved by the Agency's Software Architects. No deliverable will be accepted by the Agency without prior approval of the analysis and design documentation. The exact format of this documentation will be agreed in an annex to the relevant Specific Contract. An example of the type of documentation required is given below:
 - System use cases (where not provided by the Agency as part of the initial specifications)
 - Class diagram
 - Data model
 - Activity diagrams to illustrate the functioning of the important functionality of individual classes or of the system
 - Architectural diagrams
5. During the project, the Contractor will be required to provide a test plan, test scripts, the results of the execution of the test scripts and a summary of the defects raised, offering the Agency sufficient assurance that the deliverables have been appropriately tested.
6. After delivery and acceptance of the system (e.g. via UAT including performance and load testing), the Contractor will be required to finalise all the documentation to the Agency's satisfaction.
7. On completion of the project, the measure of quality will be the number of defects in the deliverable against the relevant use cases for the system, taking into account the relative size and complexity of each use case.

Monitoring of the quality of fixed-price projects that are not software development projects will be undertaken using a combination of the above methodologies as applicable and as agreed in the relevant Specific Contract.

5.3.2.8.1.2. Quality of the service delivery for quoted time and materials contracts

Monitoring of the quality of service delivery will measure whether the Contractor is delivering a standard of service in line with expectations. Measurement will be based on the quality indicators below.

Service Quality Indicator	
1	Respect of delivery dates
2	Conformance of sub-tasks delivered

5.3.2.8.2. Quality audits

The Agency will audit the Contractor's processes related to the delivery of the service. Two 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.

- Announced shallow system audit:
 - Notice period: 5 working days
 - Content: On-site audit (Contractor's premises) of all auditable processes and systems (cf. Infra)
 - Maximum duration: 0.5 days
 - Maximum frequency: One per quarter or iteration
- Well-announced in-depth system audit:
 - 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: Two per specific contract. If there are amendments to the specific contract, one additional audit of this type can be executed per amendment

The auditable processes and systems will 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 application in practice of the software development process at the Contractor's premises where the subject of the contract is being developed.
- The systems used for:
 - Source code control, including version control
 - Defect management
 - Tracking from requirements to source code to testing artefacts
- The processes and systems the Tenderer has referred to in his response to this ITT as far as relevant to the delivery of the service.

5.3.2.9. Measures in case of underperformance

The measures in case of underperformance will be specified in the specific contracts.

5.3.2.10. Reporting requirements

Please refer to section 5.3.2.8.1. *Quality of the service delivery*: Point 3 Reporting.

6. Information visit

Information visits are not foreseen for this tender.

7. Participation in the tender

7.1. 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.

7.2. 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 subcontractor.
- 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.

8. 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 :
 - <https://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/https/general/admin/tenders/contracts.htm>

9. Variants

Not applicable.

10. Estimated contract volume

10.1. Estimated contract volume for Lot 1

The Agency estimates, without this being binding, that the volume of services required under the contract for Lot 1 over a four year period is as shown below:

	Sum of Estimated Days 2013	Sum of Estimated Days 2014	Sum of Estimated Days 2015	Sum of Estimated Days 2016	Sum of Estimated Days 2017	Sum of Days
Grand Total	1600	3839	4174	5038	1821	16472

The estimates are based on current planning and budget estimates for the four year period of the contract and include on-going projects, new projects to be started during the period of the contract and on-going support requirements for systems which are already in production. There will also be projects that complete during the period of the framework contract. All these factors may lead to variations in the annual requirement for persons/days over the lifespan of the contract.

10.2. Estimated contract volume for Lot 2

The Agency estimates, without this being binding, that the value of the contract over a four year period will be Euro 5 million.

11. Price

11.1. 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.

11.2. Prices

11.2.1. Time and materials contracts and quoted time and materials contracts

All prices are exclusive of expenses, which will be reimbursed in line with the Agency's reimbursement rules. All expenses are subject to agreement by the Agency prior to the expenses being incurred.

11.2.2. Fixed price

All prices are inclusive of expenses including travel, accommodation and any other costs incurred during performance of the services.

11.3. Price revision for Lot 1

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 framework contract.

From the beginning of the second year of performance of the framework 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

11.4. 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.

11.5. Period of validity of the tender

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

11.6. 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.

12. 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 30 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 ITT.
- A reference to the framework contract number and specific contract number.
- A reference to the Agency's purchase order number.

13. Contractual details

A draft Framework Contract for each Lot, each with a draft Specific Contract in annex, is attached to these Technical Specifications as **Annex 7: Draft Framework Contracts, including draft Specific Contracts**. Tenderers must confirm acceptance of the relevant draft contract 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 for each Lot, 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.

13.1. 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**.

14. 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.

Contracts may not be awarded to candidates or tenderers who, during the procurement procedure:

are subject to a conflict of interest;

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 and 6 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 European Union 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.

15. 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*.

Requirements:

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

The minimum financial turnover requirement for tenderers is:

For Lot 1: Euro 8,853,000 per annum for each of the last three financial years.

For Lot 2: Euro 500,000 per annum for each of the last three financial years.

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 whereby a consolidation assessment shall be made) and parent companies where the parent company is providing a guarantee. In addition to verifying that the financial turnover meets the required minimum amounts, as listed above and in the Official Journal notice, the on-going economic capacity will be assessed including financial independence and liquidity.

Evidence required:

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

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.

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.

16. Selection criteria: professional and technical capacity

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

Requirements: Lot 1

1. Tenderers are required to prove that they have authorisation to perform the contract under national law.
2. Tenderers must have a level of staff turnover in the relevant business area during the most recent financial year of no more than 20%
3. Tenderers must have sufficient manpower of staff for the required services with relevant qualifications and professional experience (CVs are requested here and will not be further examined in the technical evaluation stage).
4. Tenderers must have experience in the domain of the lot with references to three similar contracts for the required services, each of which 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
5. Tenderers must have a policy on subcontracting and a means of ensuring quality when subcontractors are used.
6. Tenderers must have a quality assurance methodology.
7. Tenderers must be able to ensure the quality of service and thus must have the required skills available in the tenderer's organisation. Tenderers are expected to be able to provide, as a minimum, the skills requested by the Agency in Annex 04. The Tenderer's Skills List to be completed by the Tenderer.

Tenderers must meet all of the above requirements. 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.

Evidence Required: Lot 1

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: 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 5.2.3. **Detailed specifications of the profiles required.**

3.2 The CVs of the individuals proposed to manage the account evidencing their expertise in this area.

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 following information is to be provided:

- Customer name and address
- 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 Data Architect: xyz person-months; ...) during the complete duration of the contract.
- Evidence that the Tenderer has in the recent past provided resources of the type (See section 5.2.3.) and in the quantities (See section 10.) requested in this ITT. Any evidence that can be

independently verified will be accepted. This includes e.g. a Contract Award Notice if this information is clearly mentioned.

5. A statement of the Tenderer's policy on the use of subcontractors, and of the means of ensuring quality when subcontractors are used. Where the tenderer does not intend to use subcontractors, a copy of the policy must still be provided. A confirmation whether or not subcontractors will be used for this contract and if so the full name and address of the subcontractor(s). If the tenderer does not intend to use subcontractors, the policy and quality documents must still be provided as the draft framework contract allows for the later addition of subcontractors with the agreement of the Agency. 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 relevant 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. Proof of measures employed to ensure quality of services as indicated by the skills available. The Tenderer's Skills List to be completed by the Tenderer, the minimum figures concerning the necessary number of relevant staff indicated in Indicative Minimum Resources in Annex 14 will apply.

Requirements: Lot 2

1. Tenderers are required to prove that they have authorisation to perform the contract under national law.
2. Tenderers must have a level of staff turnover in the relevant business area during the most recent financial year of no more than 20%
3. Tenderers must have individuals with appropriate qualifications and experience in the area of Account Management for contracts similar to that described in this ITT.
4. Tenderers must have experience in the domain of the lot with references to three similar contracts for the required services, each of which must have the following characteristics:
 - Relevant to the contract required by the Agency
 - In respect of which fixed price or quoted time and materials services 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
5. Tenderers must have a policy on subcontracting and means of ensuring quality when subcontractors are used.
6. Tenderers must have a quality assurance methodology.

Tenderers must meet all of the above requirements. 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.

Evidence Required: Lot 2

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: percentage of staff that have worked within the relevant business area for over 3 years.
3. The Tenderer will provide the CVs of the individuals proposed to manage the account evidencing their expertise in this area. Evidence of expertise in the area of account management and of either one similar assignment covering a minimum four year period or of two previous similar assignments each covering two years is required.

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:
 - Customer name and address
 - 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 the project undertaken under this contract
 - A brief description of how this project 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 upon initial signature.
 - Financial volume of the contract effectively delivered (i.e. total amount effectively invoiced to the customer) during the complete duration of the contract.
 - Development projects: total number of use-case points delivered during the complete duration of the contract.
 - A short description of (or reference to) how the use-case points are calculated.
 - 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.
 - Quoted success criteria and statement that they were achieved
5. A statement of the Tenderer's policy on the use of subcontractors, and of the means of ensuring quality when subcontractors are used. Where the tenderer does not intend to use subcontractors, a copy of the policy must still be provided. A confirmation whether or not subcontractors will be

used for this contract and if so the full name and address of the subcontractor(s). If the tenderer does not intend to use subcontractors, the policy and quality documents must still be provided as the draft framework contract allows for the later addition of subcontractors with the agreement of the Agency. 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 relevant 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.

17. Award criteria

17.1. Award criteria for Lot 1

17.1.1. Overview of the award criteria for Lot 1

Tenderers should provide the information requested in this section by completing the sheet "05 Award Criteria Lot 1" in Annex 2: Response Questionnaires and sheets "01 Price Lot 1" and "03 Expenses Scenario Lot 1" 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	20
2. Personnel Management	20
3. Account Management	10
4. Skills Assurance	10
5. Relationship with <i>extra-muros sites</i>	5
6. Price	35
Total:	100

A detailed breakdown of the points per Criterion is shown in sheet 05 Award Criteria Lot 1 in Annex 2, Response Questionnaire.

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.

17.1.2. Description of the award criteria for Lot 1

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.

17.1.2.1. 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 5.2.3. Detailed specifications of the profiles required. To that end, the Tenderer will provide a description of the methodology used.

The description should address the following elements:

- a) How does the Tenderer propose to evaluate the requirements from the Agency, based on the service request (see section 5.2.4.1. Overview of the operation of Lot 1) and the profile description(s) (See section 5.2.3. Detailed specifications of the profiles required at entry level)?
- b) How does the Tenderer select the best suited candidate?
- c) How does the Tenderer propose to present the candidate(s) to the Agency?
- d) 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?
- e) How does the Tenderer ensure proactive recruitment?

17.1.2.2. 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 the following elements:

- a) 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?
- b) How does the Tenderer stay informed of the day-to-day activities, issues and concerns of its personnel (full-time staff and freelancers)?
- c) What process does the Tenderer have in place to deal with issues raised by its personnel (full-time staff and freelancers)?
- d) How does the Tenderer propose to manage the replacement of personnel (full-time staff and freelancers) and the hand-over to new personnel (full-time staff and freelancers) during a specific contract?
- e) What are the Tenderer's back-up measures that will be put in place in case of temporary unavailability of its personnel working in the premises of the Agency?

17.1.2.3. 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 the following elements:

- a) How does the Tenderer propose to manage this account?
- b) What would be the proposed communication model?
- c) What governance structure would the Tenderer put in place to manage this contract?
- d) What would be the escalation mechanism?

Tenderers should note that section 5.2.4. contains some mandatory requirements in this area.

17.1.2.4. Skills Assurance

This criterion will evaluate:

- a) How the tenderer ensures that its personnel has the appropriate skills to provide the service prior to starting work at the Agency
- b) How the tenderer ensures that the skills levels of personnel assigned to Agency projects are maintained throughout the period that they are working at the Agency
- c) What skills assurance methodology the Tenderer proposes to use?

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 5.2.4.5. Replacement of Contractor personnel not initiated by the Agency, where the project-related training is part of the handover.

17.1.2.5. Relationship with extra-muros sites

This criterion will be used to evaluate the appropriateness of the arrangements the Tenderer proposes to put in place to execute projects *extra muros*.

17.1.2.6. Price

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

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

Prices to be evaluated will be based on the pricing and expenses scenario worksheets (See **Annex 3: Response Questionnaire - Financial - Lot 1**). The grand total of the *intra* and *extra muros* prices in the pricing scenario worksheet plus the grand total of the expenses from the expenses scenario worksheet will be added together, before applying the formula indicated above. Tenderers will be ranked according to the outcome of the initial evaluation of the award criteria, including price. Tenderers should also refer to the Agency's reimbursement rules contained in the Draft Framework Contract for Lot 1 in **Annex 7: Draft Framework Contracts, including draft Specific Contracts**.

17.2. Award criteria for Lot 2

17.2.1. Description of the award criteria for Lot 2 for the Framework Contract

Tenderers should provide the information requested in this section by completing the sheets "06a Award Lot 2" and "06b Sample Project" in Annex 2: Response Questionnaire and sheet "04 Price Scenarios Lot 2" in Annex 3: Response Questionnaire - Financial

For Lot 2, a Multiple Framework Contract (MFC) with reopened competition will be concluded. Framework Contracts will be awarded to a maximum of five Tenderers (a minimum of three are required for the successful operation of the MFC) with the highest overall scores after the conclusion of the evaluation detailed below.

Having established the capacity of the Tenderer to provide the service (i.e. provision of ICT artefacts) during the selection phase, the award phase will establish the best offers. The award criteria will be considered in relation to the tender as a whole.

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

Award Criteria	Points
1. Quality of Service	80
2. Price	20
Total:	100

A detailed breakdown of the points available for this Criterion is shown in sheet 06a Award Criteria Lot 2 in Annex 2, Response Questionnaire.

The technical evaluation will consist of an assessment against the Quality of service award criterion. Tenders not meeting the minimum benchmark score of 60% overall in the Quality of service criterion will be excluded.

Price will then be evaluated for those tenderers which meet or exceed the required benchmark and an overall score will be obtained.

17.2.1.1. Quality of Service

Quality of service relates to the manner, completeness and level of appropriate detail with which specified deliverables are made available. These aspects are further described in section 5.3.2.8.1. *Quality of the service delivery.*

Tenderers should provide a detailed description of the approach and project methodology that they would use when undertaking the projects described in Scenario 1 and Scenario 2 contained in Annexes 12a & 12b. In addition, tenderers should provide examples of any templates that they use to implement their project methodology. Tenderers should complete details in the worksheet(s) entitled Scenario 1 and Scenario 2 in **Annex 2: Response Questionnaire and sheet "06b Project Methodology"**.

Please note that Scenario 3 requires a response in Annex 3: Response Questionnaire – Financial – Lot 2 only.

Some more information on the documents required can be found in section 5.3.2.8.1. *Quality of the service delivery*

17.2.1.2. Price

Evaluation of price for the award of the framework contracts will be conducted according to the following formula using the total price of the scenarios indicated in the worksheets (See Annex 3: Response Questionnaire – Financial – Lot 2):

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

The total of all the scenarios (see **Annex 13, Scenarios for Lot 2**) in the pricing scenario worksheet will be added together, before applying the formula indicated above. Tenderers will be ranked according to the outcome of the initial evaluation of the award criteria, including price.

At the conclusion of this evaluation process a framework contract will be awarded to the tenderers with the highest overall scores. It is anticipated that framework contracts will be awarded to a maximum of four (4) parties for this Lot (a minimum of three are required for the successful operation of the MFC).

17.2.2. Lot 2 award criteria for Specific Contracts to be awarded following reopened competition

Once Framework Contracts have been awarded, specifications for each Specific Contract will be sent to all successful parties, there will be no declared or effective priority or ranking amongst the parties. All parties will be eligible to respond if they wish to do so and a Tender procedure will be conducted for each Specific Contract.

When competition is reopened for the placing of specific contracts under the framework contracts awarded, the parties will compete again on the basis of the same two criteria:

Award Criteria	Points
1. Quality of Service	** tbc < 60
2. Price	** tbc > 40
Total:	100

******The number of points allocated to each criterion may vary, depending on the precise requirements of each specific contract, but price will always account for a minimum of 40% of the points available.

The technical evaluation will consist of an assessment against the Quality of Service award criterion. Tenders not meeting the minimum benchmark score of 60% of points available in the quality award criterion will be excluded.

Evaluation of price for award of specific contracts will be conducted according to the following formula:

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

18. 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 15 and 16 above).
- Documentation requested to enable assessment of Award Criteria (section 17 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 14. 15. 16. and 17. 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.

19. 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 contracts, including draft specific contracts

- Draft Framework Service contract – Lot 1
- Draft Framework Service contract – Lot 2

Annex 8: Standard timesheet

Annex 9: Confidentiality statement

Annex 10: Standard Profile Specification and Request Form

Annex 11: Standard Expense Form

Annex 12a: Scenarios for Lot 2 – scenario 1

Annex 12b - Scenario for lot 2 – scenario 2

Annex 13: Scenarios for Lot 2

Annex 14: Minimum Resources per skill

Annex 1: Summary Checklist

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.
 - 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.