EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
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CALL FOR TENDERS

N° SANTE/2018/B3/030

European Reference Network:

Clinical Practice Guidelines and

Clinical Decision Support Tools

TENDER SPECIFICATIONS

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1. INFORMATION ON TENDERING

1.1. Participation

Participation in this procurement procedure is open on equal terms to all natural and legal persons coming within the scope of the Treaties, as well as to international organisations.

It is also open to all natural and legal persons established in a third country which has a special agreement with the Union in the field of public procurement on the conditions laid down in that agreement. Where the plurilateral Agreement on Government Procurement[1] concluded within the World Trade Organisation applies, the participation to this procedure is also open to all natural and legal persons established in the countries that have ratified this Agreement, on the conditions it lays down.

Please be aware that after the UK's withdrawal from the EU, the rules of access to EU procurement procedures of economic operators established in third countries will apply to candidates or tenderers from the UK depending on the outcome of the negotiations. In case such access is not provided by legal provisions in force candidates or tenderers from the UK could be rejected from the procurement procedure.

1.2. Contractual conditions

The tenderer should bear in mind the provisions of the draft contract which specifies the rights and obligations of the contractor, particularly those on payments, performance of the contract, confidentiality, and checks and audits.

1.2.1. Duration

The duration of the contract is 48 months. During the 3 years following the conclusion of the initial contract, it may be decided by the Contracting Authority to award, to the same Contractor, an additional contract for developing additional clinical guidelines if needed, using a negotiated procedure without prior publication of a contract notice.

1.3. Compliance with applicable law

The tender must comply with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to Directive 2014/24/EU[2].

[1] See http://www.wto.org/english/tratop_E/gproc_e/gp_gpa_e.htm

[2] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).

1.4. Joint tenders

A joint tender is a situation where a tender is submitted by a group of economic operators (natural or legal persons). Joint tenders may include subcontractors in addition to the members of the group.

In case of joint tender, all members of the group assume joint and several liability towards the Contracting Authority for the performance of the contract as a whole, i.e. both financial and operational liability. Nevertheless, tenderers must designate one of the economic operators as a single point of contact (the leader) for the Contracting Authority for administrative and financial aspects as well as operational management of the contract.

After the award, the Contracting Authority will sign the contract either with all members of the group, or with the leader on behalf of all members of the group, authorised by the other members via powers of attorney.

1.5. Subcontracting

Subcontracting is permitted but the contractor will retain full liability towards the Contracting Authority for performance of the contract as a whole.

Tenderers are required to identify subcontractors whose share of the contract is above *5* % and whose capacity is necessary to fulfil the selection criteria.

During contract performance, the change of any subcontractor identified in the tender or additional subcontracting will be subject to prior written approval of the Contracting Authority.

1.6. Structure and content of the tender

The tenders must be presented as follows:

Part A: Identification of the tenderer (see section 1.7)

Part B: Non-exclusion (see section 4.1)

Part C: Selection (see section 4.2)

Part D: Technical offer

> The technical offer must cover all aspects and tasks required in the technical specifications and provide all the information needed to apply the award criteria. Offers deviating from the requirements or not covering all requirements may be rejected on the basis of non-compliance with the tender specifications and will not be evaluated.

Part E: Financial offer

> The price for the tender must be quoted in euro. Tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to bear the risks or the benefits deriving from any variation.

Prices must be quoted free of all duties, taxes and other charges, including VAT, as the European Union is exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Union. The amount of VAT may be shown separately.

The quoted price must be a fixed amount, which includes all charges (including travel and subsistence). Travel and subsistence expenses are not refundable separately.

For informative purposes, the financial offer must also present a breakdown of the costs by work package.

1.7. Identification of the tenderer

The tender must include a **cover letter** signed by an authorised representative presenting the name of the tenderer (including all entities in case of joint tender) and identified subcontractors if applicable, and the name of the single contact point (leader) in relation to this procedure.

In case of joint tender, the cover letter must be signed either by an authorised representative for each member, or by the leader authorised by the other members with powers of attorney. The signed powers of attorney must be included in the tender as well. Subcontractors that are identified in the tender must provide a letter of intent signed by an authorised representative stating their willingness to provide the services presented in the tender and in line with the present tender specifications.

All tenderers (including all members of the group in case of joint tender) must provide a signed Legal Entity Form with its supporting evidence. The form is available on: http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm

Tenderers that are already registered in the Contracting Authority's accounting system (i.e. they have already been direct contractors) must provide the form but are not obliged to provide the supporting evidence.

The tenderer (or the leader in case of joint tender) must provide a Financial Identification Form with its supporting documents. Only one form per tender should be submitted. No form is needed for subcontractors and other members of the group in case of joint tender. The form is available on:

http://ec.europa.eu/budget/contracts_grants/info_contracts/index_en.cfm

The tenderer (and each member of the group in case of joint tender) must declare whether it is a Small or Medium Size Enterprise in accordance with Commission Recommendation 2003/361/EC. This information is used for statistical purposes only.

2. TECHNICAL SPECIFICATIONS

2.1. General background and reference documents

European Reference Networks (ERN) are virtual networks bringing together healthcare providers across Europe to tackle complex or rare medical conditions that require highly specialized treatment and a concentration of knowledge and resources.

ERNs are set up under Directive 2011/24/EU on the application of patients' rights in cross-border healthcare[3] which not only sets rights for patients seeking healthcare abroad including reimbursement for treatment in another EU Member State but also promotes cooperation in healthcare among Member States. In particular, the Directive asks the Commission to "*support Member States in the development of European reference networks between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases*"[4].

Following up to the Directive, the Commission adopted on 10 March 2014 the Delegated Decision 2014/286/EU setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil[5], as well the Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks[6].

Member States keep the lead in the ERN process as they are responsible for the endorsement of the applications of healthcare providers wishing to become members of a new or an existing Network, as well as for the approval of the proposed Networks and their Members.

24 ERNs approved by the ERN Board of Member States were launched in March 2017, including 956 highly specialised healthcare units from 298 hospitals located in 25 EU Member States (plus Norway).

The 24 ERNs cover major disease groups, from bone disorders to haematological diseases, from paediatric cancer to immunodeficiency. One member of each Network acts as Coordinator.

The 24 Coordinators are gathered within the ERN Coordinators group (ERN-CG) which was set up in March 2017. This strategic group establishes a common ground on several key technical and organisational aspects of the implementation of the ERNs.

More information can be found in the ERN EUROPA website available at this link: http://ec.europa.eu/health/ern/events/ev_20140623_en.htm

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3 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF

4 See article 12 of the Directive.

5 Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil (OJ L 147, 17.5.2014, p. 71) http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2014_147_R_0006

6 Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 147, 17.5.2014, p. 79) http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2014_147_R_0007

Concerning the specific topic of these tender specifications, it is relevant to remind that Annex 1, point 4(c) of the above mentioned Delegated Decision establishes that Networks "shall (…) develop and implement clinical guidelines and cross-border patient pathways" while Annex II, point 1(e)(iv) states that the healthcare providers applying to become members of the Networks "must (…) develop and use clinical guidelines and pathways in their area of expertise".

Moreover the European Commission developed the "ERN Assessment Manual" for the Network proposals for the first call for ERNs launched in March 2016 (Annex I) where are defined the Operational Criteria[7] that Networks must fulfil to meet the requirements outlined in the above mentioned ERN Delegated Decision. Chapter 6 of these Operational Criteria set the criteria to fulfil the requirement set out in Article12(4)(a)(iii) of Directive 2011/24/EU ("offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control") as follows:

- <u>The Network develops and/or implements clinical guidelines and cross border patient pathways following a formal process for developing or selecting and disseminating clinical guidelines.</u>

  Clinical Guidelines comprise recommendations on the care of patients with specific conditions, based on the best available research, evidence, and practice/experience. Where there are existing clinical guidelines that are agreed upon nationally, regionally or locally, the Network adopts these requirements, where appropriate.

  The process for developing or selecting clinical guidelines may include inter alia using content experts; a consensus panel; Grades of Recommendation Assessment, Development and Evaluation (GRADE); or the Appraisal of Guidelines Research and Evaluation (AGREE) II instrument, which allows Networks to evaluate the methodological development of clinical guidelines from six perspectives: scope and purpose, stakeholder involvement, rigor of development, clarity and presentation, applicability, and editorial independence.

  When developing and/or selecting clinical guidelines, the Network obtains patient and family input. Patients and families are consulted to determine whether the method of deciding among guidelines follows a patient-centred approach. Patient and family input is used to select guidelines that are appropriately linked to improved patient experience.

- <u>The Network adheres to ethical criteria, is transparent, and avoids any conflict of interest when developing and implementing clinical guidelines, patient pathways, and other clinical decision making tools</u>.

  The Network Board should define specific rules and procedures to ensure transparency and adherence to ethics requirements. In particular, the Board should define a strong policy on the declaration and management of conflict of interest of the participants in the development of such tools given the high ethical standards and social responsibility required. A conflict of interest is a set of circumstances that creates a risk that professional judgement or actions regarding a primary interest of

[7] http://ec.europa.eu/research/participants/data/ref/other_eu_prog/hp/guide/pse/hp-asses-manual-ern-op-criteria-ntw_en.pdf

the science or the patient will be unduly influenced by a secondary interest. Conflict of interest may distort the interpretation of results and evidence, the analysis of data, and the development of research methods. To ensure fairness, this policy should respect relevant National and European legislation and follow the recommendations and guidelines developed by independent organisations and recognised bodies.

- The Network monitors implementation of established clinical guidelines and patient pathways to encourage consistent use across its Members and monitor their appropriateness. Information is used to make ongoing quality improvements.

  The Network should establish both process and clinical outcome measures before implementing any clinical guideline or pathway. Process measures evaluate how well a Healthcare Provider is implementing related processes of care. Outcomes measures look at measurable changes in a patient's condition as a result of treatment or other interventions.

For the sake of clarity the following concepts will be used as from now in this document:

- Clinical Practice Guidelines (CPGs) and its acronym when referring to clinical guidelines or evidence based clinical guidelines.

- Clinical Decision Support Tools (CDSPs) when referring to other types of support tools for the clinical decision making process different to CPGs, mostly based in opinions and the expertise of the healthcare professionals (e.g. consensus documents, clinical recommendations, consensus protocols etc.).

The Institute of Medicine of the USA defined CPGs[8] as "statements that include recommendations intended to optimize patient cares that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options".

Most of the ERNs are actively working in the domain of development or implementation of Clinical Practice Guidelines (CPGs) with different levels of maturity or organisational approaches. While some of the networks are already in the phase of implementation or adaptation, other ERNs are starting to set-up their plans and priorities. There are as well important differences between networks on the number of existing CPGs or Clinical Decision Support Tools (CDSTs) in the different domains of expertise and in the methodological knowledge and capacity to elaborate, appraise or evaluate such tools.

Some ERNs are already counting on the CPGs produced by National or International institutions and organisations and/or the support of Professional Societies or Academic Institutions with an important experience in the development of CPGs [9] [10] [11] [12] [13] [14] [15] [16].

[8] https://www.ncbi.nlm.nih.gov/books/NBK209539/

[9] https://www.has-sante.fr/portail/jcms/c_431294/en/clinical-practice-guidelines-cpg

[10] https://www.has-sante.fr/portail/jcms/c_431294/en/clinical-practice-guidelines-cpg

[11] https://www.nice.org.uk

Many institutions and professional societies across the EU have a long experience in the methodological elements, development and assessment of CPGs and other CSDTs in many areas of expertise and for many diseases and conditions. However most of them are aimed at common diseases and recommendations dedicated to rare diseases (RDs) remain scarce. This is due the low number of patients and casuistic (In the European Union, a disease is considered as rare when it affects not more than 5 per 10,000 persons) and the difficulty to gather reliable information across healthcare providers and countries.

According to a recent ORPHANET publication on guidelines for RDs[17], large national and international databases gathering CPGs are available, but they generally contain very few guidelines specific to RDs which are difficult to find amongst the mass of recommendations available for more frequent diseases. Moreover, a significant number of the guidelines produced for RDs by research networks, reference centres or other organizations are not published in international peer-reviewed journals, and thus cannot be found in biomedical literature databases.

This situation leads, in many cases, to a lack of systematic reviews and strong evidence which affects the development of high quality guidelines which are substituted in many cases by other types of support tools for the clinical decision making process mostly based in opinions and the expertise of the healthcare professionals (e.g. consensus documents, clinical recommendations, consensus protocols etc.) which, although very valuable, are heterogeneous in terms of nomenclature, quality and methodology and should not be confused with the evidence based CPGs.

A well-defined methodology for the development of each of the CDSTs is therefore deemed fundamental as those tools will represent the best available knowledge in the absence of CPGs.

In addition, the use of existing guidelines is frequently not spread across the EU and, as a consequence, the benefit of this knowledge for healthcare providers and patients is limited to a certain number of Member States and healthcare providers.

There are as well some key players and research projects financed by the EU in the approach and expertise on CPGs in the field of rare o low prevalence complex diseases that have contributed with valuable knowledge and resources to the development and evaluation of CPGs on RDs (Orphanet[18], Rare-Bestpractices[19]) and other EU financed

[12] www.guiasalud.es

[13] https://www.g-i-n.net/home

[14] http://uroweb.org/guidelines/

[15] https://www.escardio.org/Guidelines

[16] http://www.esmo.org/Guidelines

[17] Clinical Practice Guidelines for Rare Diseases: The Orphanet Database" S.Pavanet al.

[18] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5242437/

[19] http://www.rarebestpractices.eu/pagine-1-project_description

Joint Actions addressing the methodology and development of CPGs in the specific environment of the ERNs (Joint Action on Rare Cancers[20] and Joint Action on Rare Diseases[21]).

The Commission launched in 2018 a tender that is currently under development by the selected contractor to establish taxonomy, templates and a repository model on CPGs and other CDSTs to be used by the ERNs. The timing for the production of all deliverables of the mentioned tender, included those to be taken in account in relation with this tender, are detailed in the tender specifications[22].

2.2. General and specific objectives

The overall purpose of this call for tender is to provide assistance to the ERNs and their healthcare providers in the process of development, appraisal and implementation of CPGs and CDSTs taking in account the objectives and criteria set under the framework of Article 12 of Directive 2011/24/EU on patients' rights in cross-border healthcare and relevant implementing measures and procedures.

The technical assistance will contribute to implement the capacity of the Networks and their members in their task to produce and adhere to high quality CPGs and CDSTs in their area of expertise.

For the performance of the tasks defined in this tender, the contractor will work in constant collaboration and consultation with the ERN Coordinators and other designated representatives of the Networks in charge of CPGs including healthcare professionals, experts and patient representatives. Consultation with the Members of the ERN Board of Member States will take place as well. Other stakeholders would also be consulted upon request of DG SANTE.

2.3. The Work Packages

The tender is structured in 4 Work Packages (WPs) whose general and specific objectives are detailed below:

2.3.1. Work package A. - Advisory Body and Expert panels on CPGs and CDSTs: establishment, maintenance and support

The overall purpose of this WP is to create and maintain an efficient and technically sound advisory structure for the ERNs in the field of CPGs and CDSTs.

The specific objectives are:

[20] http://jointactionrarecancers.eu/

[21] http://www.rd-action.eu/european-reference-networks-erns/workshop4/

[22] SANTE/2017/B3/083 - Taxonomy and templates for the European Reference Networks documents

1. *To provide technical advice and guidance to the European Commission, to the Member States and to the ERN Coordinators on the overall process of development, appraisal and implementation of CPGs and CDSTs by the creation of an Advisory Body.*

2. *To support and help the ERNs to carry out the process of development, appraisal and implementation of specific CPGs and CDSTs in each of the 24 approved ERNs by the definition of the model, characteristics and rules of the Expert panels in charge of the CPGs and CDSTs at Network level.*

Tasks to be performed by the contractor

Task A.1 Carry out a literature review and an experts consultation identifying existing models, rules and procedures of the technical, scientific or advisory committees, panels, taskforces or boards of organisations, networks or other entities involved in the development, appraisal and implementation of CPGs and CDSTs.

The review and consultation shall address models of:

- general and technical advisory bodies;
- specific panels for the development of guidelines.

The contractor shall consult with experts belonging to internationally recognised institutions and organisations in the field of CPGs and CDSTs and with the ERN Coordinators considering the different approaches and structures already defined or created by the 24 approved ERNs.

Task A.2: Propose a model for an Advisory Body on CPGs and CDSTs (the ERNs CPGs Advisory Body), to fulfil the content of objective 1 of this work package ,defining its standard composition and functioning and the procedures for the appointment of its Chair and members including the overall roles and responsibilities.

The membership shall include a combination of profiles with different backgrounds including at least: clinical experts, methodologists, experts from recognised institutions and organisations in charge of CPGs and / or CSDTs, ERNs Coordinators or designated CPGs contact points at Network level, the European Commission and Members of the ERN Board of Member States or other Member States representatives. The Board shall have a maximum of 15 members.

The contractor shall consult the ERN Coordinators about the model and have it approved by DG SANTE.

Task A.3: Propose a model of a standard ERN Expert panel that would be in charge of the development and appraisal of specific CPGs at ERN level.

The model will include a description of the standard procedures for the creation, composition, and functioning of CPGs Expert panels on specific CPGs, the appointment of their Chairs and other positions, and the overall roles and responsibilities in developing, reviewing, and proposing specific CPGs and rules for each of the 24 approved ERNs.

The contractor shall consult the ERN Coordinators about the model and have it approved by DG SANTE.

Task A.4: Organise and support the selection of members and the creation of the ERNs CPGs Advisory Body as defined above in task A.2. DG SANTE will approve the final

composition. The contractor will produce the needed documentation and coordinate all the working procedures for the operation of the Advisory Body.

This task includes:

1. The identification and proposal to the Commission of the potential candidates for the Advisory Body.

2. The establishment of contacts with the potential members of the Advisory Body agreed by the Commission and the assurance of their agreement to participate.

3. The organisation of the first, constitutive, meeting of the ERNs CPGs Advisory Body in Brussels covering all costs for meeting facilities as well as for travel, subsistence and accommodation expenses of the members.

4. The organisation of virtual and online consultations and meetings using web conference means and the provision of a virtual working space to the members. The Advisory Body will hold at least two virtual meeting every year (max. 12 in total).

5. The organisation of a yearly physical meeting in Brussels of the ERNs CPGs Advisory Body (4 in total), covering meeting facilities as well as the travel, subsistence and accommodation expenses of the members.

The contractor will prepare for each virtual and physical meeting an agenda, the technical documents to be discussed, the minutes of the meeting and any other needed document. Preparatory documents of the meetings must be sent to the Commission for approval at least 4 weeks in advance to the date of the meeting. After each meeting the contractor will produce a report including minutes, working documents and a financial report on the coverage of meeting facilities as well as travel, subsistence and accommodation expenses for the meeting that will be included in the yearly report.

TaskA.5: Support the creation and / or functioning of the Expert panels that would be in charge of the development and appraisal of a specific CPG at ERN level.

The contractor will work in cooperation with the 24 ERN Coordinators or designated CPGs contact points to analyse the level of current development of CPGs and CDSTs at network level and the different needs for advice or support of each of the ERNs in this field.

The contractor will advise and support the 24 ERNs in the tasks related to:

a) the effective functioning of the Expert panels in charge of the development, appraisal and implementation of CPGs or CDSTs of each of the 24 ERNs;

b) the application of the procedures and rules described in task A.3;

The contractor will provide the support of a technical "helpdesk" that will advise the 24 CPGs contact points on the above listed areas. This support will continue during the total duration of the contract.

The tasks of the helpdesk will include:

1. The organisation of virtual and online consultations and meetings using web conference means and the provision of a virtual working space to the panel members if needed. The number of virtual meetings should not exceed three meetings per year and per ERN (a total of maximum 288 meetings). Otherwise the communication and advice will be based on standard teleconferences and email communication.

2. The preparation for each virtual meeting of an agenda, the technical documents to be discussed and any other needed document. Furthermore the contractor shall produce a short executive meeting report including the agenda, main agreements and actions points decided and technical documents used and / or produced to be distributed to the panellists.

3. All the documents and deliverables produced or uploaded in the environment of the virtual working space shall be made available to the Commission at its request.

Input by the Contracting Authority

I-A.1: DG SANTE will provide relevant background material on the ERNs state of play and structure.

I-A.2: DG SANTE will facilitate the contacts of the contractor with the ERN Coordinators and will provide the contractor with the full list and contact details of ERN Coordinators and project managers.

I-A.3: DG SANTE will facilitate the contacts of the contractor with the members of the ERN Board of Member States and will provide the contractor with the full list and contact details of the members of the ERN Board of Member States while respecting the applicable data protection legislation and procedures .

I-A.4: DG SANTE will make available the ERN logo and visual identity directions to be used for all material.

Requested deliverables to be produced by the contractor

- **D-O** General Kick-off meeting. The contractor will participate in a general kick-off meeting during which the different work packages will be presented to DG SANTE. During this meeting, the contractor will take minutes of every discussion and agreement or conclusion with a view of producing minutes of the meeting and an inception report.
- **D-A.1** Inception report. After the kick-off meeting the contractor will produce an inception report including the minutes of the meeting, the main agreements achieved and a detailed timeline for the execution of the tasks of each work package.
- **D-A.2** A report with the methodology and the result of the literature review including the consultation process on the existing models, rules and procedures of the technical, scientific or advisory committees, panels, taskforces or boards of organisations, networks or other entities involved in the development, appraisal and implementation of CPGs and CDSTs. The report shall be written in English and structured in three sections: Literature review, consultation outcomes and conclusions and recommendations.
- **D-A.3** A proposal for a model of the ERNs CPGs Advisory Body.
- **D-A.4** A proposal for a standard Expert panel to be in charge of the development, appraisal and implementation of specific CPGs at ERN level.

- **D-A.5** A report with the outcomes of the selection process and composition of the members of the ERNs CPGs Advisory Body**.**

- **D-A.6** A report describing the proposed virtual online consultations, web conference and working space system for the virtual support to the members of the ERNs CPGs Advisory Body.

- **D-A.7** A proposal for each virtual (8) and physical meeting (5) of the ERNs CPGs Advisory Body including an agenda and the technical documents to be discussed as well as a description of the plan to cope with practicalities including venue, technical equipment, travel, subsistence and accommodation of participants. The preparatory documents of the meetings must be sent to the Commission for approval at least 4 weeks in advance of the date of the meeting. The deliverables will be identified as D-A.7.1 (for the first meeting) to D-A.7.13 (for the last meeting).

- **D-A.8** The organisation of the first constitution meeting and of the annual meetings of the ERNs CPGs Advisory Body in Brussels during 4 years (5 meetings) covering the expenses for the meeting facilities as well as the travel, subsistence and accommodation of the members.. The deliverable will be identified as D-A.8.1 (for the first meeting) to D-A.8.5 (for the last meeting).

- **D-A.9** The organisation of at least two virtual Advisory Body meeting every year during 4 years (8 virtual meetings). The deliverable will be identified as D-9.1 (for the first meeting) to D-9.8 (for the last meeting).

- **D-A.10** A report after each of the 5 meetings of the ERNs CPGs Advisory Body, including minutes of the meeting, any agreement reached, and a summary financial report on the costs of the meeting The deliverables will be identified as D-A10.1 (for the first meeting) to D-A.10.5 (for the last meeting) and will be part of the yearly report described in deliverable D-A.16

- **D-A.11** A report of each of the virtual meetings (8) held with the ERNs CPGs Advisory Body. Including minutes of the meeting and any agreement reached. The deliverables will be identified as D-A.11.1 (for the first meeting) to D-A.11.8 (for the last meeting).

- **D-A.12** An initial plan and timetable of the virtual meetings of the contractor with the 24 ERN Coordinators or nominated CPGs contact points to be approved by DG SANTE.

- **D-A.13** The organisation of 24 virtual meetings of the contractor with the 24 ERN Coordinators or nominated CPGs contact points in order to analyse the level of current development of CPGs and CDSTs at network level and the different needs for advice or support of each of the ERNs in this field and the different needs for advice or support of each of the ERNs in this matter.

- **D-A.14** A final plan, strategy and timetable of the supportive actions of the contractor to the 24 ERNs related with task A.5.

- **D-A. 15** A project for the organisation and functioning of the technical "helpdesk" that will advise the 24 CPGs contact points including a description of the virtual online consultations foreseen, web conference and working space system.

- **D-A.16** A yearly report of no more than 50 pages (annexes excluded) written in English including:

  - A summary of the physical and virtual meetings of the ERNs CPGs Advisory Body based in deliverables D-A.10 and D-A.11.

  - A summary of the meetings and online consultations actions and outcomes described in D-A.13 provided to the 24 ERNs.

  - A separated annex including the deliverables D-A.10 and D-A.11 related with the yearly activities of the ERNs CPGs Advisory Body

  - 24separated annexes (one per ERN) including the description and outcomes of the yearly meetings and communication activities carried out as described in deliverable D-A..13

  The deliverables will be identified as D A.16.1 (for the first year) to D A.16.4 (for the last year).

  Final Deliverable

- **D-A.17** A final report containing a summary description of each deliverable produced, of the difficulties encountered to achieve it and recommendations for further supporting the work of the ERNs. The final report will be preceded by an index. The final report shall be accompanied by a PowerPoint presentation highlighting the main issues, outcomes and conclusions.

Delivery time and number of progress meetings planned with the Contracting Authority are detailed in the general time plan table.

The delivery time for deliverables D-A7.2 to D-A.7.13, D-A8.2 to D-A.8.5, D-A 9.2 to D-A9.8, D-A.10.2 to D-A.10.5, D-A.11.2 to D-A.11.8 and D-A.16.1 to D-A.16.4 will be agreed during the progress meetings.

2.3.2. Work package B: Preparation of the methodologies for the development, appraisal and implementation of clinical practice guidelines and Clinical Decision Support Tools

The overall purpose of this WP is to prepare a structured, standardised and user-friendly set of methodologies for the development, appraisal and implementation of CPGs and CDSTs for the ERNs.

The specific objective is:

1. To prepare the methodologies for the development, appraisal and implementation of CPGs and CDSTs, ensuring that it is based on the state of the art and the recommendations and practices recognised at EU and international level. The methodologies set will comprise a toolkit including guidance documents, practical tools and recommendations to the Expert panels of each of the 24 approved ERNs and in general to the healthcare professionals' community.

Tasks to be performed by the contractor

Task B.1: Carry out a literature review and an expert consultation, identifying and reviewing the methodologies and tools used and recognised at International level for the development, appraisal and implementation of CPGs and CDSTs.

The literature review will be structured around the definitions and taxonomy of CPGs and CDSTs that will be provided by the European Commission.

The consultation will address in particular the Working Group on Clinical Guidelines and Knowledge Generation of the ERNs Coordinators Group and the deliverables produced by the group.

The consultation process will include the 24 identified ERNs CPGs contact points and key informants of at least six organisations and institutions with expertise and knowledge on the matter and mainly devoted to the development, appraisal and implementation of CPGs and CDSTs. The contractor will combine consultation of the EU (public institutions and scientific organisations) and international organisations.

The selection of CDSTs of which the methodologies shall be reviewed and synthetized must be based on the taxonomy and definitions produced as a result of the contract SANTE/2017/B3/083[23]. The timing for the production of the taxonomy and definitions are detailed in the SANTE/2017/B3/083 tender specifications.

The contractor must pay special attention to the identification of methodologies and type of tools to be used in the development of CPGs and CDSTs in the case of very rare or low and complex diseases due the limited evidence-based sources of information, the lack of expertise and the reduced number of patients.

The contractor shall in particular review the outcomes of research projects financed by the EU on the matter of CPGs development, appraisal and implementation and make a consultation with the contact persons and researchers involved in those projects.

The Contractor shall produce an exhaustive report on the literature review and consultation carried out including an executive summary detailing the conclusions, recommendations and advantages and disadvantages of the different methodologies that would be presented to DG SANTE for approval and to the ERN CG and the Board of Member States.

The report shall be accompanied by a PowerPoint presentation including the main highlights, concussions and recommendations.

Task B.2: Produce the ERNs Methodological Manual and Tool Kit for the development, appraisal, adaptation and implementation of CPGs and CDSTs.

The contractor shall, based on the outcome of task B.1, develop a detailed set of standardised methodologies for the development, appraisal, adaptation and implementation of ERNs CPGs and CDSTs.

[23] SANTE/2017/B3/083 - Taxonomy and templates for the European Reference Networks documents

The contractor must consider the current state of art of the methodologies for the accelerated development of clinical guideline aiming to produce CPGs or recommendations in a short amount of time without losing in scientific quality, like the ones proposed in the ADAPTE manual.[24]

The methodologies set and tools shall be detailed in a systematic way in a Manual and Tool Kit.

Each dimension of the methodologies (see below) or each tool will include, when possible, a specific section on the approach to diseases or conditions where the evidence is scarce and which methods could be best fitted for the development of CPGs and CDSTs in that case.

The structured and robust methodological guidance will include at least the following:

- Development of CPGs and CDSTs identified in the taxonomy, including the criteria, steps, actions and in general all the standard operation procedures (SOP) to be followed in the development phase. That will include the description of the type and roles of the different experts and stakeholders to be involved.

  The methodologies set must address the following dimensions:

  - overall working procedures for the development of CPGs and CDSTs
  - establishment of a multidisciplinary guideline development group;
  - conflict of interest;
  - patients involvement;
  - identification of clinical questions or problems;
  - conduct of systematic searches and appraisal of the evidence retrieved;
  - procedures for drafting recommendations rated according to their strength and to be practically useful for the clinicians;
  - external consultation process and
  - ongoing reviewing and updating existing CPGs.
  - quality check and validation process

  The Grades of Recommendation Assessment, Development and Evaluation (GRADE) methodology[25] developed by the GRADE Working Group should be the common ground to grade the evidence in relation with the clinical questions and the outcomes of the systematic reviews.

- Appraisal of CPGs :

  This section shall include a detailed description describing, when available the concrete methods and procedures of a short list of the most comprehensively

[24] https://www.g-i-n.net/document-store/working-groups-documents/adaptation/adapte-manual-for-guideline.pdf/at_download/file

[25] http://www.gradeworkinggroup.org

validated appraisal tools. This list must complement the widely recognised AGREE II instrument which will be the base of this methodology.

- CPGs implementation tools (GItools)

  The contractor should identify a set of useful and robust implementation tools addressing the following categories of interest: point-of-care decision making, implementation, evaluation and patient engagement.

- Evaluation of the uptake of the CPG and CDST by the Health Care Providers within the ERN:

  The contractor shall propose a methodology including specific indicators to evaluate the degree of acceptance, use and application of the recommendations established in the CPG and CDST.

The Manual and Tool Kit shall be produced in English both in paper and electronic format. The tools and scales must be user-friendly and accessible using online and e-training means and tools.

The manual and Tool Kit will be accompanied by a PowerPoint presentation and a short video (of maximum 10 minutes) produced by the contractor.

Input by the Contracting Authority

I-B.1: DG SANTE will provide relevant background material including the taxonomy and definitions of CPGs and CDSTs produced under the framework of the call for tender published by Commission in May 2018 as described in task B.1. The relevant documentation should be availaible as from April 2019.

Requested deliverables to be produced by the contractor

- **D-B.1.** An exhaustive report on the literature review and consultation carried out under task B.1.

- **D-B.2** The ERNs Methodological Manual and Tool Kit for the development, appraisal and implementation of CPGs and CDSTs as described in task B.2.

Delivery time and number of progress meetings planed with the Contracting Authority are detailed in the general time plan table.

2.3.3. Work package C: Training and capacity building

The overall purpose of this WP is to improve the knowledge and increase the capacity and expertise of the ERNs healthcare professionals, ERN Coordinators, ERNs CPGs contact points and members of the Expert panels at ERN level in the process of development, appraisal and implementation of CPGs and CDSTs in an effective and efficient way.

The specific objectives are:

1. *To offer expert training and support to the CPGs contact points and the members of the Expert panels of the 24 ERNs for the appropriate use of the methodologies to be developed under WP B.*

2. *To offer and provide basic training to all clinical experts, patients and other possible stakeholders involved in the development of CPGs and* CDSTs *for specific diseases and conditions.*

3. *To produce training materials in online formats for self-evaluation and training in the field of the development, appraisal and implementation of CPGs and* CDSTs *available to the entire healthcare community and other interested stakeholders and experts.*

Tasks to be performed by the contractor

Task C.1: Produce a Training Programme on CPGs and CDSTs tailored to the different audiences and to the needs and preferences of the 24 ERNs.

The design of the training programme shall allow enough flexibility to adapt it to the needs of each of the ERNs in accordance and consultation with the ERN Coordinators and /or the ERNs CPGs contact points in charge of the CPGs and CDSTs matter.

The Training Programme should be tailored to different audiences and levels of training addressing three main types of standard training activities, modules and tools:

1. Expert level training: Addressed to the ERNs CPGs contact points responsible of the overall coordination on the matter of CPGs and CDSTs at ERN level for the development, appraisal and implementation of CPGs. The Expert level training will also include specific team building activities with the aim of improving the mutual knowledge of the ERNs CPGs contact points and to encourage the mutual learning and support between ERNs.

2. User and intermediate level training: Addressed to clinical, experts, patients and other experts involved in the development of CPGs or CDSTs for specific diseases or group of diseases or conditions. This training will consist in a general intermediate training. This training could be considered as a requisite to participate in the development, appraisal or implementation of a CPG.

3. Online and standalone-training and online material, including seven educational and information modules that should be user friendly in their format and design. This material shall be made available online to all ERN members.

    - Each module shall include at least the following elements: a) Scope and definition of the module, b) explanation and conceptualisation of the subject, c) examples and literature references and, links to recognised institutions, d) specific description and guidance on the use of the tools included and e) self-administered tests and evaluations.

    - The contractor shall produce at least 7 modules: three on the Development of CPGs and CDSTs; two on the Appraisal of CPGs and CDSTs and two on the implementation of CPGs and CDSTs.

The training programme shall be presented and approved by the Commission.

The final content of each training module will be made available to the ERNs.

Task C.2: Implement the training programme

The contractor shall provide the training activities in a step wise and continuous strategy.

1. Consultation with the ERN Coordinators or CPGs contact points of the 24 ERNs. This consultation will include the offer of the training activities and will allow to define the appropriated timing and number of participants by ERNs with the following limits:

    - The expert training: should take place no later than four months after the consultation. The maximum number of participants will be 1 expert per ERN (24 in total).

    - The user level training shall take place no later than 8 months after the consultation and once the expert level training is concluded. The maximum number of participants shall be 120 (average 5 per ERN).

2. Providing the training:

Based on the agreed training programme and timeline the contractor will prepare and deliver the training activities.

- The expert level training will consist in a physical workshop of 2 days to be hosted in Brussels or in a well-connected EU capital.

  The workshop will have 1 edition (24 participants per workshop).

  The workshop will be followed by an online support by means of a technical "helpdesk" that will provide advice to the trained experts. This support will continue along the total length of the contract.

- The user level training will consist on an intensive 1 day workshop to be hosted in Brussels or in a well-connected EU capital.

  The user-level workshop will have 3 editions in order to accommodate the availability and preferences of the 120 participants (40 participants per workshop).

  A virtual training session (3) based on the standalone modules and material produced will follow each of the user-level training workshop.

- Online and self-administered CPGs e-training modules:

  The contractor will organise and provide access to the 7 online e-training modules hosting and maintaining the system in its own servers. The contractor should grant access to all ERNs participants through the use of links and will maintain a register of the users and follow the use and completeness of the online training. All the online materials and tools shall be provided to the Commission.

The contractor will provide DG SANTE with the training material for the physical training workshops and make a demonstration of the virtual training sessions.

Requested deliverables to be produced by the contractor

- **D-C.1** A report of the consultation and analysis of the training needs of the ERN Coordinators and contact points of the 24 ERNs.
- **D-C.2** A proposal of the training scheme and Programme on CPGs and CDSTs.
- **D-C.3** The proposed draft content of the training modules and tools to be approved by DG SANTE.
- **D-C.4** A final document describing the modules content and tools, including proof of having a virtual system to deliver the virtual training that is suitable for this contract purposes and demonstration of its functioning to DG SANTE.
- **D-C.5** The paper and electronic version of the standalone online material and tools modules.
- **D-C.6** The organisation and delivery of the physical training workshop at expert level (2 days including a day of team building activities) covering also the expenses of venue, travel, subsistence and accommodation of the participants.
- **D-C.7** A report of the physical training workshop at expert level including a financial summary.
- **D-C.8** A yearly report of the number and on the outcomes of the virtual and online training support actions at expert level provided to the 24 ERNs CPGs contact points. The deliverables will be identified as D C.8-1 (for the first year) to D C.8.4.
- **D-C.9** The organisation and delivery of the 3 physical training workshops at user and intermediate level (1 day) covering the expenses related to venue, travel, subsistence and accommodation of participants.
- **D-C.10** A report of the 3 physical training workshops at user and intermediate level including information on the virtual module trainings and a financial summary related to the physical training workshops.
- **D-C.11** A report on the online e-training activities (number of users, completeness rate of the online training, and other outstanding issues)

Delivery time and maximum number of progress meetings planned with the Contracting Authority is detailed in the general time plan table.

2.3.4. Work package D: Support to the development, and appraisal of CPGs and CDSTs

The overall purpose of this WP is to provide technical support and guidance to the 24 ERNs, when needed and requested, in the real development or appraisal process of CPGs and CDSTs.

The specific objectives are:

1. *To provide support and guidance for the real development and appraisal of CPGs and CDSTs to the 24 contact points on the matter and to the members of the Expert panels of the 24 ERNs.*

2. *To test and evaluate the utility and effectiveness of the methodological framework and tools for the development and appraisal of CPGs and CDSTs and to include improvements when needed.*

Tasks to be performed by the contractor

Task D.1 The contractor, using standardised procedures and the methodologies developed as described in work package B, will support each ERN in the development of 2 new CPGs or CDSTs and in the appraisal and adaptation, when needed, of 5 CPGs or CDSTs.

The contractor shall carry out a consultation process with the ERN Coordinators or the designated CPGs contact points to discuss and agree on the timing and the type of support to be provided according to the elements described below for new CPGs and for the appraisal and adaptation of existing CPGs.

Based on the preferences expressed by the ERNs Coordinators or the designated CPGs contact points the development of new CPGs could be substituted by the appraisal and adaption of a given number of existing CPGs up to the cost of the development of a new CPG.

The support will include the following steps and actions:

For new CPGs

- Support and accompany the whole process of development of a new CPG including the documentation support and the edition of the documents using the templates provided by the Commission.
- Help to determine, in cooperation with the CPGs contact points, the purpose, scope, and intended audience of the selected CPGs or CDSTs.
- Support and advice in the selection of the CPGs Expert panel.
- Help to specify the main focused clinical questions that the recommendations will address.
- Advise on the decision on the relative importance of outcomes.
- Carry out the systematic review and find and summarize the evidence supporting each recommendation providing the inputs to the CPGs Expert panel.
- Help to determine the quality of the available evidence.
- Contribute to the evaluation of the balance of desirable and undesirable consequences for a particular course of action.
- Support the formulation of recommendations, including their strength.

For the appraisal and adaptation of existing CPGs

- Support and accompany the whole process of appraisal and adaptation of existing CPGs including the documentation support and the edition of the documents using the templates provided by the Commission.
- Help to determine, in cooperation with the CPGs responsible of the ERNs, the selected diseases or conditions and the existing CPGs to appraise and eventually adapt.
- Support and advice in the selection of the panel of CPGs appraisal and adaptation experts and authors.
- Support the appraisal process as established in the methodologies detailed in work package 2.
- Help to determine the quality of the available CPGs.
- Contribute to the evaluation of the balance of desirable and undesirable consequences for a particular course of action.
- Support the process of adaptation of the positively appraised CPGs and the reformulation of recommendations, including their strength.

The CPGs or CDSTs produced shall include beside the technical content and recommendations, all the support documents as shall be described in the deliverables of the work package 2 on methodologies (information for patients, instructions to users, algorithms, summaries etc.).

Requested deliverables to be produced by the contractor

- **D-D.1** The consultation process with the ERN coordinators or CPGs contact points.
- **D-D.2** A report on the outcomes of the consultation process with the 24 ERNs including the goals, planning and intended timetable for the development and appraisal of CPGs and CDSTs.
- **D-D.3** A yearly report on the support activities carried out by the contractor specified by ERNs and type of activity. The report will include an analysis of the fulfilment of the agreed objectives and recommendations or new planning schemes if needed. The deliverable will be identified as D3.1 (for the first year) to D3.4 (for the last year).
- **D-D.4** The new and adapted CPGs or CDSTs produced by the 24 ERNs in electronic and paper format including all the instructions and supportive documents for users, patients etc. The products shall be delivered to the Commission and the ERNs once finalised and edited in any moment during the length of the contract.
- **D-D.5** A final report on the activities and outcomes of the support activities to the development by ERNs, type of activity and outcomes. The report will include, in separate annexes, each of the new and adapted CPGs or CDSTs produced by the 24 ERNs in electronic and paper format including all the instructions and supportive

documents for users, patients etc. produced from M16 to M48 (previously delivered in the subsequent D-D4 deliverables)

Delivery time and maximum number of progress meetings planned with the Contracting Authority are detailed in the general time plan table.

3. DELIVERY TIME AND MAXIMUM NUMBER OF PROGRESS MEETINGS PLANNED WITH THE CONTRACTING AUTHORITY.

Deliverable / meetings	**Timeline**
D-0: Kick off meeting	M1
D-A.1	M1
D-A.2	M3
D-B.1	M3
1st intermediary payment: 10% of total	At the approval of D-A.2 and D-B.1
D-A.3	M4
D-A.4	M4
D-C.1	M4
D-A.5	M5
D-A.6	M5
D-C.2	M5
D-B.2	M5
D-D.1	M6
1st progress meeting with DG SANTE to discuss D-A.2 to D-A.6, D-C.6, D-D.1 and present D-B.2	M6
D-A7.1	M7
D-C.3	M7
D-D.2	M7
D-A8.1	M8
D-C.4	M8
D-C.5	M8

D-C.6	M8
Teleconference progress meeting	M8
D-A.9.1	M9
D-C.7	M9
D-C.9	M10 to M16
D-A.12	M11
D-A.13	M12
D-C-8.1	M12
D-D.3.1	M12
D-A.14	M13
D-A.15	M13
2nd progress meeting with DG SANTE	M13
2nd intermediary payment 15% of total	At the approval of D-A.14 and D-A.15
D-A.16.1	M13
D-D.4	M16 to M48
D-C.10	M18
3rd progress meeting with DG SANTE to discuss D-A.16 & D-A.17.1	M18
D-D.3.2	M23
D-A.16.2	M24
D-C.8.2	M24
4TH progress meeting with DG SANTE to discuss D-A.17.2, and D-D.3.2	M25
3rd interim payment 25%	At the approval of D-A.17.2 and D-C.9.2
D-A.16.3	M36
D-C.8.3	M36
D-D.3.3	M37
5TH progress meeting with DG SANTE to discuss D-A.17.3, D-C.9.3 and D-D.3.3,	M38
4th interim payment 25%	At the approval of D-A.17.3, D-C.9.3 and D-D3.3
D-C.8.4	M47

D-A.16.4	M48
D-D.3.4	M48
D-D.5	M48
D-A.18	M48
Final payment of balance	M49

The kick-off meeting and all the progress meetings will be held at the premises of the European Commission in Brussels. In case of need, teleconference meetings will be arranged to provide clarifications or for punctual exchange of views.

4. CONTENT, STRUCTURE AND GRAPHIC REQUIREMENTS OF THE DELIVERABLES

- All deliverables shall be written in English. The contractor shall foresee in his time allocation the performance of a quality language check before delivering the documents to the Commission as well as a layout quality check.
- The contractor must provide a PowerPoint presentation on the outcomes of the contract and a short informative video.

4.1. Content

4.1.1. Final report

The final report must include:

- a description, of no more than 50 pages (annexes excluded), including the content and story of the course of works carried out during the contract and an executive summary index with references to all documents produced during the performance of this contract;
- an electronic structured collection of annexes organised in different chapters for the outcomes of the different work packages and including all approved deliverables;
- specific identifiers which must be incorporated on the cover page provided by the Contracting Authority;
- the following disclaimer:

> *"The information and views set out in this [report/study/article/publication…] are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein."*

4.1.2. Publishable executive summary

The publishable executive summary must be provided in English and must include:

- specific identifiers which must be incorporated on the cover page provided by the Contracting Authority;
- the following disclaimer:

> *"The information and views set out in this [report/study/article/publication…] are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein."*

4.1.3. Requirements for publication on Internet

The Commission is committed to making online information as accessible as possible to the largest possible number of users including those with visual, auditory, cognitive or physical disabilities, and those not having the latest technologies. The Commission supports the Web Content Accessibility Guidelines 2.0 of the W3C.

For full details on the Commission policy on accessibility for information providers, see: http://ec.europa.eu/ipg/standards/accessibility/index_en.htm

For the publishable versions of the final report, abstract and executive summary, the contractor must respect the W3C guidelines for accessible pdf documents as provided at: http://www.w3.org/WAI/ .

4.2. Graphic requirements

The documents shall have a common layout and graphical elements, as established in the templates that will be provided by the Commission, and be user-friendly. They shall reflect a common visual identity for all ERN documents and online materials and must also highlight the support that the ERNs receive from the EU. They shall be made available in both electronic and printable version. The source files shall be made available to DG SANTE.

The contractor must deliver the final report and all publishable deliverables in full compliance with the corporate visual identity of the European Commission, by applying the graphic rules set out in the European Commission's Visual Identity Manual, including its logo and by including also the logo of ERNs which will be provided by DG SANTE services. The graphic rules, the Manual and further information are available at:

http://ec.europa.eu/dgs/communication/services/visual_identity/index_en.htm

The contractor must apply the rules set out in Visual Identity Manual for the graphic design of both the cover page and the last page of the reports of this contract.

5. EVALUATION AND AWARD

The evaluation is based solely on the information provided in the submitted tender. It involves the following:

- Verification of non-exclusion of tenderers on the basis of the exclusion criteria
- Selection of tenderers on the basis of selection criteria
- Verification of compliance with the minimum requirements set out in these tender specifications
- Evaluation of tenders on the basis of the award criteria

The contracting authority may reject abnormally low tenders, in particular if it established that the tenderer or a subcontractor does not comply with applicable obligations in the fields of environmental, social and labour law.

The Contracting Authority will assess these criteria in no particular order. The successful tenderer must pass all criteria to be awarded the contract.

5.1. Verification of non-exclusion

All tenderers must provide a declaration on honour (see Annex II), signed and dated by an authorised representative, stating that they are not in one of the situations of exclusion listed in that declaration on honour.

In case of joint tender, each member of the group must provide a declaration on honour signed by an authorised representative.

In case of subcontracting, subcontractors whose share of the contract is above *5* % and those whose capacity is necessary to fulfil the selection criteria must provide a declaration on honour signed by an authorised representative.

The Contracting Authority reserves the right to verify whether the successful tenderer is in one of the situations of exclusion by requiring the supporting documents listed in the declaration of honour.

The successful tenderer must provide the documents mentioned as supporting evidence in the declaration on honour before signature of the contract and within a deadline given by the contracting authority. This requirement applies to each member of the group in case of joint tender and to subcontractors whose share of the contract is above *5*% and those whose capacity is necessary to fulfil the selection criteria.

The obligation to submit supporting evidence does not apply to international organisations.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit the documentary evidence if it has already been submitted for another procurement procedure and provided the documents were issued not more than one year before the date of their request by the contracting authority and are still valid at that date. In such cases, the tenderer must declare on its honour that the documentary evidence has already been provided in a previous procurement procedure, indicate the reference of the procedure and confirm that that there has been no change in its situation.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit a specific document if the contracting authority can access the document in question on a national database free of charge.

5.2. Selection criteria

Tenderers must prove their legal, regulatory, economic, financial, technical and professional capacity to carry out the work subject to this procurement procedure.

The tenderer may rely on the capacities of other entities, regardless of the legal nature of the links which it has with them. It must in that case prove to the Contracting Authority that it will have at its disposal the resources necessary for performance of the contract, for example by producing an undertaking on the part of those entities to place those resources at its disposal.

The tender must include the proportion of the contract that the tenderer intends to subcontract.

Declaration and evidence

The tenderers (and each member of the group in case of joint tender) and subcontractors whose capacity is necessary to fulfil the selection criteria must provide the declaration on honour (see Annex II), signed and dated by an authorised representative, stating that they fulfil the selection criteria applicable to them. In case of joint tender or subcontracting, the criteria applicable to the tenderer as a whole will be verified by combining the various declarations for a consolidated assessment.

This declaration is part of the declaration used for exclusion criteria (see section 4.1) so only one declaration covering both aspects should be provided by each concerned entity.

The Contracting Authority will evaluate selection criteria on the basis of the declarations on honour. Nevertheless, it reserves the right to require evidence of the legal and regulatory, financial and economic and technical and professional capacity of the tenderers at any time during the procurement procedure and contract performance. In such case the tenderer must provide the requested evidence without delay. The Contracting Authority may reject the tender if the requested evidence is not provided in due time.

After contract award, the successful tenderer will be required to provide any missing evidence before signature of the contract and within a deadline given by the contracting authority. This requirement applies to each member of the group in case of joint tender and to subcontractors whose capacity is necessary to fulfil the selection criteria.

In the course of the procedure the EU Validation Services may contact tenderers via the Participant Register and ask for supporting documents with respect to the legal existence and status and economic and financial capacity. Please note that a request for supporting documents in no way implies that the tenderer has been successful.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit the documentary evidence if it has already been submitted for another

procurement procedure and provided the documents were issued not more than one year before the date of their request by the contracting authority and are still valid at that date. In such cases, the tenderer must declare on its honour that the documentary evidence has already been provided in a previous procurement procedure, indicate the reference of the procedure and confirm that that there has been no change in its situation.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit a specific document if the contracting authority can access the document in question on a national database free of charge.

5.3. Legal and regulatory capacity

Tenderers must prove that they are allowed to pursue the professional activity necessary to carry out the work subject to this call for tenders. The tenderer (including each member of the group in case of joint tender) must provide the following information in its tender if it has not been provided with the Legal Entity Form:

- For legal persons, a legible copy of the notice of appointment of the persons authorised to represent the tenderer in dealings with third parties and in legal proceedings, or a copy of the publication of such appointment if the legislation applicable to the legal person requires such publication. Any delegation of this authorisation to another representative not indicated in the official appointment must be evidenced.

- For natural persons, if required under applicable law, a proof of registration on a professional or trade register or any other official document showing the registration number.

5.4. Economic and financial capacity criteria

The tenderer must have the necessary economic and financial capacity to perform this contract until its end. In order to prove their capacity, the tenderer must comply with the following selection criteria.

- **Criterion F1**: In order to meet the financial capacity criterion, the tenderer must obtain a score of at least 8 points (out of a total of 16 points), which corresponds to 50% of the maximum number of points.

Evidence (to be provided on request):

- Copy of the profit and loss accounts and balance sheets for the last two years for which accounts have been closed from each concerned legal entity;

If, for some exceptional reason which the Contracting Authority considers justified, a tenderer is unable to provide one or other of the above documents, it may prove its economic and financial capacity by any other document which the Contracting Authority considers appropriate. In any case, the Contracting Authority must at least be notified of

the exceptional reason and its justification. The Commission reserves the right to request any other document enabling it to verify the tenderer's economic and financial capacity.

For contracts with a value of 144,000 EUR or more, tenderers (and in case of a consortium, the consortium leader and the consortium members) are also requested to fill in the 'simplified balance sheet' and the 'simplified profit and loss accounts' enclosed in the 'Simplified Presentation' form in Annex VI for the last year for which accounts have been closed. Alternatively, the tenderers may fill in only the fields marked in bold and the ones marked in italics. All amounts must be expressed in Euro using the conversion rate of the month of the publication of the tender.

On the basis of the data from the 'Simplified Presentation' form in Annex VI, a number of values and ratios will be calculated in order to evaluate the economic and financial capacity of the tenderers.

The following values will be calculated:

Value	**Formula/source**	**Unfavourable if:**
own funds	from the balance sheet	negative
	own funds - paid-up capital	negative
working capital	permanent capital - fixed assets	negative
gross operating surplus	from the P&L accounts	negative
net result	from the P&L accounts	negative
self-financing capacity (SFC)	net result after tax + amortization – capitalized production	negative

Following ratios are calculated:

Ratio	**Formula**	**Unfavourable if**	**Average if**	**Favourable if**
general liquidity	current assets/short-term debts	below 1	between 1 and 1.25	Above 1.25
financial independence	own funds/total liabilities	below 0.20	between 0.20 and 0.40	above 0.40
indebtedness	own funds/medium & long-term debts (MLT)	below 0.30	between 0.30 and 0.60	above 0.60

coverage of deposits and borrowed funds by the SFC	SFC / MLT debts	below 0.25	between 0.25 and 0.50	above 0.50
profitability	gross operating surplus / turnover	below 0.10	between 0.10 and 0.20	above 0.20

Each type of evaluation has a corresponding scoring (number of points) as follows:

Scoring	
Unfavourable value/ratio	0 points
Favourable value	1 point
Average ratio	1 point
Favourable ratio	2 points

If, for some exceptional reason which the contracting authority considers justified, the tenderer or candidate is unable to provide the references requested by the contracting authority, or if he feels that the financial viability check does not provide an accurate picture of his organisation's financial status, he may prove his economic and financial capacity by any other means which the Commission considers appropriate.

5.5. Technical and professional capacity criteria and evidence

5.5.1. Criteria relating to tenderers

Tenderers (in case of a joint tender the combined capacity of all members of the group and identified subcontractors) must comply with the criteria listed below. The evidence must be provided only on request.

The project references indicated below consist in a list of relevant services provided in the last five years, with the sums, dates and clients, public or private, accompanied by statements issued by the clients.

The tenderer must prove the fulfilment of the following criterion and provide the requested evidences for each criterion:

- **Criterion A1**: highly specialised experience in the methodologies, development, appraisal, implementation and dissemination of CPGs and other possible CDSTs

  Evidence A1: references of 5 projects delivered in these fields in the last five years including a list of publications and references.

- **Criterion A2:** experience in training, including e-learning/e-training production and dissemination.

  Evidence A2: references of 8 projects delivered in the fields of healthcare post-graduate education in the last five years.

- **Criterion A3**: experience on systematic review of evidence

  Evidence A3: references of 10 projects delivered in the field of healthcare in the last five years.

- **Criterion A4**: demonstrated knowledge and experience in leading and in project management and administration of EU wide projects involving highly specialised healthcare providers.

  Evidence A4: references of 3 projects delivered in the field of healthcare involving at least 10 EU countries in the last five years.

- **Criterion A5:** experience and capacity in the organisation and management of workshops and physical meetings across EU cities outside their venue including a) technical and expert capacities related to the content, dynamic and outcomes production of the meetings b) logistics (travel, accommodation , meeting spaces selection and contracting, catering, It tools provision, facilitation, etc.)

  Evidence A5: references of 3 projects delivered in these fields, in the in the last five years.

- **Criterion A6**: solid knowledge of the EU healthcare systems organisation and functioning and in particular in the area of highly specialised healthcare.

  Evidence A6: references of 5 projects delivered in these fields in the last five years including a list of publications and references.

- **Criterion A7**: experience in the use of standard tools for the development and appraisal of clinical guidelines, including GRADE and AGREE methodologies.

  Evidence A7: the tenderer must provide references of 5 projects delivered in these fields in the last five years.

- **Criterion A8**: experience in the work and creation of multidisciplinary working or experts groups including highly specialised providers, scientific societies, patients' organisations and other stakeholders.

  Evidence A8: the tenderer must provide references of 3 projects delivered in these fields in the last five years.

- **Criterion A9:** capacity of working and writing in English

  Evidence A9: the tenderer must provide one document of at least 10 pages (report, study, etc.) in this language that it has drafted and published or delivered to a client in the last two years. The verification will be carried out on 5 pages of the document.

5.5.2. Criteria relating to the team delivering the service:

The team delivering the service shall include, as a minimum, the following profiles.

Evidence will consist in CVs of the team responsible to deliver the service. Each CV must indicate the intended function in the delivery of the service. The detail of experience shall indicate the beginning and end dates of each appointment.

B1 - Project Manager: At least 7 years' experience in project management, including overseeing project delivery, quality control of delivered service, client orientation and conflict resolution experience in project of a similar size (minimum € 400.000). At least C1 level in the Common European Framework for Reference for Languages in English.

Evidence: CV

B2 - Team leader: a team leader shall be assigned to each work package team and must have:

- a university degree on public health or public administration specialised in healthcare administration, planning, education or training.
- at least 6 years of relevant professional experience in the field of health with relevance to healthcare planning, management and evaluation.
- at least 4 years' experience in managing multidisciplinary teams and working in liaison with healthcare professionals, healthcare managers, and other related stakeholders.
- At least C1 level in the Common European Framework for Reference for Languages[26] in English.

B3 team members: the tenderer shall have the capacity to put together a multidisciplinary team of at least 6 members including the following professional's profiles:

- 2 members with a university degree in medicine or related area of activity, with postgraduate education/ training in the methodologies, development, appraisal, implementation and dissemination of CPGss and other related CDSTs and at least 5 years professional experience in the field and in the review and production of technical, scientific and methodological articles or documents.
- 2 members with a university degree in medicine or related area of activity, with at least 4 years of professional experience in the performance of systematic reviews of scientific literature, Cochran collaboration methodology and analysis and retrieval of evidence.
- 2 members with a university degree in medicine or related area of activity and at least 4 years professional experience in healthcare post-graduate training and tele-training (e-training/e-learning)
- 2 members with a university degree in healthcare , public health , public administration or management or related professions, with at least 4 years of relevant professional experience in liaising with healthcare professionals and organisations, bodies or agencies dealing with healthcare, healthcare management, and professional experience in the use of qualitative technics for the management of experts groups and panels.

[26] See http://www.coe.int/t/dg4/linguistic/Cadre1_en.asp

- 2 members with university degree in medicine, epidemiology, public health or related areas of activity with at least 4 years' experience in the area of rare or low prevalence complex diseases.

Evidence: CV

It is possible that one team member fulfils several of the profiles in B3.

B4 - Language quality check: all the members of the team shall have at least C1 level in the Common European Framework for Reference for Languages [1] in English.

Evidence: CV and a language certificate or past relevant experience.

5.6. Award criteria

The contract will be awarded based on the most economically advantageous tender, according to the 'best price-quality ratio' award method. The quality of the tender will be evaluated based on the following criteria. The maximum total quality score is 100 points.

- **QC1: Quality of the proposed methodology** (45 points - – minimum score 60%)
  - Sub-criterion 1.1: Methodology for the creation of and support to the Advisory Body and Expert panels on CPGs and CDSTs. (15 points – minimum score 50%):
  - Sub-criterion 1.2: Methodology for the development, appraisal and implementation of CPGs and CDSTs. (15 points – minimum score 50%)
  - Sub-criterion 1.3: Methodology for the production of the Training Programme on CPGs and CDSTs (15 points – minimum score 50%)

  Tenderer should describe in their tender their methodological approach regarding the required services regarding the CPGs and CDSTs. These sub-criteria will assess the clarity, logic and adequacy of the methodologies. It will be assessed in particular whether the methodological approach is based on the state of art and on the recommendations issued by the leading international organisations in the field of CPG and CDST.

- **QC2: Quality of the planning of the general guidance and of the support actions** to the ERNs and their healthcare providers in the effective development and appraisal of CPGs and CDSTs: (25 points – minimum score 50%)

  This criterion will assess how the guidance and support actions will be carried out by the tenderer in terms of timing, allocation of resources, definition of standard operating procedures and efficiency during the implementation of the contract. It will be considered in particular the quality control, risk management and contingency plan proposed methods and plans to identify and correct potential operational inefficiencies.

- **QC3: Organisation of the work and resources** (20 points – minimum score 50%)

This criterion will assess how the roles and responsibilities of the proposed team and of the different economic operators (in case of joint tenders, including subcontractors if applicable) are distributed for each task. It also assesses the global allocation of time and resources to the project and to each task or deliverable, and whether this allocation is adequate for the work. The tender should provide a detailed table on the allocation of time and human resources per task and the rationale behind the choice of this allocation. Details should be provided as part of the technical offer. It is not a budget requested as part of the financial offer.

- **QC4: Quality control measures** (10 points – minimum score 60%)

  This criterion will assess the quality control system applied to the service foreseen in this tender specification concerning the quality of the deliverables, the language quality check, and continuity of the service in case of absence of the member of the team. The quality system should be detailed in the tender and specific to the tasks at hand; a generic quality system will result in a low score.

Tenders must score minimum 60% for QC1 and QC4, minimum 50% for QC2 and QC3, and minimum 60% in total. Tenders that do not reach the minimum quality levels will be rejected and will not be ranked.

5.6.1. Ranking of tenders

The contract will be awarded to the most economically advantageous tender, i.e. the tender offering the best price-quality ratio determined in accordance with the formula below. A weight of 60/40 is given to quality and price.

score for tender X	=	$\frac{\text{cheapest price}}{\text{price of tender X}}$	*	100	*	40 %	+	total quality score (out of 100) for all award criteria of tender X	*	60 %

The tender ranked first after applying the formula will be awarded the contract.

FINANCIAL PART

Prices must be presented in the standard format of annex V.

ANNEXES:

Annex I - Tender submission form

Annex II - Declaration on honour

Annex III - Power of attorney

Annex IV - Letter of intent from subcontractor

Annex V - Budget

Annex VI - Simplified financial statements

Annex VII - Contract and annexes: Draft Contract

Annex VIII - Financial Identification form

http://ec.europa.eu/budget/contracts_grants/info_contracts/index_en.cfm

Annex IX - Legal identification:
Privacy Statement

Legal Entity form - Private Company