SENSITIVE NON-CLASSIFIED

Call for tenders HaDEA/2023/OP/0038 Study on the quality of life of cancer patients and survivors

Open procedure

TENDER SPECIFICATIONS

based on EU4Health Work Programme 2023 topic CR-p-23-43

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1. SCOPE AND DESCRIPTION OF THE PROCUREMENT

1.1. Contracting authority: who is the buyer?

This call for tenders is launched and managed by the European Health and Digital Executive Agency (henceforth "HaDEA"), referred to as the contracting authority for the purposes of this call for tenders.

HaDEA, acting under the powers delegated by the European Commission (henceforth "the Commission"), is launching the present invitation to tender for the conclusion of a service contract (henceforth "the contract").

HaDEA was established on 16 February 2021. HaDEA implements parts of the following Union programmes:

- e. EU4Health Programme
- b. Single Market Programme: Food safety
- c. Horizon Europe, Pillar II, cluster 1: Health
- d. Connecting Europe Facility: Digital
- f. Digital Europe Programme
- f. Horizon Europe, Pillar II, cluster 4: Digital, industry and space

The Agency is entrusted by the Commission with programme implementation tasks and works closely with the Directorate-General for Communications Networks, Content and Technology; Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs; Directorate-General for Research and Innovation; Directorate-General for Defence Industry and Space and Directorate-General for Health and Food Safety and Directorate-General for Health Emergency Preparedness and Response.

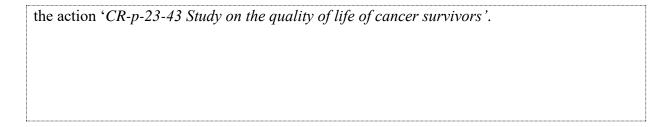
The EU4Health programme (2021-2027)1 is the main financial instrument supporting the Member States' efforts in the implementation of Healthier Together initiative aimed at addressing non-communicable diseases, including those related to mental health. One of the objectives of the EU4Health Programme is to improve and foster health in the EU to reduce the burden of communicable and non-communicable diseases, by supporting health promotion and disease prevention, by reducing health inequalities, by fostering healthy lifestyles and by promoting access to healthcare. The EU4Health programme, which has a budget of EUR 5.3 billion for the period 2021-27, has foreseen the reservation of a minimum of 20% of the total EU4Health budget to addressing health promotion and disease prevention, including in the field of mental health.

In this context, the activities to be implemented under this call for tenders were included in the EU4Health 2023 Work Programme, adopted on 21 November 20222 - in particular under its section 3.1 Prevention of Cancer, Cancer Screening and Quality of Life of Survivors and

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¹ EUR-Lex - 32021R0522 - EN - EUR-Lex (europa.eu).

² https://health.ec.europa.eu/publications/2023-eu4health-work-programme en.



1.2. Subject: what is this call for tenders about?

The subject of this call for tenders is to conduct a study across all 27 EU Member States, Iceland and Norway, to identify common indicators for data collection across those countries that can be used to measure the progress on Quality of Life level of cancer patients' and survivors'.

On the basis of the identified indicators and evidence collected, the study will document and analyse the major inequalities detected across countries concerning the Quality of Life of cancer patients and survivors and how those inequalities are addressed.

Recommendations developed by the contractor will be directed at Member States, Iceland and Norway with the relevant strategies for improving the Quality of Life of cancer patients and survivors, for reducing inequalities across countries and for improving data collection.

For the purposes of this call for tenders, 'cancer patients' and 'cancer survivors' are defined as 'people with a history of cancer'.

1.3. Lots: is this call for tenders divided into lots?

This call for tenders is not divided into lots.

1.4. Description: what do we want to buy through this call for tenders?

The purchases that are the subject of this call for tenders, including any minimum requirements, are described in detail below.

Variants (alternatives to the model solution described in the tender specifications) are not allowed. The contracting authority will disregard any variants described in a tender.

1.4.1. Background and objectives

The EU4Health programme, established by Regulation (EU) 2021/522, was adopted on 24 March 2021, as a response to the COVID-19 crisis and to pave the way to a European Health Union by investing in health priorities, such as beating cancer. The EU4Health 2023 work programme³ (EU4Health WP 2023) which was adopted on 21 November 2022, focuses on

³https://health.ec.europa.eu/publications/2023-eu4health-work-programme_en_

crisis preparedness, disease prevention, stronger health systems and healthcare workforce and digital, with cancer as a cross-cutting priority.

As part of the EU4Health WP 2023, the action CR-p-23-43 'Study on the quality of life of cancer survivors' is expected to assess the existence and availability of data as well as initiatives implemented by EU Member States, Iceland and Norway to improve the quality of life of cancer survivors. There is a lack of evidence on differences and disparities in the quality of life of cancer survivors between EU Member States and regions (including Iceland and Norway). This action will aim to close this gap by triangulating data from different sources.

This topic supports one of the aims of <u>Europe's Beating Cancer Plan</u>⁴, namely to improve the quality of life of cancer patients and survivors. The Plan's 'Quality of life' pillar has ambitious actions to help ensuring that they live long, fulfilling lives, free from discrimination and subsequent obstacles.

Quality of Life is defined by WHO as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"5. Quality of Life measurement is highly challenging. It is a subjective measure, based on an individual's perception, which causes problems with establishing unambiguous definitions of this phenomenon and obtaining unequivocal results. Furthermore, in the context of disease, needs of patients from different age groups differ, which makes it impossible to create one, unified tool for measurement. When considering the quality of life of patients and survivors, one should consider not only health-related Quality of Life (HRQoL) indicators, such as self-perceived physical and mental health status and individuals' experiences of disease manifestations. Patients' quality of life is also indirectly affected by features such as appropriate access to treatment and care, properly educated health care workers, equal access to psychosocial support and educational programmes, equal treatment on the labour market, equal access to healthy and appropriate food requirements, etc. Considering these factors, it is truly challenging to establish clear recommendations on the aspects to be measured in a standardised process of Quality of Life assessment. These gaps lead to lack of unified indicators able to compare Quality of Life of patients in different countries. In addition, without clearly defined indicators, it is impossible to detect and eliminate inequalities among countries. Overall, there is a need for standard and common indicators for data collection to appropriately measure Quality of Life.

In the field of cancer, along with the development of advanced methods of diagnosis, prevention and treatment used in oncology, the number of cancer survivors increases year by year. This fortunate development raises the issue of measuring, in addition to Quality of Life for cancer patients, the Quality of Life of cancer survivors.

⁴https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union/cancer-plan-europe en

⁵ https://iris.who.int/bitstream/handle/10665/77932/WHO_HIS_HSI_Rev.2012.03_eng.pdf?sequence=1

At EU level, a number of ongoing projects under Horizon Europe⁶ programme currently address the challenge of measuring and improving Quality of Life of cancer patients and survivors, namely 'EUonQuality of Life⁷', 'PREFERABLE-II⁸', 'MyPal⁹', and 'PanCareFollowUp¹⁰'. In addition, under the EU4Health programme, the on-going actions aiming to improve the quality of life of cancer patients and survivors are the following: the Work Programme (WP) 2021 DP-p-11.1 'Cross-cutting cancer actions: improving the quality of life for cancer patients, survivors and carers, including the reduction of inequalities in cancer care and childhood cancers'¹¹, the related WP 2021 DP/C-g-11.1.1 'Call for proposals: action grants to create a 'Cancer Survivor Smart Card', and the WP 2022 action CR-p-22-11.01 'Study on obstacles for cancer survivors to return to work'. The latter focuses on identifying gaps and challenges related to the return to work of cancer survivors and reducing inequalities in employment and social protection policies.

At International level, the OECD's Patient-Reported Indicator Surveys initiative (PaRIS)¹² aims to develop and implement a new generation of indicators that measure the outcomes and experiences of healthcare. As part of the initiative, the 'International Survey of People Living with Chronic Conditions'¹³ is the first of its kind to assess the outcomes and experiences of patients managed in primary care across countries, in relation to access to healthcare and waiting times, as well as quality of life, pain, physical functioning and psychological well-being.

To complement this on-going body of work, the objective of the present study is to better understand how to measure, monitor and improve management of cancer patients' and survivors' Quality of Life in a systemic way, using objective indicators and data gathered from public and private, international, national, and sub-national sources. In addition to the factors related to patients' physical and emotional needs, the study will also cover factors at social and health system level, which indirectly impact quality of life and for which data are scattered and incomplete. These may include, but not limited to, the level of education and

⁶ https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/horizon-europe_en

⁷ Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe

⁸ Personalised Exercise-Oncology for improvement of supportive care: a super umbrella trial to demonstrate the (cost)effectiveness of live-remote exercise in cancer survivors

⁹ MyPal: Fostering Palliative Care of Adults and Children with Cancer through Advanced Patient Reported Outcome Systems

PanCareFollowUp: Novel, patient-centred survivorship care to improve care quality, effectiveness, costeffectiveness and accessibility for survivors and caregivers

¹¹ Service contract for the supply of a software to develop an IT tool for a 'Cancer Survivor Smart Card'

¹²https://search.oecd.org/health/paris/#:~:text=PaRIS%20is%20the%20OECD%E2%80%99s%20Patient-Reported%20Indicator%20Surveys%20initiative,experiences%20of%20healthcare%20that%20matter%20most%20to%20people.

¹³ https://www.oecd.org/health/health-systems/PaRIS-survey-Patients-with-Chronic-Conditions-June-2019.pdf

awareness of healthcare workers and patients; access to specialists and specialistic infrastructure; access to psychological support for patients and survivors, their families and healthcare workers; the amount of funds dedicated to psycho-social support; programmes and protocols facilitating access to social, educational sport activities; legal rules and administrative procedures for long-term sick leave and return to work. The study will also provide clear recommendations on which direct and indirect factors are the most meaningful in Quality of Life management.

To this end, the study will be conducted across all 27 EU Member States, Iceland and Norway, in order to explore and understand parameters/factors (other than subjective patients' observations) which can contribute to measuring cancer patients' and survivors' Quality of Life. A preliminary data collection on Quality of Life of cancer patients and survivors will be conducted in all EU27 Member States, Iceland and Norway. Based on the assessment and comparison of existing data collected at national level, the study will identify common indicators that can be used to collect data and measure Quality of Life. On the basis of the identified indicators, information and data will be gathered and data gaps will be closed with the help of extrapolation and projection techniques. The study will also document and analytically discuss the major inequalities detected across countries concerning the Quality of Life of cancer patients and survivors and how these inequalities are addressed. The contractor will develop recommendations directed at Member States, Iceland and Norway on strategies for improving the Quality of Life of cancer patients and survivors, for reducing inequalities across countries and for improving data collection.

1.4.2. Detailed characteristics of the purchase

The following tasks shall be carried out by the contractor:

<u>Task 1 (M1 – M4): Desk research and data mapping on cancer patients' and survivors'</u> <u>Quality of Life</u>

Sub-task 1.1: Desk research

As a first step the contractor will conduct a critical review of existing sources and literature to identify which factors are typically included in the measurement of the Quality of Life of cancer patients and survivors in EU Members States, Iceland and Norway. To ensure in-depth analysis of the topic, the contractor shall focus on following issues:

- 1. *Differences in definition* of Quality of Life of cancer patients and survivors among countries.
- 2. *Differences in terminology* (e.g. health status, health-related Quality of Life (HRQoLife), and Quality of Life (QoL) and *in methodologies* (various forms, stages of the disease, main age groups, national authorities involved in Quality of Life data collection). The contractor should also analyse how these differences are reflected in terms of the indicators used to measure Quality of Life.
- 3. *Different perspectives* which may indirectly have an impact on Quality of Life. In these terms, the thematic areas of interest should be focused mainly, but not limited to:
 - a. Patients and survivors perspective, i.e., self-perceived health status, access to treatment, rehabilitation programmes, psychological support, comorbidities, palliative care, educational programmes for cancer patients, cancer survivors and their families.

- b. Healthcare workers' perspective, i.e., professions which are included in multidisciplinary teams providing care of cancer survivors, access to educational programmes, years spent on specialisation, cross-cutting specialisations.
- c. Socio-economic perspective, i.e., education, marital status, place of residence, employment status, wealth, financial support programmes for cancer survivors.
- d. Infrastructure availability, i.e., specialised clinics, rehabilitation centres, disability-related facilities.

The contractor shall furthermore seek to consider a wide range of areas in which cancer patients and survivors could experience discrimination or unequal treatment, e.g., access to financial services (e.g. loans and mortgages, insurances), access to certain occupational profiles, career progression or work-related benefits, etc. The contractor will also draw on the (preliminary) results of relevant ongoing studies at European and International level, such as the EUonQuality of Life study.

The contractor will summarise the results of this review in a report describing factors, which have direct and indirect impact on quality of life of cancer patients and survivors. For each identified thematic area, the contractor should propose indicators that are, or could be, collected at national level, and where possible regional level, to measure Quality of Life. These could include, but not limited to, the following indicators on which administrative data are or could be available, which could be presented in a statistical and comparable manner:

- the number of support services offered relative to the number of patients;
- financial incentives for participation in support programmes;
- cost recognition;
- measures for labour market re-integration;
- legal protection mechanisms to prevent unemployment;
- re-qualification programmes.

The contractor shall list in the report relevant indicators usually used and recommended in literature to assess Quality of Life in each of detected thematic areas.

Deliverable 1.1 (D1.1):

Report on literature review on existing indicators and data sets for cancer patients' and survivors' Quality of Life measurement

As a part of their tender, tenderers shall propose a methodology for conducting desk research and literature review, relevant for performing Task 1. Such methodology should highlight sources of information and thematic areas, which will be included in the study.

Sub-task 1.2: Data mapping exercise at country level

The contractor will conduct a data mapping exercise across all 27 EU Member States, Iceland and Norway, to identify already existing datasets which collect data on Quality of Life of cancer patients and survivors, and the relevant authorities/institutions at national and subnational level responsible for such data collection.. The contractor shall provide an overview of the available indicators and highlight the gaps and differences of the data collected across countries. Specific focus should be taken to reveal if there are any thematic areas, identified in sub-task 1.1, that are omitted by Member States, Iceland and Norway in measurements of

Quality of Life of cancer patients and survivors, and analyse potential reasons for this exclusion. Where possible, the contractor will also assess the completeness, quality, and interoperability of the identified datasets.

The contractor will present a report summarising the methodology and results of this assessment, accompanied by individual "country fiches" for each EU-27 Member State, Iceland and Norway. The report shall include a comparison of thematic areas and indicators used in Member States, Iceland and Norway to measure Quality of Life of cancer patients and survivors, as well as the identified data gaps and differences in data collection methods across countries. It shall include the following sections: Executive summary; Methodological Approach; Desk research; Analysis of existing data; Comparison between countries; Conclusions; Annex 1: Country fiches; further Annexes. The country fiches will provide an overview of data sources and indicators, as well as summary information on gaps, completeness, quality and interoperability of the data for each country. They shall include the following sections: Data sources; Thematic areas and indicators; Characteristics of the dataset.

Deliverable 1.2 (D1.2):

a) Report on the assessment and comparison of national data sources and indicators for measuring cancer patients' and survivors' Quality of Life and accompanying "country fiches"
b) Analysis on potential Data Protection Impact Assessment (DPIA) requirement under EU Data Protection Regulation (hereafter EU DPR¹⁴)

As a part of their tender, tenderers shall present a methodology for conducting a data mapping exercise relevant for completing Task 1.2. Such methodology should also describe how the completeness, quality, and interoperability of the identified datasets will be assessed and provide suggestions for improving interoperability and addressing data gaps, which will be included in the report (D1.2a).

<u>Task 2 (M5 – M8): Stakeholder consultation to identify existing needs in Quality of Life</u> measurement

Sub-task 2.1: Stakeholder mapping

The contractor will conduct a mapping exercise in order to draw up a list of national key stakeholders involved in managing the quality of life of cancer patients and survivors and participating in the development of comprehensive indicators for Quality of Life measurement. The contractor should choose stakeholders, who collect data, as well as those who do not provide their own measurements and statistical data on Quality of Life. Examples of relevant bodies and fields of expertise on which the contractor should focus are: public health authorities, patients and survivors organisations, national oncological institutes and /or societies, specialised cancer centres or healthcare structures providing oncological care, associations of health professionals, trade unions and any other relevant organisations with

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.

knowledge and experience on the topic of cancer patients' and survivors' needs. The contractor shall make every effort to identify the widest possible group of stakeholders in each of the EU countries, Norway and Iceland.

Deliverable 2.1 (D2.1):

Report on stakeholder mapping

Sub-task 2.2: Stakeholder consultation

Based on D1.1, D1.2 and D2.1, the contractor will carry out stakeholder consultations in the form of targeted interviews and focus groups with selected stakeholders. The aim of the consultations will be to understand the key challenges, needs and current practices in measuring Quality of Life, and the results should contribute to the establishment of a list of relevant indicators for measuring the Quality of Life of cancer patients and survivors.

The contractor shall prepare a methodology for conducting the interviews and focus groups, which will include the sampling strategy, the number of stakeholders (minimum 50) who will be interviewed, an interview guide with a list of questions divided into thematic areas and instructions on how to lead the interviews, relevant information for respondents, and methods of data analysis.

The analysis of structured interviews and focus groups should result in drafting a broad list of potential indicators, which could be included in Quality of Life measurement. Indicators shall be divided into thematic sections, understandable to a lay audience. Similarly to the outcomes of Task 1, identified areas and potential indicators should be indirectly linked to Quality of Life, and shall broaden and complement state-of-art established through desk research and literature review.

The results of the stakeholder consultations shall be presented in a report, summarizing the interviews and focus group meetings conducted, the number of participants from each country and stakeholder group identified, the methodology adopted for the consultations, as well as the key thematic areas and challenges discussed by the participants with regards to measuring Quality of Life for cancer patients and survivors. The report should also present a list of indicators for Quality of Life measurements, as suggested by stakeholders, with an explanation of how the results from the interviews and focus groups discussion have contributed to their selection.

Deliverable 2.2 (D2.2):

- a) Final Data Protection Notice (DPN) for stakeholder consultation on cancer patients' and survivors' Quality of Life measurement
- b) Report on stakeholder consultations for cancer patients' and survivors' Quality of Life measurement

As part of their tender, tenderers shall propose a methodology for mapping relevant stakeholders and conducting stakeholder consultations, a methodology for development of questionnaires for interviews and focus groups (incl. preliminary list of questions), and suggested thematic areas, sampling strategy and other tools, as described in Task 2.

<u>Task 3 (M9 – M12): Development of a common set of indicators for data collection on cancer patients' and survivors' Quality of Life across EU27, Norway and Iceland</u>

Sub-task 3.1: Preliminary list of indicators

The aim of this task is to compile a preliminary set of common indicators for Quality of Life measurement across the EU27, Iceland and Norway. On the basis of the results obtained in Task 1 and Task 2, the contractor will combine indicators identified from the literature review and data mapping (D1.1, D1.2), and those pointed out by stakeholder consultation (D2.2).

To do so the contractor shall assess and evaluate the different approaches used in European countries, compare methodologies and meta-data and come forward with a proposal for data integration leading to a common indicator. The contractor shall first indicate an initial proposal for prioritisation and make suggestions for omitting, re-wording, combining or splitting certain indicators identified in Tasks 1 and 2. As a result, the contractor shall make a proposal for a preliminary, maximally comprehensive list of relevant unified indicators (minimum 30) ordered by thematic focus area identified.

Deliverable 3.1 (D3.1):

Preliminary list of common indicators set for Quality of Life measurement across EU 27, Norway and Iceland

As a part of their tender, tenderers shall present a methodology for developing and integrating a common set of indicators for Quality of Life measurement, taking into account the outcomes of D1.1, D1.2 and D2.2.

Subtask 3.2: Stakeholder validation survey to define consolidated set of indicators

The aim of this step is to seek stakeholder feedback and validation on the preliminary indicator list (D3.1) as well as to define a consolidated set of at least 8, at most 30 indicators, which, according to the assessment of stakeholders and national representatives are the most relevant to measure and monitor the Quality of Life of cancer patients and survivors. To obtain that, the contractor will develop a validation survey, together with a methodology for its administration and roll out, to seek the feedback of stakeholders and Member States, plus Iceland and Norway representatives.

The survey should be conducted in all EU Member States, Iceland and Norway. The contractor will ensure to receive at least one response from a relevant public authority at national level, such as Health or Research ministries or national health or research institutes, in each EU27 Member State, Iceland and Norway. This is to be complemented by a wide variety of responses across all other identified stakeholder groups and the minimum participation in the survey should reach 100 respondents. Respondents from the previous stakeholder consultation may be recontacted.

The contractor will analyse and assess participant responses and based on the results of the validation survey they will identify the set of consolidated indicators. These should cover various thematic areas, and according to what country representatives (EU27, Iceland and Norway) consider is most relevant and useful to compare data between countries.

Deliverable 3.2 (D3.2):

- a) Final DPN for stakeholder survey on cancer patients' and survivors' Quality of Life measurement
- b) Report on stakeholder validation survey for cancer patients' and survivors' Quality of Life measurement

c) The consolidated list of common indicators for cancer patients' and survivors' Quality of Life measurement

As a part of their tender, tenderers shall describe the methodology for survey questionnaire preparation (incl. preliminary list of questions), ways of communications to ensure proper number of responses, sampling strategy, survey piloting and roll-out, and other tools.

<u>Task 4 (M13 – M18): Data collection on the consolidated indicator set for EU 27, Norway and Iceland, including data extrapolation</u>

Sub-task 4.1: Methodology for data collection and closing data gaps

On the basis of D3.2 and the consolidated indicator set (D3.2b), the contractor shall outline the most appropriate methodology to be used for collection, extraction, and analysis of data on the consolidated indicator set for measuring Quality of Life. The methodology shall describe a strategy for reaching relevant national authorities involved in data collection and requesting access to national dataset (such as those identified in D1.2) where relevant, with a clear explanation of the objectives of the study. In case the datasets contain personal data, the contractor will ensure compliance with EU DPR and report to the contracting authority.

The contractor shall anticipate the major data gaps, based on those that have been identified through D1.1 and 1.2, and propose in the methodology to overcome the possible lack, or partial lack, of data for certain indicators and certain countries, as well as propose a strategy to address the lack of interoperability among the datasets identified. This methodology may include the use of alternative indicators or proxy measures of Quality of Life but for which data is more readily available; it may also include strategies for using such proxy measures to estimate the value of the target indicator. The methodology will lay out how different projection and extrapolation techniques can be used and are proposed to be used and combined to obtain estimates for indicators for which no data are available. Extrapolation should be carried out sensibly, to provide data as close as possible to the actual state of reality. In the description of the methodology the contractor should include an explanation of extrapolation criteria from one country to another, and estimation of risk of bias, while using the chosen methodology.

Deliverable 4.1 (D4.1):

Detailed methodology for data collection, generating estimates to close data gaps, and improve data interoperability for all EU27 Member States, Iceland and Norway

Sub-task 4.2: Data collection and extrapolation to close data gaps

On the basis of the methodology developed in D4.1, the contractor will request necessary authorisations from national authorities to access and collect all available data and combine them into a common database. The contractor shall aim to gain access to relevant data in at least 19 countries among EU Member States, Iceland, and Norway.

As a part of this task, the contractor will assess and ensure compliance with applicable data protection rules and provide information to the contracting authority. In particular, the contractor will ensure that the use of existing datasets constitutes a lawful use of personal data.

Then the contractor will apply the methodology developed in sub-task 4.1 to overcome the possible lack of data for certain indicators in certain countries. Appropriate projection and extrapolation techniques will be used to fill data gaps and, as a result, come up with sound estimates for all indicators and countries for which there is lack of data for the indicator set put forward in D3.2b.

Deliverable 4.2 (D4.2):

- a) Complete set of data collected for the consolidated indicator set measuring the Quality of Life of cancer patients and survivors in EU27, Iceland and Norway
- b) Aggregated common database, including information on compliance with data protection rules

As a part of their tender, tenderers shall present a methodology for data collection on the consolidated indicator set for measuring Quality of Life. Tenderers shall also present potential methods of gaps identification and closure, together with data extrapolation, as described in Task 4.1 and 4.2.

Task 5 (M19 – M24): Assessment of inequalities and development of recommendations

Based on an in-depth analysis and assessment of the data gathered and generated in Task 4 (data collection, aggregation, projection and extrapolation activities), the contractor will document and analytically discuss the major inequalities between EU Member States, Iceland and Norway concerning the Quality of Life of cancer patients and survivors and how these inequalities are addressed. On the basis of the evidence collected, the contractor will also develop recommendations directed at Member States, Iceland and Norway authorities on strategies for improving the Quality of Life of cancer patients and survivors, reducing inequalities across countries and improving data collection. To do so the contractor will develop two separate reports, one on the inequalities and one on the recommendations, to be published.

29 Country Factsheets (publishable) – for each EU27 Member State, Iceland and Norway – will be produced by the contractor, providing a detailed narrative description of the situation in each country, based on an in-depth analysis and assessment of the data gathered and generated in Task 4. In addition, an outline of the strengths and areas for development will be provided for each country, as well as related recommendations.

Deliverable 5.1:

Report on assessment of inequalities in cancer patients' and survivors' Quality of Life in EU27, Iceland and Norway

Deliverable 5.2:

Report on developed recommendations for EU 27 Member States, Iceland and Norway on strategies for improving the Quality of Life of cancer patients and survivors, reducing inequalities across countries and improving data collection

Deliverable 5.3:

Publishable Country Factsheets for each EU27 Member State, Iceland and Norway, highlighting cancer patients' and survivors' Quality of Life, areas for development and related recommendations.

As a part of their tender, tenderers shall present a methodology for analysis of the data gathered in Task 4. The methodology shall also outline how the contractor will identify and assess inequalities in Quality of Life measurement in EU27, Iceland and Norway, as well as how recommendations targeted at national authorities to address inequalities and improve data collection will be developed.

Timeframe overview

The outputs relating to the above-described tasks should be delivered according to the following timeline:

Month	Activity/Deliverables/Meetings	
M1	Kick-off meeting	
M1/M2	Draft Inception report	
M2	Inception meeting	
M2	Inception Report	
	Draft DPNs for stakeholders' consultations (sub-tasks 2.2 and 3.2)	
M3	Draft analysis on potential DPIA requirement	
IVIS	D1.1: Literature review on existing indicators and data sets for cancer patients' and survivors' Quality of Life measurement	
M4	 D1.2a: Report on the assessment and comparison of national data sources and indicators for measuring cancer patients' and survivors' Quality of Life and accompanying "country fiches" D1.2b: Analysis on potential Data Protection Impact Assessment (DPIA) requirement under EU Data Protection Regulation 	
M6	D2.1: Report on stakeholder mapping	
M8	D2.2a: Final DPN for stakeholder consultation on cancer patients' and survivors' Quality of Life measurement D2.2b: Report on stakeholder consultations for cancer patients' and survivors' Quality of Life measurement	
M10	D3.1: Preliminary list of common indicators set for Quality of Life measurement across EU 27, Norway and Iceland	
M10	First Interim Progress Report (incl. D1.1; D1.2a; D1.2b; D2.1; D2.2a; D2.2b; D3.1)	
M10	First Interim meeting	
M12	D3.2a: Final DPN for stakeholder survey on cancer patients' and survivors' Quality of Life measurement D3.2b: Report on stakeholder validation survey for cancer patients' and survivors' Quality of Life measurement D3.2c: The consolidated list of common indicators for cancer patients' and survivors' Quality of Life measurement	
M13	D4.1: Detailed methodology for data collection, generating estimates to	

	close data gaps, and improve data interoperability for all EU27 Member States, Iceland and Norway	
M18	D4.2a: Complete set of data collected for the consolidated indicator set measuring the Quality of Life of cancer patients and survivors in EU27, Iceland and Norway D4.2b: Aggregated common database, including information on compliance with data protection rules	
M18	Second Interim Progress Report (incl. D3.2a; D3.2b; D3.2c; D4.1; D4.2a; D4.2b)	
M18	Second Interim meeting	
M20	D5.1: Report on assessment of inequalities in cancer patients' and survivors' Quality of Life in EU27, Iceland and Norway	
M22	D5.2: Report on developed recommendations for EU 27 Member States, Iceland and Norway on strategies for improving the Quality of Life of cancer patients and survivors, reducing inequalities across countries and improving data collection	
M23	D5.3: Publishable Country Factsheets for each EU27 Member State, Iceland and Norway, highlighting cancer patients' and survivors' Quality of Life, areas for development and related recommendations.	
M23	Final Progress report (incl. D5.1; D5.2; D5.3)	
M24	Final study report (publishable) on cancer patients' and survivors' Quality of Life in EU27, Iceland and Norway (with recommendations and Country Factsheets)	
M24	Final meeting	

Inception, progress and final **meetings** between the contractor and the Contracting Authority and the Commission will take place at each stage of reporting, either in Brussels/Luxembourg, or via videoconference. The contractor will prepare a draft agenda ahead of the meetings and will produce minutes that will be shared with the Contracting Authority and the Commission five days after the meetings at the latest.

The contractor shall organise a **kick-off meeting** with the contracting authority and the Commission within two weeks after signature of the contract to communicate a clear understanding of the terms of the service contract. This meeting shall review and clarify:

- the study's background, objectives, scope, approach and methodology;
- the tasks, deliverables, and timeline.

After the kick-off meeting, the contractor shall submit to the contracting authority a draft Inception Report to discuss during the Inception meeting foreseen to take place during M2 of the contract. The purpose of the Inception meeting is to discuss and fine-tune all aspects concerning the execution of the service, documented in the draft Inception report, containing the methodology, the exact planning and timeline, as well as the stakeholder consultation process. The contractor will deliver the final Inception report within 2 weeks after the Inception meeting, taking into account the comments/suggestions made at the Inception meeting.

Confidentiality

For the purpose of this contract any facts, information, knowledge, documents, data or other matters which may have been communicated to or obtained by the contractor in the context of the Contract shall be deemed confidential per se even after the completion of the tasks.

Data protection

Specific technical security measures for processing special categories of data (e.g. use of pseudonymisation when processing health data, encryption, etc.) will be used.

As part of their tender, tenderers are requested to provide:

- The mapping of all actors involved in the processing of personal data (including subcontractors identified in the offer or not);
- The mapping of data processing activities
- Proposed measures for ensuring that the service delivery will be compliant
 with the data protection rules, principles and obligations. The description shall
 reflect specific data processing tasks identified within the above mentioned
 mapping exercise and will also include a description of the proposed technical
 security measures for personal data processing.

Please refer to Criterion 3 in the award criteria, see section 3.4.

Intellectual property rights

Compliance with copyright law and other intellectual property legislation is of utmost importance for the contracting authority. When providing the services, the contractor has to ensure compliance with the applicable copyright and other intellectual property legislation. Tenderers should note that all copyright costs relating to the exploitation of copyright-protected material, which originates from third parties and not from the tenderer, shall be included in the pricing of this call for tender.

It is in the responsibility of the contractor to ensure that all copyright agreements are adhered to, related to the delivery of these services.

The contractor shall hold the contracting authority harmless and shall provide compensation in the event of any action, claim or proceeding brought against the contracting authority by a third party as a result of damage caused by the contractor in performance of the Contract, especially due to the fact that the contractor would not hold the rights and authorisations required under the contract to be concluded. In the event of any action brought by a third party against the contracting authority in connection with performance of the contract, the contractor shall assist the contracting authority.

1.4.3. Deliverables linked to payments

The two (2) interim progress reports, the final progress report and the final study report (cf. 'Final study report (publishable)') are linked to payments, according to the timeline specified in the recapitulative Table below. Progress reports shall contain a narrative part summarising the work carried out during the reporting period and the corresponding deliverables.

The Contractor shall ensure that all reports and deliverables under the contract are clear, concise, and comprehensive. All reports must be drafted in English using simple and non-technical language for a non-specialised audience. Technical explanations shall be given in annexes.

Electronic files must be provided in Microsoft® Word for Windows format and/or Excel format for any figures provided. Additionally, besides Microsoft® Word for Windows, the final study report must be delivered in Adobe ® Acrobat PDF format. All reports should have numbered points and pages and a clear identification, including:

- the contract number (not the call for tenders number);
- the version number;
- the status (draft, revision or final);
- the date.

This identification has to appear on the cover page and also in the header or in the footer.

The contractor shall submit the 1st Interim Progress Report to the contracting authority, accompanied with all respective deliverables, at the latest 10 months after the signature of the contract. Following the 1st interim meeting (month 10), the approval of this report by the contracting authority is linked to the 1st interim payment in Article I.5.3 of the contract.

The contractor shall submit the 2^{nd} Interim Progress Report to the contracting authority, accompanied with all respective deliverables, at the latest 18 months after signature of the contract. Following the 2^{nd} interim meeting (month 18), the approval of this report by the contracting authority is linked to the 2^{nd} interim payment in Article I.5.3 of the contract.

The contractor shall submit the **Final progress report** to the Contracting authority at the latest **23 months** after signature of the contract. The Final progress report shall describe all the work carried out under tasks 1-6 and the related outcome. In addition, it shall specify any deviations and changes from the initial time plan and any difficulties encountered. The Final progress report shall contain data on *performance indicators* (cf. 1.4.4).

The contractor shall submit the **Final study report (cf. 'Final study report (publishable)')** to the contracting authority at the latest **24 months** after signature of the contract. The Final study report shall give an overview of development and data collected on the complete indicator set for Quality of Life measurement of cancer patients and survivors in EU27, Iceland and Norway; present the assessment of the major inequalities between countries; and propose recommendations on strategies for improving the Quality of Life of cancer patients and survivors, reducing inequalities across countries and improving data collection. Country Factsheets will also be provided as Annex Following the **final meeting (month 24)**, the approval of the Final progress report and the Final study report by the contracting authority is linked to the **payment of balance (final payment)** in Article I.5.3 of the contract.

Recapitulative Table of deliverables / reports linked to payment upon submission

Month	Deliverable
M10	1st Interim progress Report (incl. D1.1; D1.2a; D1.2b; D2.1; D2.2a; D2.2b; D3.1)
	First Interim Meeting
	The approval by the contracting authority of the final version of the 1 st Interim Progress Report will lead to the 1 st Interim payment (30%).
M18	2 nd Interim progress Report (incl. D3.2a; D3.2b; D3.2c; D.4.1; D4.2a; D4.2b)
	Second Interim Meeting
	The approval by the contracting authority of the final version of the 2 nd Interim Progress Report will lead to the 2 nd Interim payment (30%).
M23	Final progress report (incl. D5.1; D5.2; D5.3)
M24	Final study report (with recommendations and Country Factsheets) (publishable)
	Final Meeting
	The approval by the contracting authority of the 'Final progress report' and the 'Final study report' will lead to a payment of the balance (40%).

Final study report (publishable)

The final study report must include:

- an abstract of no more than 200 words and an executive summary of maximum
 6 pages, both in English and French;
- specific identifiers which must be incorporated on the cover page provided by the contracting authority;
- the following disclaimer:

"This report was produced under the EU4Health Programme under a service contract with the European Health and Digital Executive Agency acting under the mandate from the European Commission. The information and views set out in this report are those of the author(s) and do not necessarily reflect the official opinion of the Commission / Executive Agency. The Commission/Executive Agency do not guarantee the accuracy of the data included in this study. Neither the Commission / Executive Agency nor any person acting on the Commission's / Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein."

The title of the final study report shall be:

'Final study report on cancer patients' and survivors' Quality of Life in EU27, Iceland and Norway (with recommendations)'.

In terms of content, the Final study report shall include, but not limited to:

- an overview of the development of the complete indicator set for Quality of Life measurement of cancer patients and survivors in EU27, Iceland and Norway;
- the assessment of the major inequalities between EU Member States, Iceland and Norway concerning the Quality of Life of cancer patients and survivors and how these inequalities are addressed;
- recommendations on strategies for improving the Quality of Life of cancer patients and survivors, reducing inequalities across countries and improving data collection.
- 29 Country Factsheets (as Annex), including a detailed narrative description of the situation, an outline of the strengths and areas for development, as well as related recommendations, for each EU27 Member State, Iceland and Norway.

Publishable executive summary

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

- specific identifiers which must be incorporated on the cover page provided by the contracting authority;
- the above-mentioned disclaimer.

Requirements for publication on Internet

The Commission/ Executive Agency 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 2.1 of the W3C as provided at: 01. Accessibility overview - WEBGUIDE - EC Public Wiki (europa.eu).

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 study, abstract and executive summary, the contractor must respect the W3C guidelines for accessible pdf documents as provided at: http://www.w3.org/WAI/.

Structure

All reports should have numbered paragraphs and pages and a clear identification, containing:

- the contract number (not the call number),
- the acronym,

- the version (draft, revision or final) and
- the date.

The reports and the deliverables shall be in English, unless otherwise indicated in these tender specifications.

Graphic requirements

The contractor must deliver the study 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. The graphic rules, the Manual and further information are available at:

http://ec.europa.eu/dgs/communication/services/visual identity/index en.htm

A simple Word template will be provided to the contractor after contract signature. The contractor must fill in the cover page in accordance with the instructions provided in the template. The use of templates for studies is exclusive to European Commission's/HaDEA's contractors. No template will be provided to tenderers while preparing their tenders.

1.4.4. Performance indicators

The contractor shall collect data on the following specific action-level indicators in their regular reporting activities, as listed in Table below.

The tenderers are required to include in their tender additional specific action-level indicators, which will be agreed with the contracting authority at the inception phase.

When deemed necessary to complement the above indicators, the Contracting authority will require, and agree with the contractor, to collect data for a maximum of three additional specific action-level indicators.

An overview of the data on performance indicators should be included in the **Final progress report**.

Task	Performance Indicators
Task 1	
Sub-task 1.1	Number of thematic areas which are taken into a consideration when Quality of Life is measured Number of indicators existing in the literature to measure Quality of Life of cancer patients and survivors
Task 2	
Sub-task 2.2	Number of stakeholders consulted, by country and by sector
Task 3	
Sub-task 3.2	Total number of responses from official representatives of public authorities (at least one from each country) and other stakeholders (at least 2). Total response rate on the survey from each Member State (plus Iceland and Norway)

	Number of consolidated indicators to measure cancer patients' and survivors Quality of Life
Task 4	
Sub-task 4.1	Number of authorities at national and, where applicable, regional level in each country, which collect chosen data Number of indicators for which data exist in each country
Sub-task 4.2	Number of unified indicators for data collection to measure Quality of Life
Task 5	
Sub-task 5.1	Number of national stakeholders from whom data were collected Number of identified major data gaps Number of extrapolation techniques used to obtain estimates for indicators for which data are lacking
Sub-task 5.2	Number of data sets acquired from each country
Task 6	Number of recommendations developed

1.5. Place of performance: where will the contract be performed?

The services will be performed at the following locations:

- the contractor's premises;
- the location(s) indicated under Section II.2.3 of the contract notice;
- for the purposes of the activities required (e.g. organisation of meetings), at any other location agreed with the contracting authority.

1.6. Nature of the contract: how will the contract be implemented?

The procedure will result in the conclusion of a direct contract.

In direct contracts all the terms governing the provision of the services, supplies or works are defined at the outset. Once signed, they can be implemented directly without any further contract procedures.

Tenderers need to take full account of the full set of procurement documents, including the provisions of the draft contract as the latter will define and govern the contractual relationship to be established between the contracting authority and the successful tenderer. Special attention is to be paid to the provisions specifying the rights and obligations of the contractor, in particular those on payments, performance of the contract, confidentiality, and checks and audits.

Please be aware that if a tenderer to whom the contract is awarded (any of the group members in case of a joint tender) has established debt(s) owed to the Union, the European Atomic Energy Community or an executive agency when the latter implements the Union budget, such debt(s) may be offset, in line with Articles 101(1) and 102 of Regulation (EU,

Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union (Financial Regulation)¹⁵ and the conditions set out in the draft contract, against any payment due under the contract. The contracting authority will verify the existence of overdue debts of the successful tenderer (any of the group members in case of a joint tender), and, if any such debt is found, will inform the tenderer (the group leader in case of a joint tender who will then have the obligation to inform all other group members before signing the contract) that the debt(s) may be offset against any payment under due the contract.

1.7. Volume and value of the contract: how much do we plan to buy?

The maximum total amount of all purchases under this call for tenders is indicated under Section 2.1.3 of the contract notice.

1.8. Duration of the contract: how long do we plan to use the contract?

The contract resulting from this call for tenders will be concluded for at most **24 months**. The details of the initial contract duration and possible renewals are set out in the draft contract.

1.9. Electronic exchange system: can exchanges under the contract be automated?

For all exchanges with the contractor during the implementation of the contract resulting from this call for tenders as well as for future possible subsequent proceedings, including, but not limited to, for the purposes of EDES (European Union's Early Detection and Exclusion System), the contracting authority may use an electronic exchange system meeting the requirements of Article 148 of the Financial Regulation. At the request of the contracting authority, the use of such a system shall become mandatory for the contractor at no additional cost for the contracting authority. Details on specifications, access, terms and conditions of use will be provided in advance.

¹⁵ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193 of 30.07.2018, p.1).

2. GENERAL INFORMATION ON TENDERING

2.1. Legal basis: what are the rules?

This call for tenders is governed by the provisions of the Financial Regulation.

The contracting authority has chosen to award the contract resulting from this call for tenders through an open procedure pursuant to Article 164(1) (a) of the Financial Regulation. In an open procedure any interested economic operator (any natural or legal person who offers to supply products, provide services or execute works) may submit a tender.

2.2. Entities subject to restrictive measures and rules on access to procurement: who may submit a tender?

Tenderers must ensure that no involved entities (see Section 2.4) nor any subcontractors, including those which do not need to be identified in the tender (see Section 2.4.2), are subject to <u>EU restrictive measures</u> adopted under Article 29 of the Treaty on the European Union (TEU) or Article 215 of the Treaty on the Functioning of the EU (TFEU)¹⁶, consisting of a prohibition to make available or transfer funds or economic resources or to provide financing or financial assistance to them directly or indirectly, or of an asset freeze. The prohibition applies throughout the whole performance of the contract.

Following the Council Implementing Decision (EU) 2022/2506, as of 16th December 2022, no legal commitments can be signed with Hungarian public interest trusts established under Hungarian Act IX of 2021 or any entity they maintain. This applies to all contractual level commitments, including subcontractors.

Participation in this call for tenders 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 provided that it has a special agreement with the European Union in the field of public procurement on the conditions laid down in that agreement.¹⁷

Under the EEA Agreement, economic operators established in Iceland, Norway and Liechtenstein have access to all procurement procedures of the EU executive agencies, subject to the limitations set out in Annex XVI.

Stabilisation and Association Agreements:

Under the Stabilisation and Association Agreements (SAA) economic operators established in North Macedonia, Albania, Montenegro, Serbia, Bosnia and Herzegovina and Kosovo have access to the procurement procedures of the EU executive agencies, subject to the general security based restrictions.

Association Agreements:

¹⁶ Please note that the EU Official Journal contains the official list and, in case of conflict, its content prevails over that of the EU Sanctions Map.

¹⁷ EEA Agreement:

The Agreement on Government Procurement¹⁸ or the Bilateral Free Trade Agreements ¹⁹ concluded within the World Trade Organisation do not apply. Therefore, the participation to this call for tenders is not open to natural and legal persons established in the countries that have ratified this Agreement.

The rules on access to procurement do not apply to entities on whose capacity tenderers rely to fulfil the selection criteria nor to subcontractors. Subcontracting may not be used with the intent or effect to circumvent the rules on access to procurement.

Participation in this call for tenders is also open on equal terms to natural and legal persons established in a third country eligible for funding under the EU4Health programme²⁰.

Third countries negotiating association to the programme will be treated as associated countries provided that the association agreement with the third country concerned applies at the time of the award of the contract.

To enable the contracting authority to verify the access, each tenderer must indicate its country of establishment (in case of a joint tender – the country of establishment of each group member) and must present the supporting evidence normally acceptable under the law

Under the Association Agreements with Georgia, Moldova and Ukraine economic operators established in those countries have access to procurement procedures of the EU executive agencies, subject to general exceptions.

Association Agreements to Union Funding Programmes:

Association Agreements of third countries for participation in Union Funding Programmes regularly provide that entities established in the third country may participate in actions funded by the programme under conditions equivalent to those applicable to entities established in the European Union. Accordingly, economic operators established in third countries associated to a relevant Union programme under which the call is launched, have the right to participate in procurement procedures funded under that programme unless those Agreements and the rules of the relevant spending programme (the basic act, the work programme, the call text, etc.) have specific provisions regulating or restricting access to procurement.

Overseas Countries and Territories:

Economic operators established in Overseas Countries and Territories (OCT) have the right to participate in EU procurement procedures under Article 176 FR as the OCTs (listed in the Annex II of the TFEU) fall within the scope of the Treaties (under the association regime of Part IV of the TFEU).

¹⁸ The full text of the GPA and its annexes per country: https://www.wto.org/english/tratop E/gproc e/gp gpa e.htm https://e-gpa.wto.org/en/Agreement/Latest

¹⁹ The full text of the FTAs and the annexes per country https://www.wto.org/english/tratop_E/gproc_e/gp_gpa_e.htm.

Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (Text with EEA relevance)

of that country. The same document(s) could be used to prove the country/-ies of establishment and the delegation(s) of the authorisation to sign, as described in Section 4.3.

2.3. Registration in the Participant Register: why register?

Any economic operator willing to participate in this call for tenders must be registered in the <u>Participant Register</u> - an online register of organisations and natural persons (participants) participating in calls for tenders or proposals of the European Commission and other EU institutions/bodies.

On registering each participant obtains a Participant Identification Code (PIC, 9-digit number), which acts as its unique identifier in the Participant Register. A participant needs to register only once – the information provided can be further updated or re-used by the participant in other calls for tenders or calls for proposals of the European Commission and other EU institutions/bodies.

d Each participant needs to ensure that its SME status in the Participant Register is registered and kept up to date.

At any moment during the procurement procedure, the Research Executive Agency Validation Services (hereafter *the EU Validation Services*) may contact the participant and ask for supporting documents on legal existence and status [and financial capacity]. The requests will be made through the register's messaging system to the e-mail address of the participant's contact person indicated in the register. It is the responsibility of the participant to provide a valid e-mail address and to check it regularly. The documents that may be requested by *the EU Validation Services* are listed in the <u>EU Grants and Tenders Rules on Legal Entity Validation, LEAR appointment and Financial Capacity assessment</u>.

• Please note that a request for supporting documents by the EU Validation Services in no way implies that the tenderer has been successful.

2.4. Ways to submit a tender: how can economic operators organise themselves to submit a tender?

Economic operators can submit a tender either as a sole economic operator (sole tenderer) or as a group of economic operators (joint tender)²¹. In either case subcontracting is permitted.

Tenders must be drawn and submitted in complete independence and autonomously from the other tenders. A declaration in this regard by each tenderer (in case of a joint tender, by each of its members) shall be requested.

A natural or legal person cannot participate at the same time and within the same procedure either as member of two or more groups of economic operators or as a sole tenderer and member of another group of economic operators. In such case, all tenders in which that

²¹ Each economic operator participating in the joint tender is referred to as "group member".

person has participated, either as sole tenderer or as member of a group of economic operators, will be rejected.

Economic operators linked by a relationship of control or of association (e.g. belonging to the same economic/corporate group) are allowed to submit different and separate tenders provided that each tenderer is able to demonstrate that its tender was drawn independently and autonomously.

A natural or legal person may act as subcontractor for several tenderers as long as the tenders are drawn and submitted in complete independence and autonomously from each other. However, cross subcontracting among tenderers is forbidden, more precisely an entity "A" may participate as tenderer (either as sole tenderer or as member of a group of economic operators) and as subcontractor to another tenderer "B" within the same procurement procedure. However, in this case it is forbidden that tenderer "B" (or any of its participating members in case of a group of economic operators) is at the same time subcontractor for tenderer "A" (or for the group of economic operators in which "A" participates) within the same procurement procedure. In this case, both tenders A and B shall be rejected.

In order to fulfil the selection criteria set out in Section 3.2 the tenderer can rely on the capacities of subcontractors (see Section 2.4.2) or other entities that are not subcontractors (see Section 2.4.3).

An "involved entity" is any economic operator involved in the tender. This includes the following four categories of economic operators:

- sole tenderer,
- group members (including group leader),
- identified subcontractors (see Section 2.4.2), and
- other entities (that are not subcontractors) on whose capacity the tenderer relies to fulfil the selection criteria.

The role of each entity involved in a tender must be clearly specified in the eSubmission application: i) sole tenderer, ii) group leader (in case of a joint tender), iii) group member (in case of a joint tender), or iv) subcontractor²².

For an entity on whose capacities the tenderer relies to fulfil the selection criteria (that is not a subcontractor), this role is defined in the commitment letter (*Annex 5.2*).

2.4.1. Joint tenders

1

A joint tender is a situation where a tender is submitted by a group (with or without legal form) of economic operators regardless of the link they have between them in the group. The group as a whole is considered a tenderer²³.

All group members assume joint and several liability towards the contracting authority for the performance of the contract as a whole.

²² Only identified subcontractors (see Section 2.4.2) must be specified in the eSubmission application.

²³ References to *tenderer* or *tenderers* in this document shall be understood as covering both sole tenderers and groups of economic operators submitting a joint tender.

Group members must appoint from among themselves a group leader (the group leader) as a single point of contact authorised to act on their behalf in connection with the submission of the tender and all relevant questions, clarification requests, notifications, etc., that may be received during the evaluation, award and until the contract signature. All group members (including the group leader) must sign an Agreement/Power of attorney drawn up in the model attached in *Annex 3*.

The joint tender must clearly indicate the role and tasks of each group member, including those of the group leader who will act as the contracting authority's contact point for the contract's administrative or financial aspects and operational management. The group leader will have full authority to bind the group and each of its members during contract execution.

If the joint tender is successful, the contracting authority shall sign the contract with the group leader, authorised by the other members to sign the contract also on their behalf via the Agreement/Power of attorney drawn up in the model attached in *Annex 3*.

Changes in the composition of the group during the procurement procedure (after the deadline for submission of tenders and before contract signature) shall lead to rejection of the tender, with the exception of the following case[s]:

- case of a merger or takeover of a group member (universal succession), provided that the following cumulative conditions are fulfilled:
 - o the new entity is not subject to restrictive measures, has access to procurement (see Section 2.2) and is not in an exclusion situation (see Section 3.1),
 - o all the tasks assigned to the former entity are taken over by the new entity member of the group,
 - o the group meets the selection criteria (see Section 3.2),
 - o the change must not make the tender non-compliant with the procurement documents,
 - o the terms of the originally submitted tender are not altered substantially and the evaluation of award criteria of the originally submitted tender are not modified,
 - o the new entity undertakes to replace the former entity for the implementation of the contract, in case of an award.

2.4.2. Subcontracting

Subcontracting is the situation where the contractor enters into legal commitments with other economic operators, which will perform part of the contract on its behalf. The contractor retains full liability towards the contracting authority for performance of the contract as a whole.

The following shall not be considered subcontracting:

- a) Use of workers posted to the contractor by another company owned by the same group and established in a Member State ("intra-group posting" as defined by Article 1, 3, (b) of <u>Directive 96/71/EC concerning the posting of workers in the framework of the provision of services</u>).
- b) Use of workers hired out to the contractor by a temporary employment undertaking or placement agency established in a Member State ("hiring out of workers" as defined

- by Article 1, 3, (c) of <u>Directive 96/71/EC concerning the posting of workers in the framework of the provision of services</u>).
- c) Use of workers temporarily transferred to the contractor from an undertaking established outside the territory of a Member State and that belongs to the same group ("intra-corporate transfer" as defined by Article 3, (b) of <u>Directive 2014/66/EU on the conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer</u>).
- d) Use of staff without employment contract ("self-employed persons working for the contractor"), without the tasks of the self-employed persons being particular well-defined parts of the contract.
- e) Use of suppliers and/or transporters by the contractor, in order to perform the contract at the place of performance, unless the economic activities of the suppliers and/or the transporting services are within the subject of this call for tenders (see Section 1.4).
- f) Performance of part of the contract by members of an EEIG (European Economic Interest Grouping), when the EEIG is itself a contractor or a group member.

The persons mentioned in points a), b), c) and d) above will be considered as "personnel" of the contractor as defined in the contract.

All contractual tasks may be subcontracted unless the procurement documents expressly reserve the execution of certain critical tasks to the sole tenderer itself, or in case of a joint tender, to a group member.

By filling in the form available in *Annex 4* (List of identified subcontractors), tenderers are required to give an indication of the proportion of the contract that they intend to subcontract, as well as to identify and describe briefly the envisaged contractual roles/tasks of subcontractors meeting any of these conditions (hereafter referred to as *identified subcontractors*):

- subcontractors on whose capacities the tenderer relies upon to fulfil the selection criteria as described under Section 3.2;
- subcontractors whose intended individual share of the contract, known at the time of submission, is above 20 %.

Any such subcontractor must provide the tenderer with a commitment letter drawn up in the model attached in *Annex 5.1* and signed by its authorised representative.

• Each tenderer shall identify <u>such</u> subcontractors and provide the commitment letters with its tender. The information must be true and correct at the time of submitting the tender. Any changes or additions regarding the envisaged subcontractors after the deadline for submission of tenders must be justified to the contracting authority.

The above rules apply also where the economic operators, which will perform part of the contract on behalf of a successful tenderer, belong to the same economic/corporate group as the sole tenderer or a member of the group submitting the joint tender.

Changes concerning subcontractors identified in the tender (withdrawal/replacement of a subcontractor, additional subcontracting) during the procurement procedure (after the submission deadline and before contract signature) require the prior written approval of the contracting authority subject to the following verifications:

- any new subcontractor is not subject to restrictive measures, has access to procurement if the rules on access to procurement apply also to subcontractors (see Section 2.2) and is not in an exclusion situation (see Section 3.1),
- the tenderer still fulfils the selection criteria and the new subcontractor fulfils the selection criteria applicable to it individually, if any;
- the terms of the originally submitted tender are not altered substantially, i.e. all the tasks assigned to the former subcontractor are taken over by another involved entity, the change does not make the tender non-compliant with the tender specifications, and the evaluation of award criteria of the originally submitted tender is not modified.

Subcontracting to subcontractors identified in a tender that was accepted by the contracting authority and resulted in a signed contract, is considered authorised.

2.4.3. Entities (not subcontractors) on whose capacities the tenderer relies to fulfil the selection criteria

In order to fulfil the selection criteria a tenderer may also rely on the capacities of other entities (that are not subcontractors), regardless of the legal nature of the links it has with them. It must in that case prove that it will have at its disposal the resources necessary for the performance of the contract by producing a commitment letter in the model attached in *Annex* 5.2, signed by the authorised representative of such an entity, and the supporting evidence that those other entities have the respective resources²⁴.

In the above rules apply also where the economic operators on whose capacities the tenderer relies to fulfil the selection criteria (that are not subcontractors) belong to the same economic/corporate group as the sole tenderer or a member of the group submitting the joint tender.

2.4.4. Rules common to subcontractors and entities (not subcontractors) on whose capacities the tenderer relies to fulfil the selection criteria

If a successful tenderer intends to rely on another entity to meet the minimum levels of economic and financial capacity, the contracting authority may require the entity to sign the contract or, alternatively, to provide a joint and several first-call financial guarantee for the performance of the contract.

With regard to technical and professional selection criteria, a tenderer may only rely on the capacities of other entities where the latter will perform the works or services for which these capacities are required, i.e. the latter will either assume the role of subcontractors or will fall within the exceptions listed in Section 2.4.2 and will then assume the role of entities (not subcontractors) on whose capacities the tenderer relies to fulfil the selection criteria.

Relying on the capacities of other entities is only necessary when the capacity of the tenderer is not sufficient to fulfil the required minimum levels of capacity. Abstract

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²⁴ This does not apply to subcontractors on whose capacity the tenderer relies to fulfil the selection criteria – for these the documentation required for subcontractors must be provided.

commitments that other entities will put resources at the disposal of the tenderer will be disregarded.

3. EVALUATION AND AWARD

The evaluation of the tenders that comply with the submission conditions will consist of the following elements:

- Check if the tenderer is not subject to restrictive measures and has access to procurement (see Section 2.2);
- Verification of administrative compliance (if the tender is drawn up in one of the official EU languages and the required documents signed by duly authorised representative(s) of the tenderer);
- 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 specified in the procurement documents;
- Evaluation of tenders on the basis of the award criteria.

The contracting authority will evaluate the abovementioned elements in the order that it considers to be the most appropriate.

If the evaluation of one or more elements demonstrates that there are grounds for rejection, the tender will be rejected and will not be subjected to further full evaluation. The unsuccessful tenderers will be informed of the ground for rejection without being given feedback on the non-assessed content of their tenders. Only tenderers for whom the verification of all elements did not reveal grounds for rejection can be awarded the contract resulting from this call for tenders.

The evaluation will be based on the information and evidence contained in the tenders and, if applicable, on additional information and evidence provided at the request of the contracting authority during the procedure. If any of the declarations or information provided proves to be false, the contracting authority may impose administrative sanctions (exclusion or financial penalties) on the entity providing the false declarations/information.

For the purposes of the evaluation related to exclusion and selection criteria the contracting authority may also refer to publicly available information, in particular evidence that it can access on a national database free of charge.

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

3.1. Exclusion criteria

The objective of the exclusion criteria is to assess whether the tenderer is in any of the exclusion situations listed in Article 136(1) of the Financial Regulation.

Tenderers found to be in an exclusion situation will be rejected.

As evidence of non-exclusion, each tenderer²⁵ needs to submit with its tender a Declaration on Honour²⁶ in the model available in *Annex* 2.²⁷ The declaration must be signed by an authorised representative of the entity providing the declaration. Where the declaration has been signed by hand, the original does not need to be submitted to the contracting authority, but the latter reserves the right to request it from the tenderer at any time during the record-keeping period specified in Section 4.3.

The initial verification of non-exclusion of tenderers will be done on the basis of the submitted declarations and consultation of the <u>European Union's Early Detection and Exclusion System.</u>

At any time during the procurement procedure²⁸, the contracting authority may request the documents mentioned in the Declaration on Honour as supporting evidence on non-exclusion (the documentary evidence). It may also request information on natural or legal persons that are members of the administrative, management or supervisory body or that have powers of representation, decision or control, including legal and natural persons within the ownership and control structure and beneficial owners, and appropriate evidence that none of those persons are in one of the exclusion situations referred to in Section A point (1) (c) to (f) of the Declaration on Honour.

All tenderers are **invited to prepare in advance the documentary evidence**, since they may be requested to provide such evidence within a short deadline. In any event, the tenderer proposed by the evaluation committee for the award of the contract will be requested to provide such evidence.

If the tenderer does not provide valid documentary evidence within the deadlines set by the contracting authority, the latter reserves the right to reject the tender. In any event, in case a tenderer proposed for the award of the contract fails to comply with the above evidence requirement, its tender will be rejected, unless the tenderer can justify the failure on the grounds of material impossibility to provide such evidence.

²⁵ See Annex 1 which of the involved entities participating in a tender need to provide the Declaration on Honour

²⁶ The European Single Procurement Document (ESPD) may not be used yet in European Commission's calls for tenders

²⁷ Unless the same declaration has already been submitted for the purposes of another award procedure of HaDEA, the situation has not changed, and the time elapsed since the issuing date of the declaration does not exceed one year.

²⁸ The obligation to provide the supporting evidence will be waived in the following situations:

⁻ if the same documents have already been provided in a previous award procedure of the European Commission, have been issued no more than one year before the date of their request by the contracting authority and are still valid at that date;

⁻ if such evidence can be accessed by the contracting authority on a national database free of charge, in which case the economic operator shall provide the contracting authority with the internet address of the database and, if needed, the necessary identification data to retrieve the document;

⁻ if there is a material impossibility to provide such evidence.

Annex 1 specifies which of the involved entities participating in a tender need to provide the Declaration on Honour and, when requested by the contracting authority, the supporting evidence.

Please note that a request for evidence in no way implies that the tenderer has been successful.

3.2. Selection criteria

The objective of the selection criteria is to assess whether the tenderer has the legal, regulatory, economic, financial, technical and professional capacity to perform the contract.

The selection criteria for this call for tenders, including the minimum levels of capacity, the basis for assessment and the evidence required, are specified in the following subsections.

Tenders submitted by tenderers not meeting the minimum levels of capacity will be rejected.

When submitting its tender each tenderer shall declare on honour that it fulfils the selection criteria for this call for tenders. The model Declaration on Honour available in *Annex 2* shall be used.

The initial assessment of whether a tenderer fulfils the selection criteria will be done on the basis of the submitted declaration(s).

The subsections below specify which selection criteria evidence must be provided with the tender or may be requested later, at any time during the procurement procedure, within a deadline given by the contracting authority ²⁹.

The evidence must be provided in accordance with the applicable basis for assessment of each criterion: in case of a consolidated assessment – only by the involved entities who contribute to the fulfilment of the criterion, and in case of individual assessment – by each entity to whom the criterion applies individually.

In case not all selection criteria evidence is requested with the tender, all tenderers are **invited to prepare in advance the documentary evidence**, since they may be requested to provide such evidence within a short deadline. In any event, the tenderer proposed by the evaluation committee for the award of the contract will be requested to provide such evidence.

If the tenderer does not provide valid documentary evidence within the deadlines set by the contracting authority, the contracting authority reserves the right to reject the tender. In any event, in case a tenderer proposed for the award of the contract fails to comply with the above evidence requirement, its tender will be rejected, unless there is a ground for a waiver.

²⁹ The obligation to provide the supporting evidence will be waived in the following situations:

⁻ if the same documents have already been provided in a previous award procedure of the European Commission and are still up-to-date;

if such evidence can be accessed by the contracting authority on a national database free of charge, in which case the economic operator shall provide the contracting authority with the internet address of the database and, if needed, the necessary identification data to retrieve the document.

Please note that a request for evidence in no way implies that the tenderer has been successful.

3.2.1. Legal and regulatory capacity

Tenderers can be natural or legal persons. Tenderers are not obliged to take a *specific* legal form in order to submit their tenders.

Where tenderers submit a tender through an entity, which lacks legal personality (e.g., a branch), the compliance with the exclusion criteria, selection criteria, the rules on access to procurement as well as the absence of restrictive measures shall be assessed at the level of the tenderers.

Tenderers do not need to prove specific legal and regulatory capacity to perform the contract.

In addition, involved entities (see Section 2.4) and all subcontractors, including those which do not need to be identified in the tender (see Section 2.4.2), must not be subject to <u>EU restrictive measures</u> adopted under Article 29 of the Treaty on the European Union (TEU) or Article 215 of the Treaty on the Functioning of the EU (TFEU)³⁰ that constitute a legal impediment to perform the contract. This requirement will be assessed by reference to the EU restrictive measures in force. Therefore, the tenderer is not required to submit any evidence of not being subject to EU restrictive measures.

3.2.2. Economic and financial capacity

Tenderers must comply with the following selection criteria in order to prove that they have the necessary economic and financial capacity to perform the contract.

Criterion F1	
Minimum level of capacity	Average yearly turnover of the last two financial years above EUR 800.000.
Basis for assessment	This criterion applies to the tenderer as a whole, i.e. a consolidated assessment of the combined capacities of all involved entities will be carried out.
Evidence	Copy of the profit and loss accounts and balance sheets for the last two years for which accounts have been closed from each concerned involved entity, or, failing that, appropriate statements from banks. The most recent year must have been closed within the last 18 months.

All of the above-specified evidence of economic and financial capacity must be provided with the tender.

³⁰ Please note that the EU Official Journal contains the official list and, in case of conflict, its content prevails over that of the EU Sanctions Map.

3.2.3. Technical and professional capacity

• With regard to technical and professional selection criteria, a tenderer may only rely on the capacities of other entities where the latter will perform the works or services for which these capacities are required. The entity on whose capacity the tenderer relies will either assume the role of a subcontractor or fall within the exceptions listed in Section 2.4.2.

Tenderers must comply with the following selection criteria in order to prove that they have the necessary technical and professional capacity to perform the contract:

Criterion T1	
The tenderer must prove experience in the field of public health. This experience must cover several EU Member States, projects in public health, health systems and policies, particularly related to cancer.	
Minimum level of capacity	At least three similar (in scope and complexity) projects completed in the last 10 years preceding the tender submission deadline, with a minimum value for each of them of \in 450.000. The projects combined must cover at least 10 EU Member States.
Basis for assessment	This criterion applies to the tenderer as a whole, i.e. the consolidated assessment of combined capacities of all involved entities will be carried out.
Evidence	A list of projects meeting the minimum level of capacity. The list shall include details of their start and end date, total project amount and scope, role and amount invoiced.
	As supporting documents for each project reference, the contracting authority may request statements issued by the clients and take contact with them.

Criterion T2		
The tenderer must prove experience in delivering projects in the field of social protection ³¹ .		
Minimum level of capacity	At least three similar (in scope and complexity) projects completed in the last 10 years preceding the tender submission deadline, with a minimum value for each of them of \in 300.000.	
Basis for assessment	This criterion applies to the tenderer as a whole, i.e. the	

³¹ Social protection is commonly defined as a 'set of policies and actions that enhance the capacity of all people, but notably poor and vulnerable groups, to escape from poverty (or avoid falling into poverty), and better manage risks and shocks' Social Protection (europa.eu). For the purposes of this study experience is needed covering the areas of social insurance, social care, labour market interventions and other social protection systems applicable to cancer patients and survivors.

	consolidated assessment of combined capacities of all involved entities will be carried out.
Evidence	A list of projects meeting the minimum level of capacity. The list shall include details of their start and end date, total project amount and scope, role and amount invoiced.
	As supporting documents for each project reference, the contracting authority may request statements issued by the clients and take contact with them.

Criterion T3								
The tenderer must prove experience with the drafting of studies/scientific reports in the field of health or social protection in English.								
Minimum level of capacity	At least three similar in scope and complexity projects completed in the last five years preceding the tender submission deadline, with a minimum value for each of them of € 450.000.							
Basis for assessment	This criterion applies to the tenderer as a whole, i.e. the consolidated assessment of combined capacities of all involved entities will be carried out.							
Evidence	Three pdf documents (report, study, etc.) of at least 50 pages each, excluding tables and figures, in English, drafted, published or delivered to a client in the last five years.							

Criterion T4										
The tenderer must demonstrate	e the ability to provide a Core Team, with experience in the									
2 2	management; drafting of reports, guidelines or									
· -	public health, social sciences, cancer care and research;									
data collection and statistical analysis; surveys and interviews, EU data protection.										
Minimum level of capacity										
	- Project manager									
	Requirements: a university degree (at least Master's degree or									
	equivalent) in public health or science or medical or political or social science.									
	At least five years of experience in management and coordination of EU projects in the area of public health including experience of									
	collaboration with health authorities in the EU Member States.									
	C2 equivalent competence in English.									
	Two anadalists/armouts in mublic boolth anadifically server says									
	- Two specialists/experts in public health, specifically cancer care research and policies									
	Requirements: two members with university degree in public health or									
	requirements, two memoers with university degree in public health of									

science or medical science (at least Master's degree or equivalent). At least five years of experience with health policies related to cancer. C1 equivalent competence in English. - One specialist/expert in social sciences and social protection Requirements: university degree in social sciences (at least Master's degree or equivalent). At least three years of experience with social policies The experience must be related to social support and social protection. C1 equivalent competence in English - Expert in data collection and analysis at EU level, incl. data collection design (surveys, interviews, focus groups) and data analysis techniques Requirements: university degree or diploma in statistics, economics or social sciences. At least three years of experience in carrying out surveys, interviews and focus groups, as well as experience in data analysis. C1 equivalent competence in English. - Expert in drafting studies/scientific reports in English Requirements: at least three years of experience with the drafting of study reports in English at high scientific level, drafting of related publications comprehensible to non-experts. C2 equivalent competence in English. - Expert in EU data protection Requirements: university degree or relevant training in EU data protection At least three years of experience in the implementation of EU DPR C1 or equivalent competence in English. **Basis for assessment** This criterion applies to the tenderer as a whole, i.e. the consolidated assessment of combined capacities of all involved entities will be carried out. **Evidence** Tenderers will present the list of members of the core team together with their CVs. The CV of the proposed for experts must be in Europass format and shall clearly specify how the criteria are met.

All proposed team members must be available from the start of the Contract period and as far as possible until the end of the project.

Replacement of persons assigned to carry out the work

The contracting authority expects the Contract to be executed by the specific team members who were identified and named in the tender. The involvement of key experts is considered to be instrumental in the achievement of the Contract objectives.

Any replacement of experts due to unforeseen circumstances outside of the control of the contractor must be notified to the contracting authority who can request to modify the proposal if the expert proposed for replacement does not have at least equivalent qualifications (studies and professional experience) to those proposed in the technical tender. Replacement of experts could cause cancellation of the contract if not considered acceptable by the contracting authority in advance. Whenever a replacement occurs, the contractor must ensure a high degree of stability of the services and a smooth transfer of information. Any replacement must be submitted to the contracting authority for written approval at least one week before the intended date of replacement which shall not be more than two weeks after the former expert has left the team.

Not respecting these requirements may be considered by the contracting authority as failure of the contractor to perform its contractual obligations, hence may lead to the application of contractual penalties foreseen in the contract.

Unless otherwise provided, in the case where the contracting authority in writing requests a replacement, the contractor's proposal for the replacement must be given within one month from receipt of the contracting authority's request. It shall be considered as a breach of contract if such a proposal is not made within the above specified period.

The replacement shall not oblige the contracting authority to pay any additional remuneration, fees or costs other than those laid down in the initial contract. The contractor shall bear all the additional costs arising out of or incidental to such replacement. Such costs borne by the contractor shall include the costs of the return journey of the replaced member of staff and his family, the costs of the replacement's training and hand-over of information and, if necessary, the expenses arising from the need to maintain simultaneously at the place of work the member of staff to be replaced and his replacement. Replacement shall not lead to any extension of deadlines.

All of the above-specified evidence of technical and professional capacity must be provided with the tender.

3.3. Compliance with the conditions for participation and minimum requirements specified in the procurement documents

By submitting a tender a tenderer commits to perform the contract in full compliance with the terms and conditions of the procurement documents for this call for tenders. Particular attention is drawn to the minimum requirements specified in [Section 1.4 of these specifications][the Technical specifications document (Tender specifications – part 2)] and to the fact that tenders must comply with applicable data protection, environmental, social and labour law obligations established by Union law, national legislation, collective agreements or

the international environmental, social and labour conventions listed in Annex X to Directive 2014/24/EU.

The minimum requirements shall be observed throughout the entire duration of the contract. Compliance with these requirements is mandatory and cannot be subject to any assumptions, limitations, conditions, or reservations on the part of a tenderer.

Tenderers must declare when submitting their tenders in eSubmission whether their tenders comply with the minimum requirements specified in the procurement documents.

♦ Tenders that are not compliant with the applicable minimum requirements shall be rejected.

3.4. Award criteria

The objective of the award criteria is to evaluate the tenders with a view to choosing the most economically advantageous tender.

Tenders will be evaluated on the basis of the following award criteria and their weighting:

1. Price Cost – **30%**

The price considered for evaluation will be the total price of the tender, covering all the requirements set out in the tender specifications.

2. Quality – 70%

The quality of the tender will be evaluated based on the following criteria:

Quality criterion	award	Explanation of the criterion's scope	(weighting)	Minimum points to be obtained (60% per
				criterion)

	This criterion will assess the appropriateness and quality of the proposed methodologies and tools to	36
criteria):	carry out the tasks as laid down in the tender	
Methodology	specifications. The description of the methodologies and tools proposed should be as precise as possible, explaining the rationale behind the choices proposed by the tenderer.	
	The description should include for each methodology and tool the identification of adequate sources of information, data collection and analysis methods, approaches to consultation activities and use of the information to achieve the results set out in the tender specifications.	
	Sub-criterion 1.1: Quality and appropriateness of the proposed methodology for data collection and analysis, including sources of information and data estimation and extrapolation techniques, for Tasks 1, 4, and 5.	
	Sub-criterion 1.2: Quality and relevance of the proposed methodology for the stakeholder consultations, including mapping of appropriate stakeholders, and development of questionnaires and other tools for Tasks 2 and 3.	

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Appropriateness of the organisation of	This criterion will assess how the roles and responsibilities of the proposed team are distributed for each activity or deliverable. The global allocation of time and human resources to the project and to each activity or deliverable is also assessed, and whether this allocation is adequate for the work. Tenderers must describe: - the composition of the team; - the team structure and work method (definition and distribution of roles and responsibilities for each task) - workload of each proposed team member; - the proposed schedule (using Gantt chart or a similar illustrative method) for the implementation of the different tasks and activities; - the supervision and management of the project and communication with the contracting authority. In the case of joint tenders, tenderers must also define the structure set up to coordinate the work between partners and explain how each group member will provide its best expertise.	15
Award criterion 3 (with 3 subcriteria): Quality of the measures implemented for a continuous high performance, including quality control, risk management and data protection strategy	This criterion will assess the quality control system applied to the services foreseen in these tender specifications concerning the quality of the deliverables, (incl. the validation of the information collected), the language quality check, the continuity of the service and the risk management. This criterion will also assess the adequate organisational and technical measures to ensure the full compliance with the EU data protection rules when processing personal data. The <i>detailed</i> quality system, risk management strategy and data protection plan must be provided in the tender and be specific to the project and the tasks planned; a <i>generic</i> quality system, risk management strategy and data protection plan will result in a low score. Sub-criterion 3.1: Quality and relevance of the proposed quality control system to ensure high	9

quality service.		
Sub-criterion 3.2: Quality and relevance of the proposed risk management strategy.	5	
Sub-criterion 3.3: Quality of the proposed data protection plan.	5	
	100	
Total	100	60

3.5. Award (ranking of tenders)

Tenders shall be ranked according to the best price-quality ratio in accordance with the formula below:

Score for	(Cheapest price				Price weighting		Total quality		Quality weighting
		Price of tender X	*	100	*	(in 30 %)	+	score (out of 100) for all award criteria of tender X	*	(in 70 %)

[♦] The contract shall be awarded to the tender ranked first, which complies with the minimum requirements specified in the procurement documents and is submitted by a tenderer not subject to restrictive measures, having access to procurement, not in an exclusion situation and fulfilling the selection criteria.

Detection of abnormally low tenders

Tenderers must be aware of Point 23 of Annex I to the Financial Regulation on abnormally low tenders and of the possibility for rejection of the tender based on it.

4. FORM AND CONTENT OF THE TENDER

4.1. Form of the tender: how to submit the tender?

Tenders are to be submitted via the eSubmission application according to the instructions laid down in the Invitation letter and the eSubmission Quick Guide available at the link below:

https://wikis.ec.europa.eu/display/FTPortal/Open+procedures_EN

Make sure you prepare and submit your tender in eSubmission early enough to ensure it is received within the deadline indicated under Section 5.1.12 of the contract notice and/or on F&T portal.

4.2. Content of the tender: what documents to submit with the tender?

The documents to be submitted with the tender in eSubmission are listed in *Annex 1*.

The following requirements apply to the technical and financial tender to be uploaded in eSubmission:

• Technical tender.

The technical tender must provide all the information needed to assess the compliance with Section 1.4 of these specifications and the award criteria. Tenders deviating from the minimum requirements or not covering all the requirements may be rejected on the basis of non-compliance and not evaluated further.

When submitting the technical tender it is highly recommended that the tenderer:

- limits the technical tender to a maximum of 50 pages, excluding evidence provided for the assessment of exclusion and selection criteria, such as CVs, past projects or profit and loss accounts, etc.;
- and uses Times New Roman font with a minimum font size of 11, A4 page size and all margins (top, bottom, left, right) at least 15 mm (excluding any footers or headers).

Tenders shall be perfectly legible so that there can be no doubt as to words and figures. Tenders shall be clear and concise. They must be complete and consistent with all the requirements and instructions laid down in the tender specifications.

• Financial tender.

A complete financial tender, including the breakdown of the price, needs to be submitted. For this purpose, the Financial Model in *Annex 6* shall be used.

The total amount of the tender as indicated in cell G25 must be encoded in the field "Total amount" under the section "Tender data" in eSubmission.

It is the responsibility of each tenderer to ensure that the total amount of the tender inserted in the eSubmission field "Total amount" corresponds to the amount indicated in the uploaded

financial tender. In case of discrepancies, only the amount indicated in the financial tender will be taken into account.

Any modification of the template of the financial tender may lead to rejection of the tender. The tenderer must not change, add, hide or eliminate any part of the template such as row, column or cell, or change the texts already prefilled in the template.

The financial tender must fulfil the following requirements:

- prices shall be all-inclusive all costs associated with the completion of the work, including overheads such as infrastructure, administration costs and travel costs and other costs, even not mentioned, but necessary for the completion shall be included in the overall fixed price in the financial tender (no reimbursable variable costs).
- prices shall be calculated to cover all the expenditure borne by the contractor in the performance of the Contract, including travel and subsistence expenses.
- prices shall be expressed in euros. 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 should be expressed to a maximum of 2 decimal places.
- prices shall be quoted free of all duties, taxes and other charges, i.e. also free of VAT.

♦ The European Union Institutions are exempt from such charges in the EU under Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union of 8 April 1965 annexed to the Treaty on the Functioning of the European Union. Exemption is granted to the Commission/Executive agency by the governments of the Member States, either through refunds upon presentation of documentary evidence or by direct exemption.

In case of doubt about the applicable VAT system, it is the tenderer's responsibility to contact its national authorities to clarify the way in which the European Union is exempt from VAT.

4.3. Signature policy: how can documents be signed?

Where a document needs to be signed, the signature must be either hand-written or, preferably, a qualified electronic signature (QES) as defined in <u>Regulation (EU) No 910/2014</u> on electronic identification and trust services for electronic transactions in the internal market (the *eIDAS Regulation*).

Tenderers are strongly encouraged to sign with a QES³² all documents requiring a signature and only exceptionally to sign such documents by hand as hand-written signatures lead to an additional administrative burden for both the tenderer and the contracting authority. The originals of any hand-signed documents (other than the contract) do not need to be submitted to the contracting authority but the tenderer must keep them for a period of five years starting from the notification of the outcome of the procedure or, where the tenderer has been awarded

³² See <u>here</u> how to apply a QES on a document exchanged with a European institution, body or agency.

a contract resulting from this call for tenders and the contract has been signed, the payment of the balance.

All documents must be signed by the signatories (when they are individuals) or by their duly authorised representatives.

For the following documents, when signed by representatives, tenderers must provide evidence for the delegation of the authorisation to sign:

- The Declaration on Honour of the tenderer (in case of a joint tender the Declarations on Honour of all group members);
- (in the case of a joint tender) the Agreement/Power(s) of attorney drawn up using the model attached in *Annex 3*.

The delegation of the authorisation to sign on behalf of the signatories (including, in the case of proxy(-ies), the chain of authorisations) must be evidenced by appropriate written evidence (copy of the notice of appointment of the persons authorised to represent the legal entity in signing contracts (together or alone), or a copy of the publication of such appointment if the legislation which applies to signatory requires such publication or a power of attorney). A document that the contracting authority can access on a national database free of charge does not need to be submitted if the contracting authority is provided with the exact internet link and, if applicable, the necessary identification data to retrieve the document.

4.4. Confidentiality of tenders: what information and under what conditions can be disclosed?

Once the contracting authority has opened a tender, it becomes its property and shall be treated confidentially, subject to the following:

- For the purposes of evaluating the tender and, if applicable, implementing the contract, performing audits, benchmarking, etc., the contracting authority is entitled to make available (any part of) the tender to its staff and the staff of other Union institutions, bodies and agencies, as well to other persons and entities working for the contracting authority or cooperating with it, including contractors or subcontractors and their staff, provided that they are bound by an obligation of confidentiality.
- After the signature of the award decision, tenderers whose tenders were received in accordance with the submission modalities, who are not subject to restrictive measures, have access to procurement, who are not found to be in an exclusion situation referred to in Article 136(1) of the FR, who are not rejected under Article 141 of the FR, whose tenders are not found to be incompliant with the procurement documents, and who make a request in writing, will be notified of the name of the tenderer to whom the contract is awarded, the characteristics and relative advantages of the successful tender and its total financial tender amount³³. The contracting authority may decide to withhold certain information that it assesses as being confidential, in particular where its release would prejudice the legitimate commercial interests of economic operators or might distort fair competition between them. Such

³³ For a call for tenders resulting in multiple framework contracts this information will be provided for all successful tenderers and tenders.

- information may include, without being limited to, confidential aspects of tenders such as unit prices included in the financial tender, technical or trade secrets³⁴.
- The contracting authority may disclose the submitted tender in the context of a request for public access to documents, or in other cases where the applicable law requires its disclosure. Unless there is an overriding public interest in disclosure³⁵, the contracting authority may refuse to provide full access to the submitted tender, redacting the parts (if any) that contain confidential information, the disclosure of which would undermine the protection of commercial interests of the tenderer, including intellectual property.

♦ The contracting authority will disregard general statements that the whole tender or substantial parts of it contain confidential information. Tenderers need to mark clearly the information they consider confidential and explain why it may not be disclosed. The contracting authority reserves the right to make its own assessment of the confidential nature of any information contained in the tender.

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³⁴ For the definition of trade secrets please see Article 2 (1) of DIRECTIVE (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure. Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.

³⁵ See Article 4 (2) of the PECH ATRION (EQ) No. 1040/2001

³⁵ See Article 4 (2) of the REGULATION (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents. See Article 4 (2) of the Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents.

APPENDIX: LIST OF REFERENCES

Award criteria	See Section 3.4
Contracting authority	See Section 1.1
Entities on whose capacities the tenderer relies to fulfil the selection criteria	See Section 2.4.3
EU Validation services	See Section 2.3 EU Grants and Tenders Rules on Legal Entity Validation, LEAR appointment and Financial Capacity assessment
Exclusion criteria	See Section 3.1
Financial Regulation	Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union
Group leader	See Section 2.4.1
Group member	See Section 2.4.1
Identified subcontractors	See Section 2.4.2
Involved entities	See Section 2.4
Joint tender	See Section 2.4.1
Participating entities	See Section 1.1
Participant Register	See Section 2.3 https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/participant-register The section 2.3
Selection criteria	See Section 3.2
Sole tenderer	See Section 2.4
Subcontracting/subcontractor	See Section 2.4.2
Treaties	The EU Treaties: https://europa.eu/european-union/law/treaties_en

ANNEXES

Annex 1. List of documents to be submitted with the tender or during the procedure $\frac{1}{2}$

Description	Sole tenderer	Joint tender		Identified Subcontractor	Entity on When and where to substitute whose capacity is being relied		Instructions for applicable)	uploading in eSubmission (i
		Group leader	Group member		(that is not subcontractor)		How to name the file?	Where to upload?
1. Identification and i	nformation	about the	tenderer.					
eSubmission view								
•								
Ways to submit		Par	ties		Tender data	Submission repo	ort	Submit
Declaration on Honour on Exclusion and Selection Criteria (see Section 3.1) model in Annex 2						With the tender in eSubmission	'Declaration on Honour'	With the concerned entity under 'Parties' →'Identification of the participant' →'Attachments'→'Declaration on Honour'. For entities that are not subcontractors and on whose capacity the tenderer relies to fulfil the selection criteria, the document must be uploaded in the section of the sole tenderer or group leader:

Evidence that the person signing the documents is an authorised representative of the entity ³⁶ (see Section 4.3)				With the tender in eSubmission	'Authorisation to sign documents'	→'Identification of the participant' →'Attachments'→'Other documents'. With the concerned entity under 'Parties' →'Identification of the participant' →'Attachments'→'Other documents'.
Agreement/Power of attorney (see Section 2.4.1) model in Annex 3				With the tender in eSubmission	'Agreement_ Power of attorney'	In the group leader's section under 'Parties' →'Identification of the participant' →'Attachments'→'Other documents'.
List of identified subcontractors (see Section 2.4.2) model in Annex 4				With the tender in eSubmission	'List of identified subcontractors'	In the sole tenderer's or the group leader's section under 'Parties' →'Identification of the participant' →'Attachments'→'Other documents'.
Commitment letter (see Section 2.4.2 and 2.4.3)		(model in	(model in Annex	With the tender in eSubmission	'Commitment letter'	With the concerned entity under 'Parties' →'Identification of the participant'

³⁶ A document that the contracting authority can access on a national database free of charge does not need to be submitted if the contracting authority is provided with the exact internet link and, if applicable, the necessary identification data to retrieve the document.

				Annex 5.1)	5.2)			→'Attachments'→'Other documents'.
Evidence of non-exclusion (see Section 3.1)		\boxtimes				Tenderers (sole tenderers/all group members in case of a joint tender) must provide the evidence when requested by the contracting authority and, in any event, if a tenderer is successful, before the award of the contract. Subcontractors and entities on whose capacity a tenderer relies to fulfil the selection criteria must provide the evidence only upon request by the contracting authority.	n.a.	n.a.
Evidence of legal existence and status (see Section 2.3)	\boxtimes	\boxtimes	\boxtimes			Only upon request by the EU Validation services At any time during the procedure In the Participant Register	n.a.	n.a.
Evidence of legal capacity (see Section 3.2.1)						Only upon request by the contracting authority At any time during the procedure	n.a.	n.a.
Evidence of economic and financial capacity F1 (see Section 3.2.2)				must be provide	ed.	With the tender in eSubmission	'Balance_sheet_ entity_year' 'Profit_Loss_ Account_entity_ year'	With the group leader or the sole tenderer under 'Parties' →'Identification of the participant' →'Attachments'→'Economic and financial capacity'.

	which	ı contribute (to reachin	g the minimum c	apacity level				
			for crit	terion F1					
Evidence of technical and professional capacity T1 –						With the tender	'Project_ reference_No.1"	With the group lea sole tenderer under	der or the Parties'
T4 (see Section 3.2.3)	The documents must be provided only by the involved entities who contribute to reaching the minimum capacity level				I	in eSubmission	'Project_ reference_No.2"	→'Identification of the participant' →'Attachments'→'Technical and professional capacity'.	
					pacity level				
			for criter	ria T1 – T4					
2. Tender data.									
eSubmission view									
•									
Ways to submit	Parties			Tender data Submission rep		port	Submit		
Failure to upload the fol	llowing docu	ıments in eSu	ıbmission	will lead to rejecti	on of the tender.				
Technical tender (see Section 4.2)	X	\boxtimes				With the tender	'Technical tender'	Under section 'Tendo' → 'Technical tender'	er Data'
Section (1.2)						in eSubmission	tender	7 Technical tender	
Financial tender (see Section 4.2)	\boxtimes	\boxtimes				With the tender	'Financial tender'	Under 'Tender Data' → 'Financial tender'	
model in Annex 6						in eSubmission		7 I maneiar telluer	

Annex 2. Declaration on Honour on exclusion and selection criteria

Annex 2 is published as a separate document.

Annex 3. Agreement/Power of attorney

Call for tenders *XXX/XX/XX/20XY/XYZ* - [TITLE OF THE PROCEDURE]

AGREEMENT/POWER OF ATTORNEY

The undersigned:

[- Signatory 1 (Name, Function, Legal entity name, Registered address, VAT Number)]

- Signatory 2 (Name, Function, Legal entity name, Registered address, VAT Number)

- ...

- Signatory N (Name, Function, Legal entity name, Registered address, VAT Number)]

having the legal capacity required to act on behalf of the entities they represent,

HEREBY AGREE TO THE FOLLOWING:

- 1) To submit a joint tender (the tender) as members of a group of tenderers (the group), constituted by [Insert names of Legal entity 1, Legal entity 2, ... Legal entity N the name of the group leader must be included here!] (the group members), and led by [Insert name of Legal entity 1] (the group leader), in accordance with the conditions of the procurement documents and the terms of the tender to which this Agreement/Power of attorney is attached.
- 2) If the contracting authority awards a contract resulting from this call for tenders (the contract) to the group on the basis of the tender to which this Agreement/Power of attorney is attached, all group members (including the group leader) shall be considered parties to the contract in accordance with the following conditions:
 - (a) All group members (including the group leader) shall be jointly and severally liable towards the contracting authority for the performance of the contract.
 - (b) All group members (including the group leader) shall comply with the terms and conditions of the contract and ensure the proper delivery of their respective share of the services and/or supplies subject to the contract.
- 3) Payments by the contracting authority related to the services and/or supplies subject to the contract shall be made through the bank account of the group leader indicated in the contract.
- 4) The group members grant to the group leader all the necessary powers to act on their behalf in the submission of the tender and the conclusion of the contract, including:
 - (a) The group leader shall submit the tender on its own behalf and on behalf of the other group members and indicate in the "Contact Person" section in eSubmission the name

and e-mail address of an individual as a single point of contact authorised to communicate officially with the contracting authority in connection with the submitted tender on behalf of all group members, including in connection with all relevant questions, clarification requests, notifications, etc., that may be received during the evaluation, award and until the contract signature.

- (b) The group leader shall sign any contractual documents including the contract,[specific contracts] and amendments thereto and shall warrant the submission of any invoices related to the performance of the contract on behalf of all group members.
- (c) The group leader shall act as a single contact point with the contracting authority in the delivery of the services and/or supplies subject to the contract. It shall coordinate the delivery of the services and/or supplies by the group to the contracting authority, and shall see to a proper administration of the contract.

This Agreement/Power of attorney may be executed in counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same document.

Any modification to the present Agreement/Power of attorney shall be subject to the contracting authority's express approval. This Agreement/Power of attorney shall expire when all the contractual obligations of the group have ceased to exist. The parties cannot terminate it before that date without the contracting authority's consent.

Name Function Name of the legal entity	Name Function Name of the legal entity
signature[s]:	signature[s]:
Done at, on	Done at, on
Name	Name
Function	Function
Name of the legal entity	Name of the legal entity
signature[s]:	signature[s]:
Done at, on	Done at, on

Annex 4. List of identified subcontractors and proportion of subcontracting

Identification details	Roles/tasks during contract execution	Proportion of subcontracting (% of contract volume)
[Full official name of the		
identified subcontractor,		
registered address,		
statutory registration number,		
VAT registration number]		
[Full official name of the		
identified subcontractor,		
registered address,		
statutory registration number,		
VAT registration number]		
[REPEAT AS MANY TIMES AS		
THE NUMBER OF		
IDENTIFIED		
SUBCONTRACTORS]		
Other subcontractors that do		
not need to be identified under		
Section 2.4.2 ³⁷		
	TOTAL % of subcontracting	0,00%

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 $^{^{37}}$ For this category of subcontractors, please provide in a general manner their intended roles/tasks during contract execution, as well as the aggregated % of contract volume for all non-identified subcontractors.

Annex 5.1. Commitment letter by an identified subcontractor

П	ettei	rhea	d.	if	anv
		IIICU	u	44	ull y

Signature:

[]

Call for tenders Ref. [reference number]

Attn:
[Insert date]
Commitment letter by identified subcontractor
I, the undersigned,
Name:
Function:
Legal entity:
Registered address:
VAT Number:
having the legal capacity required to act on behalf of [insert name of the entity], hereby confirm that the latter agrees to participate as subcontractor in the tender of [insert name of the tenderer] for the call for tenders [insert reference number] – [insert title of procedure].
In the event that the tender of the aforementioned tenderer is successful, <i>[insert name of the subcontractor]</i> commits itself to make available the resources necessary for performance of the contract as a subcontractor and to carry out the services that will be subcontracted to it in compliance with the terms of the contract. It further declares that it is not subject to conflicting interests, which may negatively affect the contract performance, and that it accepts the terms of the procurement documents for the above call for tenders, in particular the contractual provisions related to checks and audits.
Done at:
Name:
Position:

Annex 5.2. Commitment letter by an entity on whose capacities is being relied [Letterhead, if any] *[1* Call for tenders Ref. [reference number] Attn: [Insert date] Commitment letter by an entity on whose capacity is being relied I, the undersigned, Name: Function: Legal entity: Registered address: VAT Number: having the legal capacity required to act on behalf of [insert name of the entity], hereby confirm that the latter authorises the [insert name of the tenderer] to rely on its [financial and economic capacity] [technical and professional capacity] in order to meet the minimum levels required for the call for tenders [insert reference number] - [insert title of procedure]. In the event that the tender of the aforementioned tenderer is successful, *[insert name of the* entity] commits itself to make available the resources necessary for performance of the contract. It further declares that it is not subject to conflicting interests which may negatively affect the contract performance, and that it accepts the terms of the procurement documents for the above call for tenders, in particular the contractual provisions related to checks and audits. Done at:

Name:

Position:

Signature:

Annex 6. Financial tender form

Annex 6 is published as a separate document.