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eCare

Digital solutions for frailty prevention in old adults

Pre-Commercial Procurement (PCP)

Tender Document 1 (TD1)

Request for Tenders

Deadline to submit an offer:

15th September 2021, at 12:00 midday (CET)

Important notice: This Request for Tenders is composed by a set of documents listed hereafter:

- TD1 – Request for Tenders
- TD2 – Challenge Brief
- TD3 – Tender forms
- TD4 – Framework agreement
- TD5 – Specific contract template for phase 1
- TD6 – Annexes

All documents available on *https://ecare-pcp.eu/* website.

PREFACE

This eCare Request for Tenders invites all interested parties to present their offers to **develop and test disruptive digital solutions for the prevention and comprehensive management of frailty of older adults.**

eCare is a R&D (Research & Development) project which takes form as a Pre-Commercial Procurement (PCP).

In this document, **section 1** explains the PCP approach and how it differs from traditional procurement.

Section 2 introduces the overall challenge that has to be addressed by the PCP and the expected outcomes distributed by each of the 3 phases of which it is composed. Also, a description of the procurer and third parties involved is provided. Then, the contracting approach, the overall timing of the phases, budget distribution, time schedule is explained. Finally, IPR (Intellectual Property Rights) considerations are addressed.

Section 3 addresses the conditions and evaluation of tenders. Eligibility criteria for tenderers, joint tenders' requirements, subcontracting conditions, selection criteria and other considerations to be checked before presenting a proposal are explained. Then, the award criteria are defined in detail, first regarding compliance in several contextual aspects and second in direct relation with the contents of the proposal. Finally, details of the evaluation procedure are explained.

Section 4 describes the content and format of the tenders including the submission system, the envelopes in which the proposal must be split and the closing time. The description of the technical and financial section is described in a detailed way.

Section 5 contains other tender conditions are described like the communication language, confidentiality, contract implementation including monitoring, payments, eligibility for passing to the next phase and cancellation of the tender procedure. Also, procedures for appeal and other legal important information are provided.

This Request for tenders should be read jointly with the rest of documents prepared for this Pre-Commercial procurement (PCP) and annexes:

Tender documents (TD)
TD1 – Request for tenders
TD2 – Challenge brief
TD3 – Tender Forms
TD4 – Framework agreement
TD5 – Specific contract template for phase 1
TD6 – Annexes

Please, find below the list of forms that you will encounter in the TD3- Forms:

TD3 - Tender Forms	
Form 1. General Tender Submission	Qualification Envelope
Form 2. Exclusion Criteria	Qualification Envelope
Form 3. Selection Criteria Form	Qualification Envelope
Form 4. Compliance Criteria Form	Qualification Envelope
Form 5. Technical Offer Form	Technical Envelope
Form 6. Financial Offer Form	Financial Envelope

The Annexes that are included in the TD6 – Tender Annexes document must be completed, signed and uploaded in the eTendering Platform according to the instructions given in TD6. Find below the list of the different Annexes required:

TD6 –Tender Annexes (Qualification Envelope)
Annex 1: Subcontractor Information
Annex 2: Subcontractor Declaration
Annex 3: Single Tenderer Power of Attorney
Annex 4: Lead Tenderer Power of Attorney

All these documents can be downloaded from the eCare website at *https://ecare-pcp.eu/* as well as directly from the eTendering Platform after supplier's registration. Please, note that Forms will be part of the different response's envelopes from the eCare eTendering Platform.

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Acronyms list

ASL BN: Azienda Sanitaria Locale Benevento
CSI: Consorci Sanitari Integral
GPA: Government Procurement Agreement
PCP: Pre-Comercial Procurement
PPI: Public Procurement of Innovation Solutions
R&D: Research & Development
SDR: Santander City Council
UKA: Universitätsklinikum Aachen
WTO: World Trade Organization

1 General context

1.1 Pre-commercial procurement (PCP)

This procurement is a **pre-commercial procurement (PCP)** carried out within the eCare European Union funded project and is conducted by Azienda Sanitaria Locale Benevento, Italy.

The main goal is to deliver digital solutions supporting continuum of care for frailty prevention in old adults / deliver disruptive digital solutions for the prevention and comprehensive management of frailty to encourage independent living, wellbeing and to relieve health and care services budget pressure.

This procurement is a pre-commercial procurement (PCP).

PCP means that public procurers invite and encourage innovative players on the market, via an open, transparent and competitive process, to develop new solutions for a technologically demanding mid- to long-term challenge that is in the public interest and requires new R&D services.

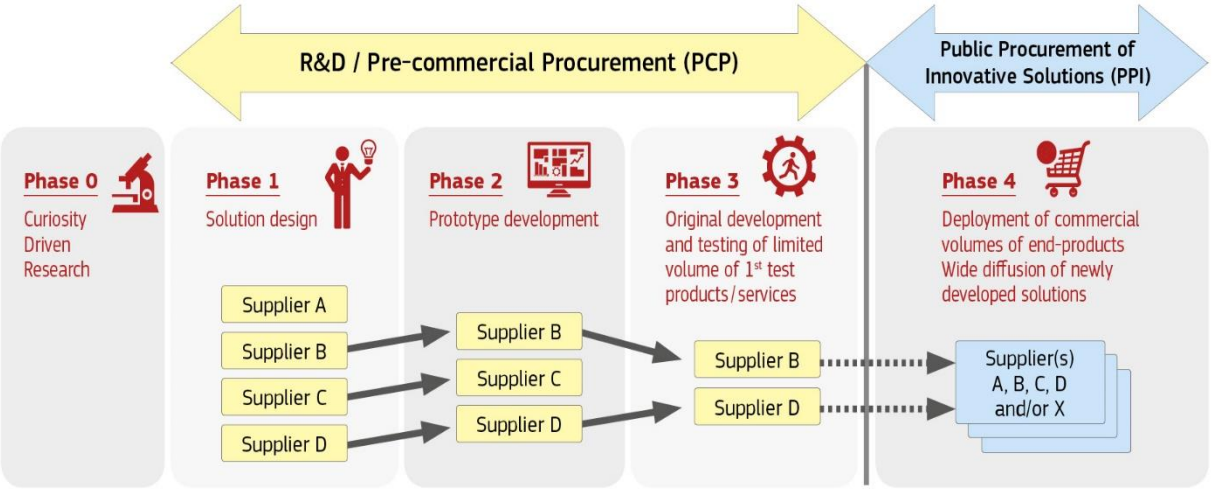

Figure 1: The PCP concept in the R&D and procurement context. Source: EU

PCP is characterised by the following four **features**:

- **Competitive development in phases to identify the solutions offering the best value for money**

PCP targets situations that require radical innovation or R&D and for which there are typically no solutions on or close to the market yet. Different competing providers may have different ideas for solutions to the problem. As R&D is yet to take place, there is not yet any proof as to which of these potential alternative solutions would best meet customers' needs.

PCP therefore awards R&D contracts to a number of competing contractors at the same time, in order to compare different approaches addressing the challenge as stated in the provisions of the eCare project. It thus offers innovators an opportunity to show how well their solution compares with others. It also allows a first customer test reference to be obtained from countries of the procurers that will test the solutions.

The R&D is split into **3 phases** (solution design, prototyping, original development and testing of a limited set of 'first' products or services). Evaluations after each phase progressively identify the solutions that offer the best value for money and meet the customers' needs. This phased approach

allows successful contractors to improve their offers for the next phase based on lessons learnt and feedback from procurers in the previous phase. Using a phased approach with gradually growing contract sizes per phase also makes it easier for smaller companies to participate in the PCP and enables SMEs to grow their business step-by-step with each phase.

Depending on the outcome of the PCP, procurers may or may not decide to follow-up the PCP with a public procurement to deploy the innovative solutions (PPI).

- **Public procurement of R&D services**

PCP addresses mid- to long-term public procurement needs for which either no commercially stable solutions yet exist on the market, or existing solutions exhibit structural shortcomings that it requires further R&D to resolve. PCP is a way for procurers to trigger the market to develop new solutions that address these shortcomings. PCP focuses on specific identified needs and provides customer feedback to businesses from the early stages of R&D. This improves the likelihood of commercial exploitation of the newly developed solutions.

PCP is explained in the PCP communication COM/2007/799 and the associated staff working document SEC/2007/1668. The R&D services can cover research and development activities ranging from solution exploration and design, to prototyping, right through to the original development of a limited set of 'first' products or services in the form of a test series. Original development of a first product or service may include limited production or supply in order to incorporate the results of field-testing and demonstrate that the product or service is suitable for production or supply in quantity to acceptable quality standards. R&D does not include quantity production or supply to establish the commercial viability or to recover R&D costs[1]. It also excludes commercial development activities such as incremental adaptations or routine or periodic changes to existing products, services, production lines, processes or other operations in progress, even if such changes may constitute improvements.

- **Open, transparent, non-discriminatory approach — No large-scale deployments**

PCP is open to all operators on equal terms, regardless of the size, geographical location or governance structure. There is, however, a place of performance requirement that they must perform a predefined minimum percentage of the contracted R&D services in EU Member States or Horizon 2020 associated countries.

Any subsequent public procurement of innovative solutions (PPI), for the supply of commercial volumes of the solutions, will be carried out under a separate procurement procedure. Providers that did not take part in this PCP (or were not chosen to go through as far as the last phase) will thus still be able to compete on an equal basis in any subsequent procurement looking for contractors to provide a solution on a commercial scale.

- **Sharing of IPR-related risks and benefits under market conditions**

PCP procures R&D services at market price, thus providing contractors with a transparent, competitive and reliable source of financing for the early stages of their research and development. Giving each contractor the ownership of the IPRs attached to the results it generates during the PCP means that they can widely exploit the newly developed solutions commercially. In return, the tendered price must contain a financial compensation for keeping the IPR ownership compared to the case where the IPRs would be transferred to the procurers (the tendered price must be the 'non-

[1] See also Article XV(1)(e) WTO GPA 1994 and the Article XIII(1)(f) of the revised WTO GPA 2014.

exclusive development price'; see Section 2.7). Moreover, the procurers must receive rights to use the R&D results for internal use and licensing rights subject to certain conditions.

ⓘ For more information, *see PCP on the Europa website*.

1.2 Exemption from EU public procurement directives, the WTO Government Procurement Agreement (GPA) and EU state aid rules

eCare procurement is exempted from the **EU public procurement directives** because the procurers do not retain all the benefits of the R&D (the IPR ownership stays with the contractors).[2]

It is also exempted from the **WTO Government Procurement Agreement (GPA)** because this Agreement does not cover R&D services[3] (the PCP being limited to such services — and any subsequent PPI procurements relating to commercial-scale supply of such solutions not being part of the PCP procurement).

The procurement does not constitute state aid under the **EU state aid rules**[4] because it follows an open, transparent, competitive procedure with risk- and benefit-sharing at market price. (The division of all rights and obligations *(including IPRs)* and the selection and award criteria for all phases must be published at the outset; the PCP must be limited to R&D services and clearly separated from any potential follow-up PPI procurements; PCP contractors may not be given any preferential treatment in a subsequent procurement for provision of the final products or services on a commercial scale.)

1.3 Open market consultation

The start of this PCP procurement was preceded by an open market consultation (OMC) with potential tenderers and end-users in order to canvass wide stakeholder opinion on the suitability of eCare PCP.

The objective of the OMC was to validate the Buyers Group needs assessment, present the PCP tender and check the innovation potential of the future solution. Other objectives include gaining a deeper insight into the current market situation from a market offer perspective and assessing potential suppliers.

The OMC related activities have been a series of participative webinars and questionnaires as well as an online survey.

All the proceedings of the OMC and Q&A are available to all OMC participants and other interested stakeholders in https://ecare-pcp.eu/omc/ .

1.4 EU funding

This PCP procurement is part of a project that is funded by the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No 856940 — eCare *(see https://ecare-pcp.eu/)*.

The procurement must therefore comply with the rules imposed by the EU Horizon 2020 grant agreement.

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2 See Article 16(f) of Directive 2004/18/EC (Article 14 of Directive 2014/24/EU), Article 24(e) of Directive 2004/17/EC (Article 32 of Directive 2014/25/EU) and Article 13(f)(j) of Directive 2009/81/EC.

3 See the EU's Annex IV of Appendix I to the WTO GPA.

4 See Point 33 of the Commission Communication on a framework for state aid for research and development and innovation (C(2014) 3282).

ⓘ For more information, *see 'innovation procurement' and 'links to regional policy' in the Funding & Tenders Portal Online Manual*.

⚠ **Attention:** The EU is not participating as a contracting authority in this procurement.

2 Tender profile

2.1 Description of services to be procured

2.1.1 PCP challenge

This procurement is for **R&D services** to develop **solutions** to tackle the following **challenge**: digital solutions supporting continuum of care for frailty prevention in old adults / deliver disruptive digital solutions for the prevention and comprehensive management of frailty to encourage independent living, wellbeing and to relieve health and care services budget pressure.

An elaborated description of **PCP challenge** and **sub challenges**, including the main **quality/efficiency improvements** sought are detailed in TD2 - PCP Challenge.

2.1.2 Expected outcomes (per phase)

All the deliverables are required to be met in a preceding phase for progression into subsequent phases. The following table contains the description of the objectives, the associated output and results and the task to carry out for each of the three phases.

IMPORTANT NOTICE: Physical meetings will be subjected to the sanitary restrictions in current COVID-19 pandemic. While the mobility restrictions persist, the remote meetings will be prioritised.

Table I. Expected outcomes. Phase 1: Solution design

Phase 1: Solution design				
Objective:	During this Phase 1, the selected Contractors are asked to provide a solution design that will address the challenge and the functional requirements requested on section 3. The purpose is to elaborate the solution design and determine the approach to be taken to develop the new solutions as well as demonstrate the technical, financial and commercial feasibility of the proposed concepts and approach to meet the procurement needs.			
Output and results:	A final solution design which includes evidence of having met the unmet needs outlined in the PCP challenge brief in section 2.1.1. A clear and feasible exploitation and commercialization plan of the solution proposed.			
Milestones and deliverables		**By when?** ***(See section 2.6 Time schedule)***	**How?**	**Output and results**
Milestones:	M1.1 Kick-off meeting	Start of Phase 1	Physical or online meeting tbc	Presentation of Phase 1 procedures, methodologies, timelines, and actors involved by the monitoring team and plans to deliver Phase 1 by contractors. Q&A.
	M1.2) Interim progress review	Mid phase 1	Report + presentation + evaluation (physical and/or online tbc)	Report and presentation, describing the progress achieved. Overview of risks and contingency plans. Evaluation of the solution design progress presented by contractors.
	M1.3) End of phase 1 review: delivery of solution design	End of phase 1	Report + Presentation + evaluation (physical and/or online tbc)	Report and presentation, describing Phase 1 outcomes. Evaluation of the contractors' solution design.

Deliverables:	D1.1) Phase 1 Project Abstract	End of Month 1 of Phase 1	Report	Abstract (in the format required by the EU for publication) template
	D1.2) Interim Progress Report	Mid Phase 1	Report + presentation (physical and/or online tbc)	Report describing the progress achieved the solution design during the period in question and plans for the next period. Overview of risks and contingency plans.
	D1.3) Solution Design Report	End of phase 1	Report + presentation (physical and/or online tbc)	Report including technical, financial and commercial feasibility of the solution design. It should also include: • a description of any results generated (incl. technical results and any videos submitted). • a section that explains the IPR measures taken by the contractor to protect the results. • a list of names and location of personnel that carried out the R&D activities. • a declaration of the resources expended, broken down as in the offer. Due evidence of the resources deployed shall be appended to the report. • the measures taken to protect results. • a declaration that at least 50% of the work was carried out within the EU27 or a country associated to Horizon 2020. • Business model and commercialisation plan.
	D1.4) Abstract of the main Results achieved	End of Phase 1	Report	Abstract (in the format required by the EU for publication) template

Table II. Expected outcomes. Phase 2: Prototyping

Phase 2: Prototyping				
Objective:	At the end of phase 2, R&D providers will have to: • Transform their solution design plans into prototypes. • Develop, demonstrate, and validate prototypes in lab conditions (limited number of first products or test series) which meet the challenge of the PCP call. • Present advanced plans for conducting field testing in phase 3, including application for ethical approval if required. To monitor the progress and facilitate the dialog, the phase will have a series of iterations, each ending with a monitor briefing, where the contractor presents the status of the prototype to the buyer's group and receives feedback on the current status.			
Output and results:	Prototypes demonstrated and validated in lab conditions containing the potential to meet the specification outlined in section 2.1.1. The End of Phase Report shall be a written documentation of the prototype including development details, operational procedures and a report explaining the output and feedback from the monitoring briefings by the buyers group. Delivery of field-testing plans (including how to approach the ethical aspects), if required.			
Milestones and deliverables		**By when?** ***(See section 2.6 Time schedule)***	**How?**	**Output and results**
Milestones:	M2.1) Kick-off Phase 2 meeting	Start of Phase 2	Physical or online meeting tbc	Presentation of Phase 2 procedures, methodologies, timelines, and actors involved by the monitoring team and plans to deliver Phase 2 by contractors. Q&A.
	M2.2) First Prototype iteration	Month 3 of Phase 2	Report + presentation + evaluation (physical and/or online tbc)	Report and presentation, describing the progress achieved. Overview of risks and contingency plans. Evaluation of the solution design progress presented by contractors.
	M2.3) Second Prototype iteration – interim progress monitoring	Month 6 of Phase 2	Report + presentation + evaluation (physical and/or online tbc)	Report and presentation, describing the progress achieved. Overview of risks and contingency plans. Evaluation of the solution design progress presented by contractors.
	M2.4) Prototype validation in lab conditions	Month 9 of Phase 2	Demonstration	Physical demonstration (in contractors' facilities) or online demonstration tbc
	M2.5) Demonstration to EU representatives	Month 9 of Phase 2	Demonstration to EU representatives	Physical demonstration or online demonstration tbc
	M2.6) End of Phase 2 review	End of Month 10	Report	Report and presentation, describing Phase 2 outcomes. Evaluation of the contractors' solution prototype.

	M2.7) Plans the development of the Phase 3 Field - Test	2 months before the end of Phase 2	Report	Description of the plans proposed for the development of the field testing, including ethical implications (if appropriate).
Deliverables:	D2.1) Phase 2 project abstract	End of Month 1 of Phase 2	Report	Abstract (in the format required by the EU for publication) template
	D2.2) First iteration prototype	Month 3 of Phase 2	Demonstration of the status of the Prototype. (Virtual / physical meeting tbc). Progress report.	Demonstration and report describing the progress achieved during the period in question and plans for the next period. Overview of risks and contingency plans. Demonstration.
	D2.3) Interim Progress Report	Month 6 of Phase 2	Demonstration of the status of the Prototype. (Virtual / physical meeting tbc). Progress report	Demonstration and report describing main progress achieved during the period in question and plans for the next period. Overview of risks and contingency plans.
	D2.4) Prototype validation in lab conditions	Month 9 of Phase 2	Physical or Online demonstration	Evaluation of the whole Prototype phase in a presentation and report, including Prototype lab test results
	D2.5) Demonstration to EU representatives	Month 9 of phase 2	Physical or Online demonstration of prototype to EU representatives	Evaluation of the whole Prototype phase in a presentation including Prototype lab test results
	D2.6) Field testing plans	Month 8 of Phase 2	Report	Plans for the field-testing including the approach to the ethical aspects.

	D2.7) Prototype development report	End of Phase 2	Report + presentation (physical and/or online tbc)	Report including technical, financial and commercial feasibility of the outcome prototype. It should also include: • a description of any Results generated (incl. technical results and any videos submitted). • a section that explains the IPR measures taken by the contractor to protect the results. • a list of names and location of personnel that carried out the R&D activities. • a declaration of the resources expended, broken down as in the offer. Due evidence of the resources deployed shall be appended to the report. • the measures taken to protect results. • a declaration that at least 50% of the work was carried out within the EU27 or a country associated to Horizon 2020. • Update business model and commercialisation plan
	D2.8) Abstract of the main results achieved	End of Phase 2	Report	Abstract (in the format required by the EU for publication) template

Table III. Expected outcomes. Phase 3: Development & testing

Phase 3: Field testing	
Objective:	In this final Phase, the prototypes are developed further into solutions that are piloted and validated in real-life settings. The objective is to provide the Buyers Group with sufficient insight into the capabilities of the vendor to provide a solution that can work in a real-life environment, in real conditions. The field testing will consist of a utilization of the solution in real life condition with a **minimum of 320 users recruited (160 as users/160 as control) during 6 months** (with 1 interim assessment), 80 users involved in each region concurrently, and the equipment is expected to remain in situ for ongoing post project testing one (1) year after the finalization of the project.
Output and results:	The output is the successful completion of the four field-testing in the environment of the final users. The results should be described in an End of Phase Report and demonstrated to the Buyers Group as input towards the potential future procurement procedure after eCare has run its course.

Milestones and deliverables		By when? *(See section 2.6 Time schedule)*	How?	Output and results
Milestones:	M3.1) Kick-off meeting Phase 3	Start Phase 3	Physical meeting	Presentation of Phase 3 procedures, methodologies, timelines, and actors involved by the monitoring team and plans to deliver Phase 3 by contractors. Q&A.
	M3.2) Participant Recruitment	End of Month 4 of Phase 3	Recruitment completion	Document containing signed informed consents from field-testing participants.
	M3.3) Field Testing starting at the different sites	Month 4 of Phase 3	Start of the Field Testing	Contractors start the Field Testing
	M3.4) Completion of the Field Testing	End of Month 10 of Phase 3	End of the Field Testing	Contractors finalize the Field Testing
	M3.5) Final demonstration to EU representatives	Month 11 of Phase 3	Physical demonstration	Physical demonstration to EU representatives
	M3.6) End of Phase 3 review	Month 11 of Phase 3	Report	Report and presentation, describing Phase 3 outcomes. Evaluation of the contractors' field testing
Deliverables:	D3.1) Phase 3 project abstract	End of Month 1 of Phase 3	Report	Abstract (in the format required by the EU for publication) template
	D3.2) Monthly monitoring Report	End of each month	Progress of the Field Testing and online presentation.	Progress report on period achievements, risks and plans for the next month. Feedback from the monitoring team. Q&A.
	D3.3) Interim Field-Testing report	Month 6 of Phase 3	Report + presentation (physical and/or online tbc)	Report describing main progress in achieved the field-testing during the period in question and plans for the next period.
	D3.4) Demonstration to EU representatives	Month 11 of Phase 3	Demonstration	At the end of phase 3, a final demonstration to the EU of the final products or services developed during the 3 phases.
	D3.5) End of Phase Report	End of Phase 3	Report	Evaluation of the solution performance, including field testing outcomes and impact report. It should also include: • a description of any Results generated (incl. technical

				results and any videos submitted). • a section that explains the IPR measures taken by the contractor to protect the results. • a list of names and location of personnel that carried out the R&D activities. • a declaration of the resources expended, broken down as in the offer. Due evidence of the resources deployed shall be appended to the report. • the measures taken to protect results. • a declaration that at least 50% of the work was carried out within the EU27 or a country associated to Horizon 2020. Update business model and commercialisation plan
	D3.6) Abstract of the main Results achieved	End of Phase 3	Report	Abstract (in the format required by the EU for publication) template

Each end-of-phase report shall contain:

- a description of any Results generated (incl. technical results and any videos submitted)
- a section that explains the IPR measures taken by the contractor to protect the results
- a list of names and location of personnel that carried out the R&D activities
- a declaration of the resources expended, broken down as in the offer. Due evidence of the resources deployed shall be appended to the report.
- the measures taken to protect Results
- a declaration that at least 50% of the work was carried out within the EU27 or a country associated to Horizon 2020

Milestones and Deliverables for the Phases 2 and 3 are indicative at this stage and could be subject to change. Any changes will be included in the respective Phase's call-off stage.

For phase 2, prototype validation is expected to be done at the premises of the procurers. The validation will preferably take place at the premises of one procurer (to be confirmed). Phase 3 field-testing, for each of the solutions, is expected to take place in **1 Hospital or care service per member of the Buyers Group Members.** Each contractor needs to set aside resources for testing the solutions on the premises of all the procurers in the buyers group. The contractor needs to plan to have resources available to carry out testing sequentially and in parallel at the different sites, if necessary.

The timing and locations for the physical meetings in all Phases, particularly in the Phases 2 and 3, are indicative at this stage and could be subject to change. The eCare Buyers Group

reserves the right to adjust the duration of the iteration periods, meetings frequency and locations if necessary. This will be communicated in a timely manner to all Tenderers.

2.2 Tender closing time

All tenders must be completed, electronically signed, and submitted via the eTendering platform provided by the closing date and time as stated: **15th September 2021, at 12:00 midday (CET)**.

Tenderers must follow all instructions given in the tender documents: TD1 - Request for tenders, TD2 – PCP Challenge and TD3 - Forms (From Form 1 to Form 6).

The eCare eTendering Platform will be the online tool for submitting tenders, accessible at: https://ecare.app.jaggaer.com/web/login.html.

The Tender documents are published on the eCare website: https://ecare-pcp.eu/tender.html

You should also download them from the eTendering Platform after registration.

An eTendering response manual to facilitate the preparation and submission of offers is available to all registered tenderers in the eTendering Platform with instructions to express interest, prepare, sign and submit the offers through the eTendering Platform. Tenderers are encouraged to carefully read the manual before submitting their offers.

2.3 Procurers and other parties involved in the PCP

This procurement relates to a joint PCP that will be carried out by the following **lead procurer**: **Azienda Sanitaria Locale Benevento (ASL BN)**, local health agency of the Campania region in Italy.

The lead procurer represents the buyer's group for the funded procurement and is also part of the buyers group.

> **Lead procurer** — Beneficiary of the EU grant that represents the buyer's group for the funded procurement (and is also part of the 'buyers group' if it contributes to the PCP procurement budget).

ASL BN will act as the authority which carries out the PCP procurement on behalf and in the name of a cross-border buyers group of eCare contracting authorities with parties from three European countries: Italy, Spain and Germany.

The lead procurer is appointed to coordinate and lead the joint PCP, and to sign and award the framework agreement and the specific contracts for all phases of the PCP, in the name and on behalf of the following **buyers group**:

- **Universitätsklinikum Aachen (UKA)**, in North Rhine-Westphalia region in Germany
- **Consorci Sanitari Integral (CSI)**, in Catalonia region, Spain.
- **Santander City Council (SDR)**, in Cantabria region, Spain.

The lead procurer is part of the buyers group.

> **Buyers group** — Beneficiaries of the EU grant that form the group of procurers that contribute to the PCP procurement budget.

The procurers in the buyers group have the following background/profile/responsibilities for:

Buyers Group	Responsibilities
ASL BN	PCP coordination, monitoring and reporting management Field testing evaluation - Coordination
UKA	Feasibility study evaluation - Coordination
CSI	Prototype development evaluation - Coordination

The **consortium as a group** are experienced public providers from 3 EU Member States. All procuring partners has experience in innovation activities and being facilitators for developing pilots in their context. All procurers are fully committed to large-scale procurements of solutions based on the outcomes of eCare project. Partners are also committed to disseminate the results to potential future procurers in general but in particular to those entities with the same profile and belonging to their communication networks.

The procurers in the buyer's group have responsibilities within their respective countries with regard to setting the acquisition and/or regulatory strategy for the innovative solutions and within eCare provision of field trial test sites.

- **Azienda Sanitaria Locale Benevento**, the lead procurer, is one of the 7 Local Health Agency of the Campania region in Italy. It is a public entity with managerial, technical and financial autonomy. This kind of public entities have been created by the Italian Public Administration so as to manage the health issues at regional level. Indeed, it carries out the tasks of the national health system in the geographical area of the province of Benevento. The population of Campania region is 5,820,268 inhabitants, from which in the Benevento province has 282,700 inhabitants. It is organized in 5 districts including hospitals and three multifunctional health centres, including prevention and mental health departments. As part of its responsibilities, it is responsible of the procurement launch, participate in the evaluation of the proposals and contract implementation.

- **Universitätsklinikum Aachen** is a supramaximal care provider and the University Hospital RWTH Aachen combines patient-oriented medicine and care, teaching and research at an international level. With 36 specialized clinics, 28 institutes and five interdisciplinary units, the university hospital covers the entire medical spectrum. More than 6,000 employees are responsible for the treatment of 50,000 inpatient and 200,000 outpatient cases per annum. The University Hospital has a bed capacity in total about 1,400, over 200 beds are in the intensive care unit. It is responsible of the joint launch of the call for tender, contribute to the PCP preparation, participate in the evaluation of the proposals and contract implementation monitoring.

- **Consorci Sanitari Integral** is a public organization of health and social services, which manages 14 centres in Barcelona and Baix Llobregat of Catalonia, in Spain. CSI activity covers a reference population of 770,000 inhabitants, 3,400 professionals and 740 beds in operation and a potential influence area of 2,400,000 inhabitants. It is an institution that covers both the social and health sectors and brings an integrate vision between the two dimensions and also with an integrated territorial vision. It is responsible of the joint launch of the call for tender, contribute to the PCP preparation, participate in the evaluation of the proposals and contract implementation monitoring.

- **Santander City Council** is a public body, local government of the city of Santander, located in the Cantabria region in Spain and competences in public health and social care. The city concentrates a population of ca. 173,000 inhabitants of the 582,206 inhabitants in the Cantabria region. The ageing rate (percentage of population over 65 years old) is 24.4%,

greater than the 21.5% of regional figure (2018). Currently, City Council provides home help service to 890 users It is responsible of the joint launch of the call for tender, contribute to the PCP preparation, participate in the evaluation of the proposals and contract implementation monitoring.

The following entities are not in the buyer's group but participate as **third parties giving in-kind contributions** to the procurers for the purpose of carrying out the PCP:

- **Azienda Ospedaliera Universitaria Federico II** is an excellence health care facility in Southern Italy, that hosts over 50 Specialist Courses and master's degrees of Federico II University Medical School. It provides in hospital admittance, day-hospitals, day-services, and outpatient activities. It participates giving in kind contributions against payment (Article 11 EU Grant Agreement) to ASL Benevento so as to reinforce the Lead Procurer Role in the validation of eCare unmet needs. They will also participate during the PCP evaluation process as expert partners in the sustainability and cost-efficiency aspects of the solutions. They will not have any right to the results or IPRs.

Third parties that provide in-kind contributions to the PCP — Entities that are neither lead procurer nor members of the buyers group but that participate in the EU grant as third parties giving in-kind contributions to the PCP.

The following entities are participating as **preferred partners** with an interest in the PCP, but without being part of the buyer's group or giving in-kind contributions for carrying out the PCP:

- **Science and Innovation Link Office (SILO)**, Calle Claudio Coello, 52 – 1º, 28001, Madrid, Spain
- **Ticbiomed,** Calle Campus Universitario, 7 Edificio CEEIM, 30100 Espinardo, Murcia, Spain
- **SCMA,** Estr. da Portela, 2610-143 Amadora, Portugal
- **Jaggaer,** Avenida de Manoteras, 20, 28050, Madrid, Spain

Preferred partners — Entities that are neither lead procurer, nor members of the buyers group, nor third parties providing in-kind contributions to the PCP, but that have a special interest in closely following the PCP. They may be beneficiaries/linked third parties involved in the EU grant *(e.g. those involved in 'related additional networking activities')* or they may be other entities that are not involved in the EU grant *(e.g. other procurers on the market that are potential buyers for the solutions and have expressed an interest in closely following the PCP)*.

The preferred partners will be informed of all aspects of the eCare PCP and will be afforded access to all information concerning the PCP as they will take part of the different evaluation and monitoring committees. However, they will not assume to results or IPRs.

Below it is presented a table with the preferred partners involved and their involvement:

Preferred partner	PCP involvement task
***SILO, Ticbiomed and SCMA **Jaggaer**	Pilot testing and implementation phases 1-2-3 (*support in monitoring and evaluation) (**eTendering Platform support and configuration)

The procurers are supported by three digital and health organisations. **Jaggaer and SILO,** Spain, are supporting the procurers throughout the PCP process and coordinating the project. **TicBioMed**, Spain, is responsible for supporting the procurers in carrying out the Open Market Consultation

activities and coordinating the dissemination and exploitation of results. **SCMA**, Portugal, is leading the identification, analysis and validation of end-users needs and the evaluation of the project results.

Apart from the entities describe above in this section and those entities forming part of the eCare consortium there are individuals, external to the consortium partners, that form part of the eCare **Advisory Board**. These individuals have special interested in closely following the PCP and besides advising the eCare steering board they will have responsibilities in the evaluation of the proposals and the results and outcome provided by the awarded entities. In any case, they will participate under full confidentiality, and they will not have any right to the results or IPRs.

2.4 Contracting approach

The PCP will be implemented by means of a **framework agreement** with call-offs for **specific contracts** for each of the 3 R&D phases (altogether 'contracts').

Following the tendering stage, a framework agreement and a specific contract for phase 1 will be awarded to a minimum of 8 (eight) contractors.

A call-off will be organised for phase 2, with the aim of awarding a minimum of 4 phase 2 contracts. Only offers from contractors that successfully completed phase 1 will be eligible for phase 2. The procurers will validate the phase 2 prototypes in a single location to be determined during the action, taking into account the pandemic restrictions.

A call-off will be organised for phase 3, with the aim of awarding a minimum of 2 phase 3 contracts. Only offers from contractors that successfully completed phase 2 will be eligible for phase 3. Phase 3 field-testing is expected to take place at all the sites where buyers are based:

- Benevento (Italy),
- Santander (Spain),
- Aachen (Germany) and
- Region of Catalonia (Spain)

The framework agreement sets all the framework conditions for the entire duration of the PCP (covering all the phases). There will be no renegotiation. The framework agreement will remain binding for the duration of all phases for which contractors remain in the PCP. Tenderers that are awarded a framework agreement will also be awarded a specific contract for phase 1 (evaluation of tenders for the framework agreement and phase 1 are combined). Tenderers are therefore asked not only to submit their detailed offer for phase 1, but also to state their goals, and to outline their plans *(including price conditions)* for phases 2 and 3, thus giving specific details of the steps that would lead to commercial exploitation of the R&D results.

In the following table a summary of the overall timing of the PCP including its individual phases (excluding evaluation periods) is detailed.

Table IV. Overall timing of the PCP individual phases (excluding evaluation periods)

Phase	Start date	End date	Duration
Call for tenders	July 2021	15th September 2021	2.5 months
Phase 1	November 2021	April 2022	5.5 months
Phase 2	July 2022	April 2023	10 months
Phase 3	July 2023	June 2024	12 months

The offers for the next phase will be requested together with the end-of phase deliverables for the previous phase (In this case all contractors of the previous phase will be invited to make offers for the next phase, successful completion of the previous phase is evaluated before evaluating the offers

for the next phase, to determine which offers are eligible to proceed to the evaluation of offers for the next phase)

2.5 Total budget and budget distribution (per phase)

The **total budget for the PCP** is **3,920,000 €** (Italian VAT, 22%, included) covering all contracts to procurers in all phases. The budget distribution is detailed in the following table:

Table V. eCare budget distribution among phases

Type	Phase 1	Phase 2	Phase 3
Maximum total budget per phase (Italian VAT included)	392,000 €	1,960,000 €	1,568,000 €
Expected minimum number of contractors to be funded	8	4	2
Maximum budget per contractor (Italian VAT included)	49,000 €	490,000 €	784,000 €
Duration of the phase	5.5 months	10 months	12 months

IMPORTANT NOTICE: In case of not reaching the minimum number of selected R&D providers that EC recommends (3) in phase 1, the call for tender will be cancelled.

- **For phase 1: Feasibility study to identify the innovative cost-effective solutions in the field of frailty**

Each solution design contract will last for a maximum of 5.5 months and is valued up to 49,000 € each (VAT included against a total budget of 392.000€ (VAT included). An expected minimum of 8 suppliers would be awarded the contract. All phase 1 contracts will start at the same date and time which will be set by the Buyers Group. The start date selected will not be later than **1st November 2021.**

This phase is a feasibility study of the selected technologies and proposals, which aims to verify the technical, economic and organizational feasibility of each company's offer. The expected output from participating companies is a report describing the results of the feasibility study and the conclusions for the start of the development activities in Phase 2.

- **For phase 2: Prototyping development**

Each Prototype development contract will last for a maximum of 10 months is valued up to 490.000€ each (VAT included) against a total budget of 1,960,000€ (VAT included). An expected minimum of 4 suppliers would be awarded the contract.

Selected companies will each develop a prototype based on the results of their feasibility study. The aim is to verify to what extent the prototype's main features meet the functional and performance requirements set in the challenge. Participating companies are expected to deliver a prototype specification during lab demonstration, as well as a plan for original development of a limited volume of first solutions and field-testing, and an updated cost/benefits evaluation including a preliminary business plan.

- **For phase 3: Pre-commercial development, field test**

Each Pre-commercial development contract will last for a maximum of 12 months and is valued up to 784,000€ each (VAT included) against a total budget of 1,568,000€ (VAT included). An expected minimum of 2 suppliers would be awarded the contract.

This phase aims to verify and compare the full feature set and performance of different solutions in real-life operational conditions. The aim is to verify to what extent the prototype's main features meet the functional and performance requirements set in the challenge.

Testing will occur at the four sites by the procurers to ensure that a comparison of performance can be made both across sites and across solutions. ASL BN, UKA, CSI and SANTANDER will identify collaborating testing participants and will lead the proof of concept.

The total budget for the 3 phases of eCare PCP is fixed at 3,920,000€ (VAT included) and will not be increased. Any surplus at the end of the PCP will be returned to the EU Commission.

For phases 1 and 2, contracts will be financed until the remaining budget is insufficient to fund the next best tender. The exact number of contracts finally awarded will thus depend on the prices offered and the number of tenders who pass the evaluation. As leftover budget from the previous phase will be transferred to the next phase, the total budget available for phases 2 and 3 may eventually be higher than stated here (but the maximum budget per contractor for phases 2 and 3 will remain the same). The lower the average price of tenders, the more contracts can be awarded. However, the total value of the contracts awarded can also be lower than initially expected if there are fewer tenders than expected that meet the minimum evaluation criteria.

2.6 Time schedule

The following table gives an overview of the planned timing of the eCare PCP phases:

Table VI. Planned Time schedule

First tender procedure (framework agreement and phase I contracts)	
Date	**Activity**
25/06/2021	**Publication of contract notice in** TED
01/07/2021	**Publication of eCare PCP call for tender**
23/08/2021	Deadline for submitting questions about tender documents
1/09/2021	Deadline for lead procurer to publish final replies to questions (Q&A document)
15/09/2021	**Deadline for submission of tenders for the framework agreement and phase 1**
16/09/2021	**Opening of tenders**
28/10/2021	**Tenderers notified of decision on awarding contracts**
02/11/2021 to 08/11/2021	Standstill period: Rejected tenderers have 5 days to contest the decision
12/11/2021	Deadline for signing framework agreements and phase 1 specific contracts
16/11/2021	Publication of contract award notice in TED
Implementation of phase I, call-off / tendering for phase II	
17/11/2021	**Start of phase 1**
15/12/2021	Names of winning phase 1 contractors and their project abstracts to be sent to EU (template) and published on eCare PCP project website

12/01/2022	**Deadline for phase 1 interim milestone(s)/interim deliverable(s)**
21/01/2022	Feedback from phase 1 supervisor/monitoring team on phase 1 interim milestone(s)/interim deliverable(s)
28/01/2022	Deadline for the contractors to visit the premises(s) of the procurer(s) in order to learn about the operational boundary conditions governing the design of targeted solutions
15/04/2021	**Deadline to deliver phase 1 final milestone(s)/final report/deliverable(s) and for submitting call-off documents for phase 2**
28/04/2022	Deadline to assess of phase 1 final milestone(s)/final report/deliverable(s)
29/04/2022	Phase 1 contractors notified as to whether they have completed this phase satisfactorily and successfully
29/04/2022	**End of phase 1**
29/04/2022	Summary of the results and conclusions achieved by each contractor during the phase sent to EU (template)
30/05/2022	Payment of phase 1 to contractors that completed this phase satisfactorily
	Second tender procedure (call-off for phase 2)
	Launch call-off for phase 2 (only offers from contractors that successfully completed phase 1 are eligible)
29/03/2022	Deadline for submitting questions on phase 2 call-off documents
05/04/2022	Deadline for lead procurer to circulate replies to questions to phase 2 bidders
15/04/2022	**Deadline to submit call-off for phase 2 (only offers from contractors that successfully completed phase 1 will be evaluated)**
02/05/2022	**Opening of phase 2 offers**
10/06/2022	**Contractors notified of decision on awarding phase 2 contracts**
13/06/2022 to 17/06/2022	Stand-Still period: Rejected tenderers have 5 days to contest the decision
30/06/2022	Deadline for signing of phase 2 specific contracts
Implementation of phase II, call-off / tendering for phase III	
01/07/2022	**Start of phase 2**
29/07/2022	Names of winning phase 2 contractors and their project abstracts published on eCare PCP project website and sent to EU
09/12/2022	**Deadline for phase 2 interim milestone(s)/deliverable(s)**
16/12/2022	Deadline for the supervisor/monitoring team to visit the contractor's / procurer's premises to check completion of interim milestone(s)/deliverable(s). This visit can be changed to a remote meeting if the supervisor/monitoring team consider it valuable.
13/01/2023	Feedback from supervisor/monitoring team on phase 2 interim milestone(s)/deliverable(s)
16/01/2023	Interim payments
27/03/2023	Lab testing of the prototype developed during phase 2
07/04/2023	Feedback from phase 2 supervisor/monitoring team on lab testing of the prototype
07/04/2023	Demonstration of prototype for the EU technical review of phase 2

14/04/2023	**Deadline to deliver phase 2 final milestone(s)/final report /deliverable(s) and for submitting call-off for phase 3 offers**
27/04/2023	Deadline for the assessment of phase 2 final milestone(s)/final report/deliverable(s)
28/04/2023	Phase 2 contractors notified as to whether they have completed this phase satisfactorily and successfully
28/04/2023	**End of phase 2**
28/04/2023	Summary of the results and conclusions achieved by each contractor during the phase sent to EU (template)
30/05/2023	Payment of balance for phase 2 to contractors that completed this phase satisfactorily
	Third tender procedure (call-off for phase 3)
27/03/2023	Deadline for submitting questions about phase 3 call-off documents
03/04/2023	Deadline for lead procurer to circulate replies to questions to phase 3 bidders
14/04/2023	**Deadline to submit call-off for phase 3 (only offers from contractors that successfully completed phase 2 will be evaluated)**
01/05/2023	**Opening of phase 3 offers**
16/06/2023	**Contractors notified of decision to award phase 3 contracts**
19/06/2023 to 23/06/2023	Stand-Still period: Rejected tenderers have 5 days to contest the decision
30/06/2023	Deadline to Sign phase 3 specific contracts
	Implementation phase 3
03/07/2023	**Start of phase 3**
31/07/2023	Names of winning phase 3 contractors and their project abstracts published on eCare PCP project website and sent to EU
15/12/2023	**Deadline for phase 3 interim milestone(s)/deliverable(s)**
12/01/2024	Feedback from phase 3 monitoring supervisor/monitoring team on phase 3 interim milestone(s)/deliverable(s) – interim assessment of the Field-testing progress
19/02/2024	Interim payments
30/04/2024	Deadline of the Field-testing of products/services developed during phase 3
17/05/2024	Feedback from phase 3 supervisor/monitoring team on field-testing of the products/services (after completed cycle testing)
10/06/2024	**Deadline to deliver phase 3 final milestone(s)/final report/ deliverable(s)**
31/05/2024	**Final demonstration of products/services developed during phase 3 (including to EU representatives)**
27/06/2024	Deadline to Assess phase 3 final milestone(s)/final report/deliverable(s)
28/06/2024	Phase 3 contractors notified as to whether they have completed this phase satisfactorily and successfully
28/06/2024	**End of phase 3**

28/06/2024	Summary of the results and conclusions achieved by each contractor during the PCP sent to EU for publication purposes (template).
30/08/2024	Payment of balance for phase 3 to contractors that completed this phase satisfactorily

Note: The time schedule is indicative. **The eCare Buyers Group reserves the right to adjust the time schedule if necessary**. This will be communicated in a timely manner to all Tenderers. The dates and total duration for Phase 2 and Phase 3, as well as the rest of intermediate dates, **are indicative at this stage and could be subject to change.**

Note: The standstill period for each phase will last 5 working days.

2.7 IPR issues

Ownership of results (foreground)

Each contractor will keep **ownership of the IPRs attached to the results they generate during the PCP implementation and also the results that are not IPRs** (i.e., know-how…). The tendered price is expected to take this into account.

Each Contractor is responsible for the management and protection of its IPRs and bears the costs associated with this.

The Lead procurer and the buyers group have the right to monitor the management of the IPRs.

The Contractors must inform the buyers group (via the Lead procurer) of results that can be exploited, regardless of whether they can be protected or not, **within ninety (90) days** from when they are generated.

The information submitted to the Lead procurer must include information about the contents of the results, the confirmation by the Contractor to protect them and the planned timing for protection.

If a Contractor does not seek protection for results that should be protected, the buyers group has the right to request that the results are transferred to them.

The Contractors grant to the members of the buyer's group irrevocable, royalty-free, non-exclusive, worldwide access rights to use the results, for their own purposes until their expiry date.

The ownership of the IPRs will be subject to the following:

- the buyers group has the right to:
  - access results, on a royalty-free basis, for their own use.
  - grant (or to require the contractors to grant) non-exclusive licences to third parties to exploit the results under fair and reasonable conditions (without the right to sub-license). As defined in the definition section of the Framework Agreement, "Fair and reasonable condition" means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, including in particular the actual or potential value of the Results or Background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged".
- The Contractors may grant non-exclusive licenses to Third parties allowing them to exploit the results (or otherwise give the right to exploit them) — unless this impedes the access rights of the Buyers group.
- The contractors will have to transfer ownership of the IPRs to the members of the buyers group if they fail to comply with their obligation to commercially exploit the results in the

following **four (4) years** after the end of the project or use the results to the detriment of the public interest, including security interests in the conditions of article 7.4 of the Framework Agreement.

Right of the Contractors to transfer the ownership of their results.

The Contractors may transfer ownership of their Results — unless this is prohibited (or restricted) by the security obligations and provided that they ensure that their obligations (in respect of the results) apply to the new owner and that this new owner is obliged to pass them on in any subsequent transfer.

In that situation, the Contractor must give them at least ninety (90) days advance notice of its intention to transfer ownership of the results and that this notification must include sufficient information on the new owner to enable the members of the Buyers group to assess the effects on their access rights. Any member of the Buyers group may object within forty-five (45) days of receiving notification, if it can show that the transfer would adversely affect its access rights. Should an objection be raised, the transfer may not take place until agreement has been reached between the parties concerned).

Commercial exploitation of results

Considering 19% of European population (Eurostat year 2018) is older than 65 and applying this factor to the EU-28 total population, 512.4 million (year 2018) there is a potential total market of more than 97 million end users. The old-age dependency ratio is 30.5% with a clear rising tendency. According to Eurostat it is forecasted that EU-28 total population will be increased up to 525 million in 2040 and then, decrease to 492.9 million in 2100. The EU-28 population over 80 is expected to rise from a 5.6% in 2018 to a 14.6% in 2100.

Older people in the European Union consumed goods and services totalling 3.7 million euros in 2015. In 2025, this expenditure is estimated to grow to 32% of EU GDP and 38% of employment with 88 million new jobs.

To promote and encourage the wide deployment of the produced solutions several actions are envisaged:

- During the market consultation, procurers were invited to participate at the dissemination meetings or at the webinar(s). The networks of the partners will be put in value to reach other potential procurers and make them aware of the future tender. Information about those that during the project lifetime express an interest on the topic will be curated and leveraged for future contact.
- At the end of each of the first two phases after the tender, there will be one written contact in the form of an email to communicate the advances and next steps within the process.
- At the end of the execution phase a webinar only for potential procurers will be held to share with them the insight, outcomes and lessons learnt. Those that express an interest to explore post-PCP adoption will be engaged in private conversations to explore synergies and follow-up actions.
- Finally, in collaboration with the EC, a final Infoday will be organized at the final stage of the project to share learnings and propose solutions to the bottlenecks identified during the project. The workshop will invite stakeholders from the PCP domain and the functional scope. After the workshop, a statement regarding policy recommendations will be produced and disseminated.

Contractors are expected to start commercial exploitation of the results, at the latest, **four (4) years** after the end of the framework agreement. Contractors shall, during this period, take measures to ensure that its results are exploited commercially (directly or indirectly, in particular through transfer or licencing).

If the Contractor fails to commercially exploit the results withing this period (or uses the results to the detriment of the public, interest, including security interest), the Buyers group has the right to require that ownership of the result be transferred to them.

"Failure to commercially exploit results" means not marketing a commercial application of the results (directly or indirectly, through a subcontractor or licensee), or undertaking specific activities beyond development to commercially exploit the results, e.g., certification of solution or contribution to standardization when applicable.

In this case, the Contractor shall be required to give the designs, source code and any element and documentation to the Buyers group for a suitable exploitation of the results.

The feasibility of the business plan to commercially exploit the R&D results will be assessed as part of the award criteria (see section 3.5).

Declaration of pre-existing rights (background)

The ownership of pre-existing rights will remain unchanged.

In order to be able to distinguish clearly between results and pre-existing rights (and to establish which pre-existing rights are held by whom):

- tenderers are requested to list the pre-existing rights for their proposed solution in their offers (see section 4.1.3)
- procurers and contractors will be requested to establish a list of pre-existing rights to be used before the start of the contract.

The Parties grant each other to each other's pre-existing rights and sideground for carrying out the tasks assigned to them in the PCP, for exploitation of results generated in the PCP and for using the results for their own purposes.

The parties must inform each other about the generation of changes in pre-existing rights and sideground within 15 days from the generation of the change and whether they rely on pre-existing rights for each phase of the PCP.

The Contractors are required to give a declaration of Background IPR in the technical offer (See Form 5: Technical Offer (TD-3 Forms) and section 4.1.3.

The Lead Procurer and other members of the Buyers group and Third parties providing in-kind contributions to the PCP do not hold any pre-existing rights relevant to the PCP contracts.

The Framework Agreement contains a provision that describes in more detail the rights and obligations of the different parties regarding the pre-existing rights and results.

Note: some of the IPR-related terms used in this document (e.g. background) do not necessarily have the same meaning as in the EU grant agreement.

3 Conditions and evaluation of tenders

3.1 Eligible tenderers, joint tenders and subcontracting

Participation in the tendering procedure is **open** on equal terms to **all types of operators from any country**, regardless of their geographic location, size or governance structure. There will, however, be a requirement relating to the place of performance of the R&D services.

At least 50% of the total value of activities covered by the framework agreement must be performed in the EU Member States or H2020 associated countries. The principal R&D staff working on the PCP must be located in the EU Member States or H2020 associated countries.

Tenders may be submitted by a **single entity** or in collaboration with others. The latter can involve either submitting a **joint tender** or subcontracting, or a combination of the two approaches.

Tender entities may not participate in more than one tender, be it as single entities or as part of a consortium submitting a joint tender. The Buyers Group reserves the right to exclude any tender in breach of this provision. For phases 2 and 3, participation is limited only to those tenderers that successfully completed the preceding phase.

The bidders, under penalty of exclusion, must meet the requirements set out in section 3.1.1. Pursuant to art. 59, paragraph 4, lett. b) of the Italian Public Procurement Code[5], offers without the qualification required by this Tender Specification are inadmissible.

3.1.1 Eligibility Criteria

In accordance with the Article 58 paragraph 2 Directive 2014/24/EU, as regards to the suitability to pursue the professional activity, the economic operators must be enrolled in one of the professional or trade registers kept in their Member State of establishment, as described in Annex XI of the Directive 2014/24/EU, or to comply with any other request set out in that Annex.

In order to prove the requirement, the contracting station automatically acquires the documents held by public administrations, subject to the indication by the economic operator of the elements necessary for the retrieval of the information or data requested.

3.1.2 Joint tenders

Consortium or a group of bidders that present a bid must assume joint and several liabilities for the performance of the contract.

A joint tender must specify the role, qualification and experience of each member of the consortium. The group of tenderers must select a 'lead contractor' who will have the power to sign the framework agreement and specific contracts provide in the name and on behalf of the group and will be the responsible for the contracts without prejudice to the existence of joint powers that they may grant for receiving and making payments of a significant amount. All members of the consortium shall be jointly and separately bound to fulfill the terms of the contracts.

The composition of the consortium cannot be altered without the consent of the lead procurer.

Joint tender submissions should indicate in the Tender:

A) Each organization/member name

[5] https://www.codiceappalti.it/Home/Legge/?legge=Italian_Procurement_Code

B) The percentage split per group/consortium member
C) How the group/organization will work in respect of this tender
D) Full contact details of the single point of contact of the 'lead contractor'.

Contact details of the tenderers must be stated in Form 1 Section of the Qualification envelope. See TD3 – Forms to obtain more information.

3.1.3 Subcontracting

As defined in the TD4 - Framework Agreement, subcontracting refers to any contract or agreement between the tenderer and any Third party whereby that Third party agrees to provide services to the tenderer to enable or assist the tenderer to provide all or any part of the services offered to the buyers group in the tender. Subcontracting is permitted in each Phase of the eCare PCP procedure.

Tenderers must state in the tender submission if they intend to subcontract any part of the PCP obligations to other suppliers and indicate in which extend. **Subcontracting must not exceed the 30% of the contract**, in compliance with the provisions of art. 105 of the Italian Procurement Code[6].

Tenderers will identify in the offer who the subcontractors are and which parts of the contract they will deliver in the project in the technical offer. Furthermore, the tenderer shall describe its approach in selecting and managing its sub-contractors. In the absence of such indications, subcontracting is prohibited.

The selection of a subcontractor to provide more than 10% of the work to be performed under any Specific Contract is subject to the approval of the Lead Procurer on behalf of the buyers group unless such subcontractor was identified in the tender or in the tenderer's offer for a phase as the entity to deliver the work concerned.

In this specific case, before subcontracted work begins in any Specific Contract, the Tenderer must provide the buyers group (Lead Procurer) with an originally signed agreement with the subcontractor including a clear description of the work to be subcontracted and a specific declaration.

The authorization request to subcontract must be presented to the Contracting Authority (Lead Procurer) at least 30 days before the start of the subcontracted services.

The Contracting Authority (Lead Procurer) receives the subcontracting request from the tenderer, with the complete documentation attached to issue the subcontract, for the verification of the technical requirements of the subcontractor as well as the anti-mafia suitability.

The terms for the issuance of this authorization by the Contracting Authority (Lead Procurer) must take place within the following thirty (30) days from the date of delivery of the Contractor's application.

In the event that the Contracting Authority (Lead Procurer) does not pronounce itself within the aforementioned terms and the requests are complete in the documentation, the tacit consent of the Contracting Authority is in force.

The Tenderer present authorization request with an originally signed agreement with the subcontractor including a clear description of the work to be subcontracted and a declaration that the subcontractor:

[6] https://www.codiceappalti.it/Home/Legge/?legge=Italian_Procurement_Code

- agrees to be bound vis-a-vis the tenderer by the provisions of the Framework Agreement and Specific Contract (in particular in relation to IPR) *mutatis mutandis*,
- meets the qualification requirements for the subcontracted services,
- has placed the required resources at the tenderer's disposal for the full duration of the specific contract,
- agrees to be bound by and complies fully with obligations imposed on subcontractors under the Grant Agreement, including those relating to the place of performance, the definition of R&D services, confidentiality, results and IPRs, the visibility of EU funding, conflicts of interest, language, obligation to provide information and keep records, audits and checks by the EU, the processing of personal data, liability for damages and ethics and security requirements,
- will not subcontract any of the work so subcontracted.

The Contractor must have adequate processes and procedures in place for managing and monitoring all of the subcontractors which the Contractor proposes to use in the delivery of this Contract. The Contractor will be responsible for the acts and omissions of its sub-contractors as though those acts and omissions were its own.

Contractors remain fully liable to the buyers group for the performance of the contract. Contractors must therefore assure that subcontractors are aware of the provisions set out in the tender documents including the related to IPRs.

Participation in the open market consultation is not a condition for submitting a tender.

3.2 Exclusion criteria

The exclusion criteria determine the situation of the Tenderers and subcontractors.

These criteria described below will be assessed based on the responses to questions in Form 2 section of the Qualification envelope on a pass/fail basis. See TD3 – Forms to obtain more information.

Table VII. Exclusion criteria

Exclusion criteria	Evidence
PART A Bankruptcy, insolvency, compulsory winding up, receivership, composition with creditors, or subject to relevant proceedings. A conviction (or convictions) for a criminal offence related to business or professional conduct. Legal or administrative finding of a commission of an act of grave misconduct in the course of business. Failure to fulfil obligations related to payment of social security contributions. Failure to fulfil obligations related to the payment of taxes. Failure to provide information required or providing inaccurate / misleading information when participating in procurement exercise.	Declaration of honor (Form 2: Exclusion criteria Part A)

Failure to obtain and maintain relevant licensing or membership of an appropriate trading or professional organization where required by law.	
PART B Criminal offences referred to in Article 2 of Council Framework Decision 2008/841/JHA of 24 October 2008 on combating organized crime. Corruption as defined in Article 3 of Council Act of 26 May 1997 preparation on the basis of Article K.3.2 c Treaty on European Union, the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of, and Article 3.1 Council Joint Action 98/742/JHA of 22 December 1998 adopted by the Council on the basis of Article K.3 of the Treaty on European Union, on corruption in the private sector. Money laundering as defined in Article 1 of Council Directive 91/308/EEC of 10 June 1991 on measures to prevent the financial system for money laundering, amended by European Parliament and Council Directive 2001/97/EC. Fraud within the meaning of Article 1 of the Convention drawn up on the basis of Article K.3 of the Treaty on European Union for the Protection of the Communities' financial interests. Terrorist offences or offences linked to terrorist activities as defined in Articles 1 and 3 of Council Framework Decision of 13 June 2002 on combating terrorism. Child labour and other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council of 5 April 2011 on preventing and combating trafficking in human beings and protecting its victims and replacing Council Framework Decision 2002/629/JHA. Is guilty of serious misrepresentation in supplying the information required under this section or has not supplied such information.	Declaration of honor (Form 2: Exclusion criteria)
PART C **C**onflict of Interest	Declaration of honor (Form 2: Exclusion criteria)

Tenderers that do not comply with these criteria (Part A, Part B and C) will be excluded.

3.2.1 PART A: DESCRIPTION

A tenderer will be excluded from further participation in the eCare PCP if it or any subcontractor on whose resources it relies upon in this procurement, does not meet one or several of the exclusion criteria. (See TD3 - Form 2 "Exclusion criteria part A")

The exclusion criteria are as follows:

- Bankruptcy, insolvency, compulsory winding up, receivership, composition with creditors, or subject to relevant proceedings.
- A conviction (or convictions) for a criminal offence related to business or professional conduct.
- Legal or administrative finding of a commission of an act of grave misconduct in the course of business.
- Failure to fulfil obligations related to payment of social security contributions.
- Failure to fulfil obligations related to the payment of taxes.
- Failure to provide information required or providing inaccurate / misleading information when participating in procurement exercise.
- Failure to obtain and maintain relevant licensing or membership of an appropriate trading or professional organisation where required by law.

Tenderers must confirm, by completing the Form 2 of the Qualification envelope that they are not subject to any of the exclusion criteria listed below; see TD3 - Form 2 "Exclusion criteria Part A" for more details.

3.2.2 PART B: DESCRIPTION

If the Lead Procurer becomes aware that a tenderer, a representative of the tenderer, or subcontractor, under a judgment that has entered into final legal force has been sentenced for a criminal offence listed below, such tenderer will be excluded from the PCP (See TD3- Form 2 "Exclusion criteria Part B"):

- Criminal offences referred to in Article 2 of Council Framework Decision 2008/841/JHA of 24 October 2008 on combating organized crime.
- Corruption as defined in Article 3 of Council Act of 26 May 1997 preparation on the basis of Article K.3.2 c Treaty on European Union, the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of, and Article 3.1 Council Joint Action 98/742/JHA of 22 December 1998 adopted by the Council on the basis of Article K.3 of the Treaty on European Union, on corruption in the private sector.
- Money laundering as defined in Article 1 of Council Directive 91/308/EEC of 10 June 1991 on measures to prevent the financial system for money laundering, amended by European Parliament and Council Directive 2001/97/EC.
- Fraud within the meaning of Article 1 of the Convention drawn up on the basis of Article K.3 of the Treaty on European Union for the Protection of the Communities' financial interests.
- Terrorist offences or offences linked to terrorist activities as defined in Articles 1 and 3 of Council Framework Decision of 13 June 2002 on combating terrorism.
- Child labour and other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council of 5 April 2011 on preventing and combating trafficking in human beings and protecting its victims, and replacing Council Framework Decision 2002/629/JHA.
- Is guilty of serious misrepresentation in supplying the information required under this section or has not supplied such information.

Tenderers must confirm, by filling the Form 2 section of the Qualification Envelope that they are not subject to any of the exclusion criteria listed below, See TD3 - Form 2 Exclusion criteria Part B for more details.

3.2.3 PART C: DESCRIPTION

Tenderers that are subject to a conflict of interest may be excluded. If there is a potential conflict of interest, tenderers must immediately notify the lead procurer in writing.

A conflict of interest is any situation where the impartial and objective implementation of the evaluation of tenders and/or implementation of the contract is compromised for reasons relating to economic interests, political or national affinity, family, personal life (e.g. family of emotional ties) or any other shared interest.

If an actual or potential conflict of interest arises at a later stage (i.e. during the implementation of the contract), the contractor must contact the lead procurer, who is required to notify the EU and to take steps to rectify the situation. The EU may verify the measures taken and require additional information to be provided and/or further measures to be taken.

Tenderers must confirm, by filling the Form 2 of the Qualification envelope that they are not subject to any conflict of interest See TD3 - Form 2 Exclusion criteria Part C for more details.

3.3 Selection criteria

The purpose of the selection criteria is to determine whether a tenderer has the technical and professional capacity necessary to carry out and perform the work.

These selection criteria will be evaluated on a pass/fail basis.

"Fail" means that the evidence given does not provide sufficient indication of the tenderer's expertise, ability and/or equipment to meet project's objectives. Any tenderer that cannot meet all requirements in this Section will not be selected. In case of joint tender, the selection requirements must be owned by the whole Consortium as a sum of the individual contributions.

3.3.1 Technical and professional capacity

The selection criteria are as follows:

Table VIII. Tenderer's selection criteria and fulfilment evidence to be provided

Selection criteria	Evidence
Ability to perform R&D up to original development of the first products or services and to commercially exploit the results of the PCP, including intangible results in particular IPRs.	Description of the capacity, materials and equipment that is available to the tenderer for research, prototyping and limited production and supply of the first set of products or services. Description of the financial and organisational structures that are available to the tenderer for management, exploitation and transfer of IPRs and for generating revenue by marketing commercial applications of the results

Tenderers that do not comply with this criterion will be excluded.

3.3.2 Ability to perform R&D up to original development of the first products or services and to commercially exploit the results of the PCP, including intangible results in particular IPRs.

Tenderers must have:

- The capacity, tools, material and equipment to:
  - Carry out research and lab prototyping
  - Produce and supply a limited set of first products or services and demonstrate that these products or services are suitable for production or supply in quantity and to quality standards defined by the procurers.

- The financial and organisational structures to:
  - Manage, exploit and transfer or sell the results of the PCP (including tangible and intangible results, such as new product designs and IPRs)
  - Generate revenue by marketing commercial applications of the results (directly or through subcontractors or licensees).

To measure this criterion, suppliers are asked to provide the following evidence:

- **Provide a description of relevant reference and /or previous projects (executed during the last 3 years)** which reflect the competences and capacity of the Tenderer in the different phases and domains of the eCare project, such as research, development, prototyping, testing and commercialization. These references will be based on previous projects of the Tenderers and /or other members of the joint consortia and subcontractors who will be working on the project. Tenderers should provide:
  - Provide a description of the capacity, materials and equipment that are available to the tenderer for research, prototyping and limited production and supply of the first set of products or services.
  - Provide a description of the digital health services and development of clinical solutions and SaMD (Software as a Medical Device) that suppliers have managed and developed during the last 3 years.
  - Provide a description of the projects related to Social and Health services for the management and prevention of frailty, in which suppliers have participated in the last 3 years.

  To describe these projects, the Tenderers will provide proof of the capacity, tools, materials and equipment to carry out research and lab prototyping and proof the capacity to produce and supply a limited set of first products or services, as well as demonstrate that these products or services are suitable for production or supply in quantity and to quality standards defined by the procurers.

  In addition, proof that they are able to manage, exploit and transfer or sell the results of the PCP (including tangible and intangible results, such as new product designs and IPRs) and able to generate revenue by marketing commercial applications of the results (directly or through subcontractors or licensees).

  Finally, tenderers have to provide the necessary competences to ensure that they are able to complete this PCP project.

- **Demonstrate the expertise and working experience required to undertake an innovative R&D project by** providing a number of CV of key personnel and competences, which they consider necessary to complete the project.
- **Confirm that the tenderer organization has a Business Continuity / Disaster Recovery / Risk Management** plan that ensure the described services are delivered in the

event of a disruption affecting your business and ensures continuity of supply / service from your critical suppliers**.**

- **Confirm that the Tenderer will take the appropriate level of insurance cover** if it is to be successful in winning the contract.

Each Tenderer shall describe, present and confirm the required references and competences in Form 3 section of the Qualification envelope. Should there be any doubt as to any of these criteria; tenderers may be requested to provide additional information **(see TD3 – Form 3 Selection criteria for more details).**

3.4 Compliance criteria

The purpose of the compliance criteria is to determine whether the Tender is compliant with the principles of PCP, public financing, place of performance, research integrity and security. These compliance criteria will be evaluated on a pass/fail basis, based on the responses to the questions in Form 4 Compliance Criteria of the Qualification envelope.

The offers for each phase will be evaluated against the compliance criteria A to E.

Tenders must comply with the following compliance criteria:

Table IX. Tenderers compliance criteria and fulfilment evidence to be provided

Compliance criteria	Evidence
A) Compliance with the definition of R&D services	Declaration of Honor (Form 4 Compliance Criteria Part A)
B) Compatibility with other public financing	Declaration of Honor (Form 4 Compliance Criteria Part B)
C)Compliance with the requirements regarding the place of performance of the contract	Evidence required as detailed below and Declaration of Honor (Form 4 Compliance Criteria Part C)
D) Compliance with ethics requirements	Declaration of Honor (Form 4 Compliance Criteria Part D) and further description of ethic assessment required.
E) Compliance with security requirements	Declaration of Honor (Form 4 Compliance Criteria Part E)
Additional compliance criteria for the call-off for phase 2	
As required for Phase 1	Evidence required as detailed below
Additional compliance criteria for the call-off for phase 3	
As required for Phase 1 and 2	Evidence required as detailed below

Tenders that do not comply with these criteria will be excluded.

These compliance criteria are fully described below:

3.4.1 A - Compliance with the definition of R&D services

Tenders that go beyond the provision of R&D services will be excluded.

R&D covers fundamental, industrial research and experimental development, as per the definition given in the EU R&D&I state aid framework[7]. It may include exploration and design of solutions and prototyping up to the original development of a limited volume of first products or services in the form of a test series. Original development of a first product or service may include limited production or supply in order to incorporate the results of field-testing and to demonstrate that the product or service is suitable for production or supply in quantity to acceptable quality standards[8]. R&D does not include quantity production or supply to establish commercial viability or to recover R&D costs. It also excludes commercial development activities such as incremental adaptations or routine or periodic changes to existing products, services, production lines, processes or other operations in progress, even if such changes may constitute improvements. The purchase of commercial volumes of products or services is not permitted.

The definition of services means that the value of any products covered by the **contract must be less than 50 % of the total value of the PCP Framework Agreement.**

The following evidence is required:

- the financial part of the offer for the framework agreement must provide binding unit prices for all foreseeable items for the duration of the whole framework agreement.
- the financial part of the offer for each phase must give a breakdown of the price for that phase in terms of units and unit prices for every type of item in the contract, distinguishing clearly the units and unit prices for items that concern products.
- the offers for all three phases may include only items needed to address the challenge in question and to deliver the R&D services described in the request for tenders.
- the offers for all three phases must offer services matching the R&D definition above.
- the total sum of the value of products offered in each phase and all previous phases must be less than 50 % of the total value of the framework agreement.

The evidence stated above demonstrating compliance with R&D services will be sought **through the breakdown of your financial offer** as stated (For each of the PCP Phases). See TD3 – Form 6 Financial offer for more details.

3.4.2 B - Compatibility with other public financing

Tenders that receive public financing from other sources will be excluded if this leads to double public financing or an accumulation of different types of public financing that is not permitted by EU legislation, including EU state aid rules.

Tenderers must- for each of the phases- sign a declaration of honor stating the absence of other incompatible public financing (See TD3 - Form 4)

3.4.3 C - Compliance with requirements relating to the place of performance of the contract

Tenderers will be excluded if they do not meet the following requirements relating to the place of performance of the contract:

- At least 50% if the total value of activities covered by the framework agreement must be performed in the EU Member States of H2020 associated countries. The principal R&D staff working on the PCP must be located in the EU Member States or H2020 associated countries.

[7] See Point 15 of the Commission Communication on a framework for state aid for research and development and innovation (C(2014) 3282).
[8] See Article XV(1)(e) GTO GPA 1994 and the article XIII (1)(f) of the revised WTO GPA 2014.

- At least 50% of the total value of activities covered by each specific contract for each PCP phase must be performed in the EU Member States or in H2020 associated countries. The principal R&D staff working on each specific contract must be located in the EU Member States or H2020 associated countries.

The percentage is calculated as the part of the total monetary value of the contract that is allocated to activities performed in the EU Member States or in other countries associated to Horizon 2020.

All activities covered by the contract are included in the calculation, i.e., all R&D and operational activities that are needed to perform the R&D services (e.g., research, development, testing and certifying solutions). This includes all activities performed under the contract by contractors and, if applicable, their subcontractors.

The principal R&D staff are the main researchers, developers and testers responsible for leading the R&D activities covered by the contract.

The countries associated to Horizon 2020 are those listed as associated countries in the Participant Portal Online Manual[9].

The following evidence is required:

- the financial part of the offer must provide binding unit prices for all foreseeable items for the duration of the whole framework agreement and give a breakdown of the price for the current phase in terms of units and unit prices (hours and unit price per hour), for every type of item in the contract (e.g., junior and senior researchers)
- a list of staff working on the specific contract (including for subcontractors), indicating clearly their role in performing the contract (i.e., whether they are principal R&D staff or not) and the location (country) where they will carry out their tasks under the contract.
- a confirmation or declaration of honor that, where certain activities forming part of the contract are subcontracted, subcontractors will be required in the financial offer to comply with the place of performance obligation to ensure that the minimum percentage of the total amount of activities that has to be performed in the EU Member States or in countries participating in Horizon 2020 is respected.

Tenderers shall - for each of the PCP Phases - provide a financial offer and present a list of staff working as well as a confirmation or declaration of honor for subcontractors as requested above.

3.4.4 D - Compliance with ethics and research integrity

Tenders will be excluded if they:

- Do not comply with the following rules:
  - Ethical principles (including the highest standards of research integrity, notably as set out in the European Code of Conduct for Research Integrity[10], and, in particular, avoiding fabrication, falsification, plagiarism and other research misconduct);
  - Applicable international, EU and national law, including those on checks, reviews and audits by the European Commission and the European Anti-fraud Office (OLAF) and on data protection.

[9] http://ec.europa.eu/research/participants/docs/h2020-funding-guide/index_en.htm
[10] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.

- Include plans to carry out activities that are prohibited in all Members States or in a country outside the EU (where those activities are allowed)

- Include activities whose aim is to:
  - Carry out human cloning for reproductive purposes.
  - Modify the genetic heritage of human beings in such a way as could make such changes heritable (with the exception of research relating to cancer treatment of the gonads)
  - Create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

- Include activities that do not focus exclusively on civil applications.

- Do not comply with the following ethics requirements included in the eCare project:
  - **Identification and Recruitment of participants for the field-testing activity:**

    Research participants will be recruited by procurers or delegated entities who ask their end-users to consider voluntary enrollment. Only certain people who have the target condition will be eligible to take part in the field test. **Details on the procedures and criteria that will be used to identify/recruit research participants will be provided.** During the PCP's Phase 3, the solutions awarded will be verified and compared against jointly defined criteria by the buyer's group and other concerned final end-users in real-life operational conditions to verify fitness for purpose in view of potential conversion into permanent service of the solutions. Expected output from participating companies includes firstly field testing, secondly field test specification, thirdly specification of the final solution and other related technical documentation, and finally an updated cost/benefit evaluation.

    Field testing will be undertaken at four (4) sites by the procurers, in Europe. **No transfer of personal data is planned to exchange or transfer with non-EU countries**. Previously collected data will NOT be used in the field tests. The consortium confirms that the ethical standards and guidelines of Horizon 2020 will be rigorously applied, regardless of the country in which the research is carried out. Furthermore, copies of the relevant ethics approvals from the host EU country and non-EU country will be submitted to the Commission.

    <u>Tenderers must be aware of this procedure and respect it.</u>

  - **Informed consent procedures**: Copies of templates of Informed Consent Forms and Information Sheets will be provided to the Commission. These must be drafted in a language and terms understandable to the participants. They will follow the Directive 2001/20/EC relating to the implementation of good field test practices. Hospitals involved in the field testing will implement these procedures.

    <u>Tenderers must be aware of this procedure in each Healthcare facility and respect it.</u>

  - **Vulnerable individuals/groups will not be involved in the field tests**: Details must be provided about the measures taken to avoid that vulnerable

individuals/groups[11] participate in the field-testing. Tenderers must ensure that this requirement is maintained.

- **Copies of ethical approvals for the collection of personal data by the competent Data Protection Officer / National Data Protection authority must be submitted**: In principle, ethical review is not required for our proof-of-concept study as:

  - Assignment of end users is not decided in advance by a protocol but falls within social and health care professional practice.

  - the decision to use the product is clearly separated from the decision to include a participant in the study.

  - no diagnostic or monitoring procedures will be undertaken other than those ordinarily applied in clinical practice.

  However, during the implementation of the PCP, this procedure will be again reviewed and if necessary, the procedure to obtained ethical approvals will be implemented. Each healthcare facility will initiate the procedure according to their own protocols and timings. Tenderers must be aware of the procedure and work together with the Hospital if further information should be required.

- **Justification must be given in case of collection and/or processing of personal sensitive data:** No personal sensitive data will be collected (i.e.: racial or ethnic origin of the data, political options, religious beliefs, membership of trade unions, sexual life, offences commission, sentences of any course for such offences, mental health condition. Tenderers must ensure that this requirement is respected.

- **Detailed information must be provided on the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation:** Data collection/storage/protection/retention/destruction and confirmation will follow the EU Directives: Directive 95/46/EC21 (Data Protection Directive) harmonizing a common standard set of data protection among the member states. Article 17 of the Directive 95/46/EC establishes the rules to ensure that the data controller implements appropriate technical and organisational measures to protect personal data from destruction, loss, unauthorised alteration, unauthorised disclosure or access, whether by accident or by unlawful action. Directive 2002/58/EC (Directive on privacy and electronic communications) for data in the communication sector, and Directive 2006/24/EC (Data Retention Directive) regulating data management in the context of public services delivered electronically. The European Commission plans to unify data protection within the European Union (EU) with a single law, the General Data Protection Regulation (GDPR).

[11] Vulnerable individuals/groups: groups that experience a higher risk of poverty and social exclusion than the general population. Ethnic minorities, migrants, disabled people, the homeless, those struggling with substance abuse, isolated elderly people and children all often face difficulties that can lead to further social exclusion, such as low levels of education and unemployment or underemployment.

According to the above explanation, tenderers must clearly explain how they ensure this requirement by answering Form 4 (Part D).

- **Ethical standards and guidelines of Horizon2020 will be rigorously applied**, regardless of the country in which the research is carried out. Furthermore, copies of the relevant ethics approvals from the host EU country and non-EU country must be submitted to the Commission. Tenderers must ensure that this requirement is maintained.

If the tender involves activities that raise ethical issues, the tenderer must submit an ethics self-assessment that:

- Describes how the tender meets the legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out.
- Explains in detail how the tenderer intends to address the ethical issues identified, in particular as regards:
  - Objectives (e.g. dealing with vulnerable populations and dual-use goods[12])
  - Methodology (e.g. involvement of children and related consent procedure and protection of data collected)
  - The potential impact (e.g. issues relating to the dual use of goods, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing and malevolent use of results).

For information on ethics issues, see the guidance for EU grant beneficiaries[13] How to complete your ethics self-assessment.

This ethics further information must be completed in Form 4 (Part D) of the Qualification Envelope. See TD-3 Form 4 for further details.

Attention: Call-offs for phases 2 and 3 may request that this information be updated in the offers submitted for these phases.

Before starting the particular task that raises ethical issues, contractors must provide a copy of:

- any ethics committee opinion required under national law; and
- any notification or authorisation for activities raising ethical issues required under national law.

The framework agreement contains a provision on ethics.

3.4.5 Compliance with security

Tenders will be excluded if they do not comply with EU, national and international law on dual-use goods or dangerous materials and substances.

Tenders themselves must not contain any classified information.

If the output of activities or results proposed in the tender raise security issues or uses EU-classified information, the tenderer must show that these issues are being handled correctly. In such a case, tenderers are required to ensure and to provide evidence of the adequate clearance of all relevant facilities. They must examine any issues (such as those relating to access to classified information

[12] See Article 2(1) EU export control Regulation No 428/2009.
[13] http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

or export or transfer control) with the national authorities before submitting their offer. Tenders must include a draft security classification guide (SCG), indicating the expected levels of security classification.

Call-offs for phases 2 and 3 may request that this security information be updated in the offers submitted for that phase.

Before starting the particular task that raises security issues, contractors must provide a copy of any export or transfer licenses required under EU, national or international law.

Attention: Should there be any doubt as to any of these criteria, tenderers may be requested to provide additional information.

3.5 Award criteria

A tender will be evaluated against the award criteria set out here only if the tenderer is not excluded through application of the exclusion criteria, and only if the requirements in the selection criteria, the compliance award criteria, and the administrative instructions are met.

The award criteria scorecard and the overall tender evaluation approach developed in eCare PCP has been informed by the value-based procurement principles and guidelines in Directive 2014/24/EU, by the Horizon 2020 approach to evaluation of R&D projects, and by the national and regional experiences of the four procuring organisations.

3.5.1 Phase 1

Below we describe the weighted award criteria for entering phase 1:

Table X. Weighted award criteria phase 1: criteria breakdown

Award criteria	Description		Maximum points	Thresholds
C0	Project Management quality criteria – feasibility and organization			
	C0.1	Methodology of the project, including risk management and quality assurance	5	
	C0.2	Quality and completeness of the work-plan as well as detail of task and result descriptions	5	
	C0.3	Feasibility of plan and resources to meet the objectives specified	5	
		TOTAL Project Management quality criteria	15	6
C1	Functional quality criteria - Ability to satisfy the need			
	C1.1	Frailty screening	8	
	C1.2	Frailty management and prevention	8	
	C1.3	Develop integrated pathways	6	
	C1.4	Develop knowledge sharing	6	
	C1.5	Parameters/measuring units	2	
		Total functional quality criteria	30	12

C2	Technical soundness and non-functional quality criteria			
	C2.1	Methodology	4	
	C2.2	Data analysis	4	
	C2.3	Architecture, scalability and performance	4	
	C2.4	Compatibility, interoperability and adaptation to local context	4	
	C2.5	Security	2	
	C2.6	Usability and configurability	2	
	TOTAL Technical soundness and non-functional quality criteria		20	8

C3	Organizational and legal criteria			
	C3.1	Organizational and staff	4	
	C3.2	Commercialization	4	
	C3.3	Legal and regulatory	2	
	TOTAL Organizational and legal criteria		10	4

C4	Innovation and Impact of the proposed solution			
	C4.1	Level of innovativeness and ability to go beyond the state-of-the-art	5	
	C4.2	Value of benefits due to the solution innovation for patients and procurers including what is expected from the solutions in clinical and social aspects	5	
	C4.3	Evidence of technical and economic effectiveness, reliability and sustainability of the vision and of the business plan	5	
	C4.4	Reproducibility of the solution through an adequate industrial process in accordance with the relevant market features	5	
	C4.5	Actions implemented to limit the solution costs through its life cycle	5	
	TOTAL Innovation and Impact criteria		25	10

TOTAL QUALITY SCORE	**100**	**40**

3.5.2 Phase 2

Below we describe the weighted award criteria for entering phase 2:

Table XI. Weighted award criteria phase 2: criteria breakdown

Award criteria	Description		Maximum points	Thresholds
C0	Project Management quality criteria – prototype feasibility and development			
	C0.1	Methodology of the prototype development and demonstration, including risk management and quality assurance of prototype	5	
	C0.2	Quality and completeness of the work-plan, detail of specification, demonstration of prototype and result descriptions	5	
	C0.3	Feasibility of plan and resources to development proposed prototype	6	
		TOTAL Project Management quality criteria	16	-
C1	Functional quality of prototype solution criteria - Ability to satisfy the need			
	C1.1	Frailty screening	8	
	C1.2	Frailty management and prevention	8	
	C1.3	Develop integrated pathways	5	
	C1.4	Develop knowledge sharing	5	
	C1.5	Parameters/measuring units	2	
		TOTAL functional quality criteria	28	-
C2	Technical soundness and Non-functional quality of prototype solution criteria			
	C2.1	Methodology of the prototype development	4	
	C2.2	Data analysis	2	
	C2.3	Architecture, scalability and performance	4	
	C2.4	Compatibility, interoperability and adaptation to local context	4	
	C2.5	Security	2	
	C2.5	Usability and configurability	4	
		TOTAL Technical soundness and non-functional quality criteria	20	-
C3	Organization and Legal Criteria			
	C3.1	Organizational and staff	4	
	C3.2	Commercialization	4	
	C3.3	Legal and regulatory	2	
		TOTAL Organizational and legal quality criteria	10	-

C4	Innovation and Impact of the proposed prototype			
	C4.1	Level of innovativeness and ability to go beyond the state-of-the-art	4	
	C4.2	Value of benefits due to the prototype for patients and procurers including what is expected from the solutions in clinical and social aspects	5	
	C4.3	Evidence of technical and economic effectiveness, reliability and sustainability of the vision and of the business plan	5	
	C4.4	Reproducibility of the prototype through an adequate industrial process in accordance with the relevant market features	6	
	C4.5	Actions implemented to limit the prototype costs through its life cycle (development, setting, testing, maintenance, management, disposal and removal)	6	
		TOTAL Innovation and Impact criteria	26	-

TOTAL QUALITY SCORE	**100**	**50**

3.5.3 Phase 3

Below we describe the weighted award criteria for entering phase 3:

Table XII. Weighted award criteria phase 3: criteria breakdown

Award criteria	Description		Maximum points	Thresholds
C0	Project Management quality criteria – solution feasibility and development			
	C0.1	Methodology of the prototype implementation and assessment in real world conditions, including risk management and quality assurance	4	
	C0.2	Quality and completeness of the work-plan, detail of implementation, testing and assessment of prototype and result descriptions	4	
	C0.3	Feasibility and resources to management prototype's life cycle (industrialization, production, delivery, setting, usage, maintenance, management, disposal and removal)	8	
		TOTAL Project Management quality criteria	16	-

C1	Functional quality criteria detected by the experimentation of prototypes - Ability to satisfy the need			
	C1.1	Frailty screening	5	
	C1.2	Frailty management and prevention	5	
	C1.3	Develop integrated pathways	4	
	C1.4	Develop knowledge sharing	4	
	C1.5	Parameters/measuring units	2	
		Total functional quality criteria	20	-

C2	Technical soundness and Non-functional quality			
	C2.1	Methodology	4	
	C2.2	Data analysis	2	
	C2.3	Architecture, scalability and performance	4	
	C2.4	Compatibility, interoperability and adaptation to local context	6	
	C2.5	Security	4	
	C2.6	Usability and configurability	4	
	TOTAL Technical soundness and non-functional quality criteria		24	-

C3	Organization and legal Criteria			
	C3.1	Organizational, staff and business	2	
	C3.2	Commercialization	4	
	C3.3	Legal and regulatory	4	
	TOTAL Organizational and legal quality criteria		10	4

C4	Innovation and Impact of the implemented prototype			
	C4.1	Level of innovativeness and ability to go beyond the state-of-the-art	2	
	C4.2	Value of benefits due to the innovation for patients and procurers including what is expected from the solutions in clinical and social aspects	4	
	C4.3	Evidence of technical and economic effectiveness, reliability and sustainability of the vision and of the business plan	8	
	C4.4	Reproducibility of the prototype through an adequate industrial process in accordance with the relevant market features	8	
	C4.5	Actions implemented to limit the solution costs through its life cycle (industrialization, production, delivery, setting, usage, maintenance, management, disposal and removal)	8	
	TOTAL Innovation and Impact criteria		30	-

TOTAL QUALITY SCORE	**100**	**-**

Additional sub-criteria may be added for the call-offs for phases 2 and 3, as a way of making the award criteria more precise, provided that they do not substantially change the existing criteria.

3.5.4 Link between weighted award criteria and requirements

The weighted award criteria described in this section are directly related to the requirements described in the "TD2 - Challenge Brief" document. During the elaboration of these documents, procurers has weighted each requirement to give a relative weight in the criteria to which belong. The weighting of each procurer has been averaged and checked that the variation coefficient of the values is low as a test that their vision is homogeneous. This information is considered useful for the proposers both in terms of assessing the importance of each requirement and for having in mind that it will be used during the evaluation process. The resulting coefficient are shown in Table XIII.

Table XIII. Relation between weighted award criteria and requirements

TD1 Award criteria	TD2 Challenge Brief section	Req. Id	Relative weight given by procurers to each requirement within its criteria subgroup in a range from 0.00 to 10.00
C0	-	No direct link with requirements. Evaluated globally	
C1.1	5.1.1 Requirements related to frailty screening	FR1	8.25
		FR2	9.50
		FR3	8.50
C1.2	5.1.2 Requirements related to care frailty management and prevention	FR4	8.00
		FR5	9.50
		FR6	10.00
		FR7	7.00
		FR8	7.00
		FR9	6.75
		FR10	6.25
		FR11	8.25
		FR12	9.25
		FR13	9.00
		FR14	8.00
C1.3	5.1.3 Requirements related to develop integrated pathways	FR15	9.00
		FR16	7.25
		FR17	7.75
		FR18	9.75
		FR19	9.75
		FR20	8.75
		FR21	6.50
		FR22	7.25
		FR23	7.75
		FR24	6.75
		FR25	7.50
		FR26	7.50
C1.4	5.1.4 Requirements related to develop knowledge sharing	FR27	7.75
		FR28	7.00
		FR29	7.50
		FR30	8.00

C1.5	5.3 Parameters/measuring units' requirements	PMR1	7.25
		PMR2	7.25
		PMR3	7.25
		PMR4	7.25
		PMR5	7.25
		PMR6	7.25
		PMR7	7.25
		PMR8	7.25
		PMR9	7.25
		PMR10	7.25
		PMR11	7.25
		PMR12	7.25
		PMR13	7.25
		PMR14	7.25
		PMR15	7.25
		PMR16	7.25
		PMR17	7.25
		PMR18	7.25
		PMR19	6.50
		PMR20	7.00
		PMR21	6.75
		PMR22	7.75
		PMR23	7.00
		PMR24	7.75
		PMR25	7.50
		PMR26	7.75
C2.1	5.2.1 Methodology	NFR1	6.25
		NFR2	9.00
		NFR3	7.50
		NFR4	9.75
C2.2	5.2.5 Data analysis	NFR55	8.50
		NFR56	6.75
		NFR57	7.50
C2.3	5.2.6 Architecture, scalability and performance	NFR58	8.50
		NFR59	9.25
		NFR60	8.25
		NFR61	8.25
		NFR62	9.00
		NFR63	7.75
		NFR64	5.50
		NFR65	7.00
		NFR66	7.75
		NFR67	7.00
		NFR68	9.50
		NFR69	9.50
		NFR70	7.50
		NFR71	8.00
		NFR72	8.00
		NFR73	8.00
		NFR74	7.67

C2.4	5.2.2 Compatibility, interoperability and adaptation to local context	NFR5	9.50
		NFR6	10.00
		NFR7	7.25
		NFR8	7.25
		NFR9	7.00
		NFR10	8.50
		NFR11	10.00
		NFR12	9.00
		NFR13	8.67
		NFR14	9.00
		NFR15	9.00
		NFR16	8.00
		NFR17	10.00
		NFR18	10.00
		NFR19	8.00
		NFR20	8.00
		NFR21	7.75
C2.5	5.2.3 Security	NFR22	10.00
		NFR23	7.75
		NFR24	8.25
		NFR25	8.00
		NFR26	7.00
		NFR27	9.00
		NFR28	7.75
		NFR29	7.25
		NFR30	7.25
		NFR31	7.25
		NFR32	8.00
		NFR33	6.00
		NFR34	6.25
		NFR35	6.25
		NFR36	7.25
C2.6	5.2.4 Usability and configurability	NFR37	10.00
		NFR38	9.00
		NFR39	7.00
		NFR40	7.00
		NFR41	7.50
		NFR42	7.75
		NFR43	9.50
		NFR44	9.50
		NFR45	8.50
		NFR46	8.75
		NFR47	10.00
		NFR48	8.25
		NFR49	7.75
		NFR50	7.00
		NFR51	8.50
		NFR52	7.50
		NFR53	10.00
		NFR54	10.00

C3.1	5.4 Organizational, staff requirements	OBR1	7.50
		OBR2	9.25
		OBR3	7.00
		OBR4	8.75
		OBR5	7.25
		OBR6	6.25
		OBR7	7.00
		OBR8	7.00
		OBR9	6.50
		OBR10	9.75
		OBR11	9.75
		OBR12	9.50
		OBR13	8.50
		OBR14	7.00
		OBR15	7.50
C3.2	5.5 Commercialization requirements	CR1	6.00
		CR2	6.00
		CR3	8.00
		CR4	8.00
C3.3	5.6 Legal and regulatory requirements	LRR1	8.25
		LRR2	10.00
		LRR3	8.75
		LRR4	8.25
		LRR5	8.00
		LRR6	7.50
		LRR7	7.00
		LRR8	5.00
		LRR9	4.75
		LRR10	6.00
		LRR11	6.00
		LRR12	6.50
C4	-	No direct link with requirements. Evaluated globally	

This Table XIII will be used for weighing evaluators scores to obtain the final score for each criterion using the following formula:

$$SC_{x.y} = \frac{\sum_i (SR_i \times PW_i)}{\sum_i PW_i}$$

where,

$SC_{x.y}$ is the resulting score obtained by a tender for criteria $Cx.y$ ('TD1 criteria award' column of Table XIII)

SR_i is the score given by evaluators to the proposal after assessing its performance regarding requirement R_i ('Req. Id' column of Table XIII)

PW_i is the procurers weight given to requirement R_i by procurers within criteria $Cx.y$ ('Relative weight given by procurers to each requirement within its criteria subgroup' column of Table XIII)

Those criteria with no direct link with requirements will be globally evaluated and no weighting value will be applied, therefore, the evaluator's scores will be the final score for them.

3.6 Evaluation procedure: Opening of tenders & evaluation

There are two types of evaluations under the eCare PCP:

1) Evaluation process intended to rank the Tenderers in order to award Contracts to the best-ranked Tenders;
2) Evaluation process intended to assess the outcome of the work executed in a particular Phase. This evaluation will lead to the decision of payments and regarding the eligibility of a Contractor to bid for the next Phase.

The deadline of the first tender submission is **15th September 2021, at 12:00 midday (CET).**

After this date and time no further submissions will be permitted. It is the responsibility of the Tenderer to ensure they submit their response before the closing date and time as no submissions will be accepted after the tender submission deadline.

Successful tenderers will be requested to sign both a Framework Agreement and a Specific Contract for Phase 1. For the Phases 2 and 3, selected Contractors will be asked to sign a Specific Contract for the given Phases.

3.6.1 Opening of tenders

Expected date to convene opening committee to proceed with the administrative opening of offers is **16th September 2021 at 11 am (CET).**

The Opening Committee will have to do the legal opening of the offers received from the tenderers. The objective will be to check that each candidate has provided all the requested documents in his offer.

Tenders will be evaluated in a non-discriminatory manner in accordance with the legal requirements provided for in relevant provisions under Italian regulations.

The Opening Committee will be composed by 1 Legal advisor from the Lead Procurer (ASL BN) and the three other procurers of the Buyers group (SDR, CSI & UKA)

The Lead Procurer will open the tenders which have been submitted by the deadline mentioned in section '2.6 Time schedule' and register them.

Bidders are welcome to attend the opening of the tenders. The location will be the ASL Benevento registered office, 82100 Benevento, Italy at **12:00 (midday) (CET)**. A video webinar session may be provided and interested tenders may be provided with login data.

Tenders that have been submitted before the deadline will be opened by the opening committee following this procedure:

- A formal session will be launched by the Lead Procurer ensuring the electronic safety on the e-tendering platform.

- The Opening Committee will be in charge of opening the tenders and checking their general compliance with the conditions on the content and format of the tender as requested by the PCP request for tender specifications.

- A report with the results of the session will be compiled when the session ends including the information about the opening. This report will be agreed and signed by all members of the Opening Committee.

- The Opening Committee may request clarification or additional evidence if needed. The candidate will be notified by the Opening Committee by email or similar channel. The

candidate will have **5 working days** (from the day he receives the notification) to send the clarifications and / or evidence requested. After this deadline, if no answer is received by the candidate, the offer will be rejected and will be excluded from the tender evaluation. The candidate will be informed by the Opening Committee.

Tenders not complying with the formal and procedural requirements will be excluded from the Tender evaluation.

The opening procedure as well as the composition of the Opening Committee detailed above will be repeated for all Phases of this PCP.

3.6.2 Organisation of the tender evaluation

The tender evaluation is carried out by an Evaluation Committee, which is appointed by the Lead Procurer. The Lead Procurer will proceed with the appointment of the Evaluation Committee, according to the art. 77, paragraph 12, Legislative Decree 50/2016. The Lead Procurer draws up a list of the members of the Evaluation Committee, based on persons appointed by the other procurers.

For the evaluation of the Tenders, the Lead Procurer will chair the Evaluation Committee. The Evaluation Committee will have to assess the quality of the offers received from the tenderers, and previously validated by the Opening Committee. The evaluation committee will be composed evaluators with complementary technical background and representing the Buyers Group in a proportional way to evaluate the tenders. If necessary, the Buyers group will ask for external experts, members of the Advisory Board, for support.

In addition, the preferred partners and third party involved in the PCP will support the evaluation of the different offers. Evaluators from this group will participate in the evaluation process as part of the technical and financial committees.

The experts should reflect relevant expertise areas – procurement, clinical, technical, business, ethical, particularly, the experts should have proven experience and competence in the subject matter of the tender, chosen among administrative officials, teachers, that are not members of the political management body of the administration, that do not hold political offices and that are not union representatives or designated by confederations and trade unions or professional associations. So, the nomination is done by forwarding information on the identity, education, professional qualifications and experience of the relevant nominee to the Lead Procurer. When doing so, the procurers shall use the form provided by the Lead Procurer. It is a duty of each procurer to ensure the person appointed is in accordance with the requirements provided by the law in force and there are no reasons for excluding the candidate.

Note: External experts, members of the Advisory Board, will be required to sign a 'declaration of interest' form and confirm if there is any conflict of interest with any of the tenderers. If an assessor declares a conflict of interest for a tenderer they will be excluded from the assessment of that tenderer.

Note: Each member of the Evaluation Committee will sign in advance a declaration of absence of conflict of interest and protection of confidentiality and in addition specifically notify the Lead Procurer if there is any conflict of interest with any of the tenderers.

The Lead Procurer will keep duly certified copies of the Declaration of absence of conflict of interest and protection of confidentiality, signed by the Committee members. The Lead Procurer will refuse to accept a nomination if a conflict of interest is stated in the above-mentioned Declaration.

When carrying out their tasks, the Evaluation Committee shall not seek or take instructions from the Lead Procurer, other procurers, any institutions, bodies, offices or agencies, from any government of a Procurer or from any other body. The Committee shall respect the general principles settled in

relevant provisions under Italian Public Procurement Code, specifically (D. Lgs. N. 50 18/04/2016), and work in accordance with all the provisions and content of the Contract Notice.

Note: Tenders to the PCP Request for Tender, as well as the Tenders for the Phase 2 and 3 call-off, will preferably be assessed and ranked by the same evaluation committee.

The evaluation committee will be divided into several sub-groups that will evaluate specific steps of the process:

- Step 1 Exclusion criteria: Lead Procurer
- Steps 2-3 and 4.1 Selection, compliance and award criteria (excluding price): Technical Evaluation Committee
- Step Award criteria (price) 4.2: Financial Evaluation Committee

Tenders to the PCP Request for Tender, as well as the Tenders for the Phase 2 and 3 calls-offs, will preferably be assessed and ranked by the same Evaluation Committee. The eCare Buyers Group holds the right to replace evaluators during the project provided that the replacement evaluator has the necessary skills and represents the same member of the Buyers Group.

The evaluation process under the eCare PCP will follow different steps. In a first stage, the offers received will be checked on the basis of content and format compliance with the requirements of the tender. After that, the administrative section will be checked. Then, the technical section will be evaluated and finally, only the offers that fulfil with the functional specifications will be evaluated in the financial section.

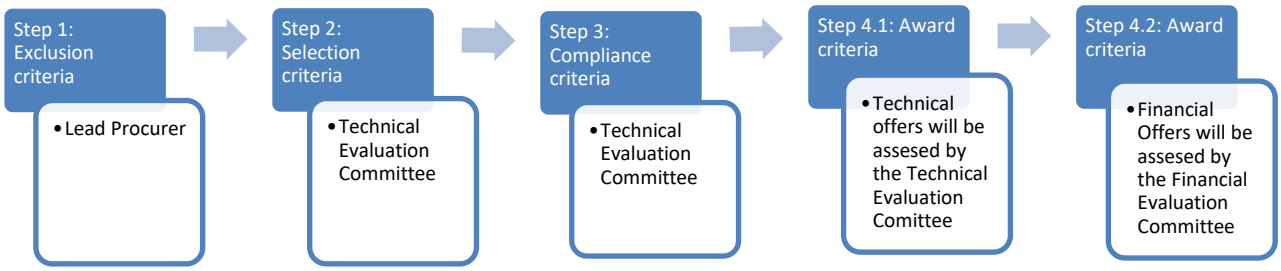

Figure 2: Evaluation process

The evaluation process will be performed as detailed below:

<u>Qualification Envelope</u>

<u>Evaluation of the Step 1: Exclusion criteria</u>

This step will involve checking whether the tenderer is not in one of the situations covered by the exclusion criteria as detailed in section 4.2. The exclusion criteria will be scored as detailed in section 4.2. Only tenderers who successfully pass all of the exclusion criteria questions will progress to Step 2 of the evaluation.

This step will be evaluated by the Lead Procurer.

<u>Evaluation of the Step 2: Selection criteria</u>

This step will involve assessing whether the tenderer has the capacities necessary to perform the contract, on the basis of the selection criteria as detailed in section 4.3. The selection criteria will be scored as detailed in section 4.3. These will be evaluated on a pass/fail (yes/no) basis. Only tenderers who successfully pass all of the selection criteria will progress to Step 3 of the evaluation.

This step will be evaluated by the Technical Evaluation Committee.

Evaluation of the Step 3: Compliance criteria

This step will involve assessing the compliance criteria as detailed in section 4.4. the compliance criteria will be scored as detailed section 4.4. Only tenderers who successfully pass all of the compliance criteria will progress to Step 4 of the evaluation.

This step will be evaluated by the Technical Evaluation Committee.

Evaluation of the Step 4: Award criteria

Step 4.1 Technical Envelope:

The awarded criteria are weighted as detailed in section 3.5.

Each question / criterion will be graded as an individual score. To ensure the same level of appreciation from the members of the Evaluation Committee, a "Scoring Grid" will be used, giving indicative appreciation of each grade. The scoring model that will be used by the evaluators to assess and score the extent to which a Tender is meeting the award criteria is as follows:

Table XIV. Weighted award criteria: judgment assigned to each sub criteria

Scoring Coefficients	Textual description	
0%	Insufficient	None of the aspects of the requirement are met. Criteria has not been analyzed and/or no aspect has been sufficiently analyzed.
20%	Very poor	Multiple important aspects of the requirement are missing. Criteria were met inadequately or not sufficiently analyzed.
40%	Poor	Multiple aspects of the requirement are present, but the provided explanation may not convince.
60%	Good	All important aspects are present. Criteria were met at a good level, and all aspects were sufficiently analyzed.
80%	Very good	All important aspects are present and the provided explanation is very convincing. Criteria were fully met and all aspects were analyzed in a clear and exhaustive way.
100%	Excellent	There is significant added value to the required feature, which is described very convincingly. Criteria were met above expectation and all aspects were analyzed in a particularly clear and exhaustive way.

The values of Table XIV will be used as a guiding scale for homogenise the evaluation according to the textual description. An evaluator will be able to give any value between 0 and 100 as long as this value fits this scale consistently. Each tender will be assessed by all members of the Technical Evaluation Committee. Only offers that reach the **minimum threshold** of the total amount points (excluding the price) or which is the same, the threshold % of the total weight of the Technical offer (excluding financial offer) will pass to the following step. There may be additional thresholds for each criterion. **Failure to pass a single threshold means that the proposal will be excluded from the entire evaluation.** Thresholds for each phase and criterion are shown in Table X for phase 1, in Table XI for phase 2 and in Table XII for phase 3.

The assessment criteria, weighting and the maximum points available are listed in section 3.5.

Step 4.2 Financial Envelope:

The financial Section of Tenders passing this step will then be evaluated.

The bid with the lowest compliant tendered price will be automatically awarded the maximum % weighting available for Price i.e., 30%.

The Financial Offer will be assessed on the basis of the following formula:

$$\text{Percentage weighted score} = \frac{\text{Price of the lowest compliant tender submitted}}{\text{Price of the tender being assessed}} \times 30$$

The price that will be evaluated is the Actual Price.

The Financial Evaluation Committee will assess the financial offers.

3.6.3 Ranking of the tenders

The contract will be awarded to the most economically advantageous tender, i.e. tender offering the best price-quality ration determined in a accordance with formula below. A weight of 70/30 is given to quality and price.

$$\text{Total Score for tender X} = \frac{\text{Price of the lowest compliant tender submitted}}{\text{Price of the tender X}} \times 30 + \text{Total quality score (TQS) for all award criteria of tender X} * \text{Quality criteria weighting (70\%)}$$

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

TOTAL QUALITY SCORE (TQS)

Regarding the evaluation criterion of the Phase Technical Offer, the Total Quality Score (TQS) is determined by the sum of the scores attributed to the tender based on the sub-criteria indicated the award criteria.

The assignment of the technical score will be as follows: each Commissioner of the Selection Board will assign a summary judgment, which corresponds to a coefficient between 0 and 100 (see Table XIV), for each element of evaluation of the parameters indicated in the tables below. Then the Selection Board will calculate the average of the coefficients assigned by the individual components for each criterion. This average will be multiplied by the maximum score available for each qualitative element.

$$\text{Total QS} = \sum \text{Criteria (i) max score} * \text{Coefficients Average (i)}$$

The more points a tender scores in total, the higher it is ranked. Based on the evaluators' individual assessments, which are all equally weighted, a preliminary ranking of the Tenders will be made.

If deemed necessary, an online hearing will take place, where Tenderers will be asked to clarify aspects of their Tender.

Subsequently, the Evaluation Committee will meet to collect, compare and discuss the comments of each evaluator for each Tender, and to review the preliminary scoring and ranking to ensure that the assessment of all Tenders is consistent and non-discriminatory. By consensus or, if that fails, by a majority of two thirds, the Evaluation Committee will make the final ranking of the tenders and the award of the contracts.

Large differences in assessment by the evaluators will be identified. If the reasoning given by the evaluators requires further clarification, this is provided by them.

The final award will be made on the basis of the Most Economically Advantageous Tender (MEAT).

After the award decision has been taken, the Tenderers will be informed about their ranking. To the selected Tenderers a Framework Contract and Specific Contract for Phase 1 will be sent shortly thereafter signed by the Lead Procurer.

Successful Tenderers will be, if awarded a contract, expected to start and finish their project in time. If the project is not finished by the deadline, the Contractor will not be eligible to submit a Tender for the next Phase.

Unsuccessful Tenderers, that have not been excluded and who comply with the selection criteria, may contact the Lead Procurer, within 5 days, to obtain additional information about their Tender not being selected for a contract. Tenderers will be given feedback on their tender.

The process will remain the same for the different call-offs, highlighting that the evaluation of offers for phase 2 has only two steps: evaluating the offers based on the compliance and award criteria.

The buyer's group and the lead procurer will evaluate the tenders and offers for the call-offs for phase 2 and 3 jointly and will make a joint award decision.

Potential conflicts of interest will be avoided.

4 Content and format of tenders

4.1 Submission, format of tenders and closing time

All tenders must be completed, electronically signed and submitted via the eTendering platform provided by the closing date and time as stated: **15th September 2021, at 12:00 midday (CET).**

Tenderers must follow all instructions given in the tender documents: TD1-Request for tenders, TD2 – PCP Challenge and TD3 - Forms (From Form 1 to Form 6).

The eCare eTendering Platform will be the online tool for submitting tenders, accessible at: https://ecare.app.jaggaer.com/web/login.html.

The Tender documents are published on the eCare website: https://ecare-pcp.eu/tender.html

You should also download them from the eTendering Platform after registration.

An eTendering response manual to facilitate the preparation and submission of offers is available to all registered tenderers in the eTendering Platform with instructions to express interest, prepare, sign and submit the offers through the eTendering Platform. Tenderers are encouraged to carefully read the manual before submitting their offers.

All Tenders must be submitted as follows:

1. Tenderers should express interest to the Current opportunity area on the eTendering Platform homepage: https://ecare.app.jaggaer.com/web/login.html
2. After expressing interest, the Tenderers should register in the eCare eTendering platform. You can follow the instructions given on the available registration guide available on the homepage.
3. Tenders have to be submitted electronically via the eCare e-Tendering platform.
4. Tenders shall contain an administrative, a technical and a financial section. See Tender Document 3: Forms, which will be related to the different Responses Envelopes included in eTendering Platform (Qualification, Technical and Financial Envelopes).
5. Annexes required should be uploaded to the system following the indications given in the eTendering platform and in the Tender Document 3: Forms. Some of the documents might require to be signed electronically before upload.
6. Qualification, Technical and Financial envelopes have to be digitally signed and submitted in the eTendering Platform to finalize the submission of the Tender process. Clear instructions on how to complete and electronically signed the envelopes are given in the eTendering Response Manual available to tenderers.

IMPORTANT: The submission of the Tender will not be completed until the Tenderer signs electronically the offer (digital signature of the three envelopes). Tenderers have to follow the instructions given in the Tendering Response Manual related to the electronically signature.

The electronical signature of the documents should be done outside the eCare eTendering platform. We recommend you use an electronically signature tool that ensures the legal value and security of the digital certificate.

Each Tenderer must sign using a valid electronically signature issued by an Authorized Certification provider that guarantee the identity and integrity of the offer and the documents associated to it.

Tenderers must be informed that the **PCP language is English and that the framework agreement and the specific phase contract will be signed in English version.** With the submission of their proposals, tenderers accept this fact.

This tender contains 3 envelopes as shown below:

- **Qualification Envelope:** exclusion, selection and compliance criteria
- **Technical Envelope:** Award criteria
- **Financial Envelope:** Financial offer

All tenders must:

- Contain administrative, technical and financial sections
- Be valid for 6 months after the closing date for submission
- Be signed.

Tenders must be submitted in PDF.

See Appendix 1 to find more details regarding the electronic submission of tenders.

Only one Tender from a Tenderer as main Contractor will be accepted. **Please do not submit the Tender on paper or submit more than one electronic Tender. The submission of a backup copy in any form is not allowed.**

The Tender can be modified, validated and (re)submitted as many times as needed until **15th September 2021, at 12:00 midday (CET)**. Each subsequent submission overwrites the previously submitted version (earlier versions are not archived and are therefore not available anymore).

Tenders that do not comply with the formal requirements will be automatically rejected.

More detailed information about the final layout requirements for the phase 2 and 3 offers will be provided in the call-off.

4.2 Administrative section of the tender

Tenders are structured in the eTendering platform as follows:

Qualification Envelope:

- Form 1: General Tender Submission and power of attorney
- Form 2: Exclusion criteria
- Form 3: Selection criteria
- Form 4: Compliance criteria

Technical Envelope:

- Form 5: Technical offer

Financial Envelope:

Form 6: Financial Offer

In addition, the following Annexes should be completed, manually and / or digitally signed (as required) and uploaded into the system:

- **Subcontractor Information** (in case of Single / Lead Tenderers that involve any subcontractor)
- **Subcontractor Declaration** (in case of Single / Lead Tenderers that involve any subcontractor). This annex requires that each subcontractor complete the necessary

information and manually signed the document. After that, the Single or Lead Tenderer will electronically sign the declaration and upload the Annex in the system again.

- **Single Tenderer Power of attorney** (complete it only if you are a Single Tenderer and electronically signed and upload to the system)

  Lead Tenderer Power of attorney (complete it only if you are a Lead Tenderer; complete it by the Lead Tenderer, each consortium members. Finally, the Lead Tenderer electronically signed and upload again the document in the system).

- **Framework Agreement and Specific Contract for Phase 1** (completed by the Single or Lead Tenderer). Single / Lead Tenderer should complete the agreements with required information, digitally signed and upload again the documents in the system. The Framework Agreement and the Specific Contract for Phase 1 templates are available in TD4 and TD5. Templates are also available for downloading directly in the system.

Templates for completing this information are available in the TD6 - Annexes.

At the end of each Envelope section, an **area for attaching additional documents / information is available.** Tenderers can attach information they consider necessary regarding any matter related to the Qualification, Technical and Financial envelopes by using this additional attachment area.

The lead procurer may request clarification or additional evidence where there is any doubt during the evaluation process. In accordance with the principle of equal treatment, no alterations to Tenders are to be sought or accepted through requests for clarifications. In case the provided clarification is found not compliant with what was requested, the Tender will be excluded from further evaluation.

More detailed information for the phase 2 and 3 offers will be provided in the Phase 2 and 3 call-offs.

Responses to the questions in the Form 2 (Exclusion Criteria) and Form 3 (Selection Criteria) will be assessed as pass/fail. Only Tenderers achieving a "pass" for all criteria will be put forward for further evaluation.

4.2.1 Technical section of the tender

Tenders must include a detailed technical offer for phase 1, containing:

- A technical plan that outlines:
  1) the tenderer's idea for addressing all the requirements given in the PCP challenge description, relating both to functionality and performance; and
  2) technical details of how this would be implemented

- A draft business plan that explains the proposed approach to commercially exploit the results of the PCP and to bring a viable product or service onto the market

- A list of the pre-existing rights (background) relevant to the tenderer's proposed solution, in order to allow IPR dependencies to be assessed

- A risk assessment and risk mitigation strategy

- A reply to the question "Does this tender involve **ethical issues**? (YES/NO)" and if YES, an ethics self-assessment, with explanations how the ethical issues will be addressed (see section 4.2)

- A reply to the question "Does this tender involve: activities or results that may raise **security issues** and/or **EU-classified information**[14] as background or results? (YES/NO)" and if YES information on how these issues will be addressed (see section 4.2)

Tenders failing to meet these requirements will be excluded.

The technical part must provide a *detailed* technical offer for phase 1 (including an explanation of the methodology, a work plan and details of deliverables and milestones) and must specify the plans for and objectives of the subsequent phases 2 and 3 and beyond (including a plan for commercial exploitation of the results).

See TD3 – Form 5 Technical offer for further details.

Information provided in the technical section of the tender will be used to evaluate the tenders, on the basis of the technical award criteria and the compliance criteria A, D and E.

More detailed information for the phase 2 and 3 offers (in particular on the technical implementation plan, updated business plan and list of IPRs) will be provided in the call-offs.

4.2.2 Financial section of the tender

The tender must include a detailed **financial offer** specifying:

- binding **unit prices** for all items needed for carrying out phase 1 and for items that are expected to be needed for phases 2 and 3 (given in euros, excluding VAT but including any other taxes and duties)
- a fixed **total price** for phase 1 and an estimated total price for phases 2 and 3, broken down to show unit prices and the number of each unit needed to carry out phase 1 (given in euros, excluding VAT but including any other taxes and duties).

In addition, the financial section must include:

- a **price breakdown** that shows the price for R&D services and the price for supplies of products (to demonstrate compliance with the definition of R&D in compliance criterion A)
- a **price breakdown** that shows the location or country in which the different categories of activities are to be carried out *(e.g., x hours of senior researchers in country L at y euro/hour; a hours of junior developers in country M at b euro/hour)* (to demonstrate compliance with the requirement relating to place of performance in compliance criterion C).
- the **financial compensation** valuing the allocation of ownership of the **IPRs** generated during the PCP to the tenderer by giving an absolute value for the price reduction between the price offered in the tender compared to the exclusive development price (i.e. the price that would have been quoted were IPR ownership to be transferred to the procurers) in order to ensure compliance with the EU R&D&I state aid framework.

The unit prices quoted for each category of items *(e.g., hourly rates for junior and senior researchers, developers and testers)* remain binding for all phases (i.e., for the duration of the framework agreement).

The Lead Procurer may reject a Tender if it has determined that the submitted price, in combination with other constituent elements of the submission, is abnormally low in relation to the subject matter of the procurement and raises concerns with the Lead Procurer as regards the ability of the Tenderer to perform the contracts. If the Lead Procurer considers that a Tender may be abnormally low, he

[14] See Decision 2015/444/EC, Euratom on the provisions on security of EU-classified information.

will request the Tenderer to provide, in writing, details of the constituent elements of the tender, in particular with respect to:

- The economy of the services provided;
- The technical solutions chosen;
- Potential exceptionally favorable conditions available to the Tenderer for the execution of the work;
- The compliance with the provisions relating to employment protection and working conditions in force at the place where the work is performed.

The financial compensation for IPRs must reflect the market value of the benefits received (i.e., the opportunity that the IPRs offer for commercial exploitation) and the risks assumed by the contractor (e.g., the cost of maintaining IPRs and bringing the products onto the market).

The information provided in the financial section of the tender will be used to evaluate the tenders on the basis of the price award criteria and the compliance criteria A and C.

More detailed information for the phase 2 and 3 offers will be provided in the call-off. The price for phase 2 and 3 offers must be based on the binding unit prices in the tender and the price conditions set out in the framework agreement. Where new units/unit prices (e.g., for new tasks or equipment) are subsequently added to the phase 2 or 3 offers, they will become binding for the remaining phases.

Similar price breakdowns will be requested for the call-offs for phase 2 and 3.

See TD3 – Form 6 Financial offer for further details.

IMPORTANT: Italian VAT regime will apply.

4.2.3 Closing time

Tenders must be completed, electronically signed and submitted via the eTendering platform provided by the closing date and time as stated: **15th September 2021, at 12:00 midday (CET).**

5 Other tender conditions

5.1 Tender constitutes binding offer

A signed tender will be considered to constitute a firm, irrevocable, unchangeable and binding offer from the tenderer.

The signature of an authorized representative will be considered as the signature of the tender (and will be binding on the tenderer or, for joint tenders, the group of tenderers).

Only electronically signature is allowed by electronically certificate issued by a certificate authority.

5.2 Confidentiality

Tenderers must keep confidential any information obtained in the context of the tender procedure (including EU-classified information[15]).

Tenderers must explicitly identify, element by element, which specific documents of their tender should be considered confidential and cannot be disclosed by the Lead Procurer. Confidentiality of the whole tender will not be accepted.

5.3 Language

All communication (relating to either the tender procedure or the implementation of the contract) must be carried out in English. Tenders as well as offers for phase 2 and 3 call-offs must be submitted in English. Deliverables must be submitted in English. The supported language of the eTendering platform is also in English.

When dealing with users (old adults, caregivers, health and care staff in charge of services) for prototype testing in phase 2 and field testing in phase 3, local languages (Italian, Spanish, Catalan and German) shall be used. Although procurers' staff involved in the eCare project will give support and interfacing with local people and local entities cannot be guaranteed on a continuous basis or whenever required.

With the submission of their proposals, tenderers accept these requirements. Tenderers must be informed that the PCP language is English, and that the framework agreement and the specific phase contract will be signed in English version.

5.4 Cancellation of the tender procedure

The procurers may, at any moment, cease to proceed with the tender procedure and cancel it.

The procurers reserve the right not to award any contracts at the end of the tender procedure.

The procurers are not liable for any expense or loss the tenderers may have incurred in preparing their offer.

[15] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU-classified information.

5.5 Communication — Q&A

The Q&A from the open market consultation can be found on https://ecare-pcp.eu/omc/.

All clarifications and doubts needed related to the call for tender must be submitted in **writing via the Messages section of the eTendering platform** before the set closing date for receipt of clarifications. Any questions received after this deadline will not be answered.

Questions must be submitted in English only and responses may be made available to all Tenderers.

In addition, there will be established a phone number to solve any doubt and incidence arise on the use of the eTendering platform: **+34 917870225** (see more details in Appendix 1).

The summary of all questions and answers will be presented in an anonymised Q&A document that will be published on https://ecare-pcp.eu/faqs/ in English (final version planned for 2 days before offers submission deadline). For phases 2 and 3, the answers will not be published, but distributed to all contractors that successfully completed the previous phase.

All clarifications and doubts needed related to the call for tender must be submitted in writing via the Messages section of the eTendering platform one week before the offer's submission deadline. Any questions received after this deadline will not be answered.

All remediations asked by the Lead Procurer for the Qualification Envelope will be communicated and receive through the Message section of the eTendering platform. The details of the remediation and the deadline to answer it will be communicated in the request message by the Lead Procurer. Failing to provide a proper answer before the established deadline will result in an exclusion from the tender process.

⚠ **Attention:** All other contacts (or attempted contacts) will be considered unauthorised and may lead to the exclusion of your tender.

5.6 Contract implementation

Successful tenderers will be requested to sign both a Framework Agreement (see the template TD4-Framework Agreement) and Specific Contracts for phases 1, 2 and 3 (see the template given in TD5 – Specific contract phase 1).

5.6.1 Monitoring

During each phase, contract implementation will be monitored periodically and reviewed against the expected outcomes (milestones, deliverables, and output or results) for the phase.

Each contractor will be assigned a main contact person (their supervisor) from the monitoring team appointed by the procurers.

There will be regular monitoring meetings between contractor and the supervisor/monitoring team of the procurement team. Online/remote meetings will be held whenever possible. The supervisor will receive the support of the monitoring team if needed with the necessary expertise.

Number of monitoring meetings can be held physically or online and will be subject to agreement between tenderer and monitoring team. The contractors could be asked to discuss the results achieved in the preceding period. The supervisor, or any party designated by it, is entitled to visit the premises of the contractor and its subcontractor. The contractor can also visit the procurer's premises and must cover its own costs and thus foresee personnel and travel budget in its offer.

The contractors are asked to obtain all information necessary for their performance. The procurers will do their best to provide the contractors with information required. The contractor must cover its own costs and thus foresee personnel and travel budgets in its offer.

The monitoring team and /or supervisor will provide regular feedback in writing or electronically to contractors after meetings or visits. Detailed information on the role of the supervisor will be provided after awarding of the contract. This will take place as indicated in the Table Expected Outcomes (estimated) in section 3.4. and will allow the contractors improve the way in which their solutions address the problem set out in the PCP description.

5.6.2 Payments based on satisfactory completion of milestones and deliverables of the phase

Payments corresponding to each PCP phase will be subject to the ***satisfactory*** completion of the deliverables and milestones for that phase.

Satisfactory completion will be assessed by an eCare Technical Committee composed of by representatives of the buyers' group and the rest members of the consortium and supported, when applicable, by the eCare Advisory Board of external experts.

Satisfactory completion will be assessed according to the following requirements:

- if the work corresponding to that milestone / deliverable has been carried out
- if a reasonable minimum quality has been delivered
- if the reports have been submitted on time
- if the monies have been allocated to the planned objectives
- if the monies have been allocated and the work has been carried out according to the on/off award criteria (place of performance, public funding and R&D definition criteria)

and

- if the work has been carried out in compliance with the provisions of the contract (including in particular verification if the contractor has duly protected and managed IPRs generated in the respective phase).
- if the feedback provided by the monitoring team has been addressed properly by the contractor making required changes or improvements or giving a sufficient justification for not having made them.

'Reasonable minimum quality' of a report means that:

- the report can be read by somebody who is familiar with the topic, but not an expert
- the report gives insight in the tasks performed in and the results
- the report uses any reasonable template or form provided to the tenderer

'Reasonable minimum quality' of a demonstration (for phase 2 or 3) means:

- the demonstration can be understood by somebody who is familiar with the topic, but not an expert (for instance, somebody with operational but not technical knowledge)
- the demonstration shows how the innovation works, how it can be used and (if applicable) how it is operated and maintained
- the demonstration is accessible to parties appointed by the procurers, unless these are direct competitors of the contractor

Satisfactory completion in each of the phases does not mean successful completion. For a phase to be satisfactory all planned tasks have to be carried out with adequate effort and diligence whether the results are positive or not. The results may indicate that the innovation is not feasible, but the phase may be satisfactory completed.

The assessment will consider the efforts made by contractors to take into account the feedback from the supervisor or the monitoring team. The submitted deliverable will be approved as 'satisfactory' or rejected according to the calendar indicated in Table Time Schedule and never later than **fifteen (15) calendar days**.

Where the eCare Technical Committee judges the completion of deliverables or milestones to be unsatisfactory, the buyer's group may decide to reduce or withdraw payments for that deliverable and/or may terminate the contract according to Article 21 of the Framework Agreement.

If a rejection event appears, the contractor will receive with the rejection notice an explanation of the motivation for the rejection including the deliverable elements categorized by three levels:

1) **Approved**: the contractor can consider the element is satisfactory
2) **Request for modifications**: the contractor has to analyse the report and the modifications requested by the contractor and elaborate a proper answer to fulfil the request in order this element may be approved and considered satisfactory.
3) **Not satisfactory**: the eCare Technical Committee has judged the element is not satisfactory and there is no possible modification in a reasonable time schedule for this element to be satisfactory.

In case of a request for modifications elements is received, the contractor has 5 calendar days to resubmit deliverables.

Invoices must be submitted to the Lead Procurer after the Lead Procurer declares satisfactory completion of the deliverables and milestones related to a payment.

Contractors' invoices must provide:

- a **price breakdown** showing the price for R&D services and the price for supplies of products (in order to demonstrate compliance with the definition of R&D in on/off award criterion A)
- a **price breakdown** showing the location or country in which the different categories of activities were performed (e.g., x hours of senior researchers in country L at y euro/hour, z hours of junior developers in country M at w euro/hour) (in order to demonstrate compliance with the requirement relating to the place of performance in on/off award criterion C).

Payment Schedule

The payment schedule will be as follows:

- Payment for **Phase 1**: 100% of the price offered by the contractor shall be paid after the date in which the lead procurer, on behalf of the buyer's group, declares the satisfactory completion of Phase 1, as described in 'Expected Outcomes'.

- Payment for **Phase 2**: 50% of the price offered by the contractor shall be paid after the date in which the lead procurer, on behalf of the buyer's group, declares the satisfactory completion of the Phase 2 Interim Results, as described in Expected Outcomes. 50% of the price offered by the contractor shall be paid after the date in which the lead procurer, on behalf of the buyer's group, declares the satisfactory completion of Phase 2.

- Payment for **Phase 3**: 50% of the price offered by the contractor shall be paid after the date in which the lead procurer, on behalf of the buyer's group, declares the satisfactory completion of the Phase 3 Interim Results, as described in Expected Outcomes. 50% of the price offered by the contractor shall be paid after the date in which the lead procurer, on behalf of the buyer's group, declares the satisfactory completion of Phase 3.

Payments will be made to the bank account provided by the contractor within 60 days from the date of receipt, by the lead procurer, of a correct and approved invoice, following verification of "satisfactory completion of the deliverables and milestones related to a payment".

5.6.3 Eligibility for the next phase based on successful completion of the phase

Eligibility for participation in the next phase will be subject to **successful** completion of the current phase.

Successful completion of a phase will be assessed by the assessment committee against the following requirements:

- if all milestones have been successfully completed
- if the R&D results meet the minimum functionality/performance requirements of the challenge description (i.e. the minimum quality/efficiency improvements which the procurers set forward for the innovative solutions to achieve)
- if the results of the R&D are considered to be promising

'Promising' means:

- for phase 1, that the feasibility is convincing
- for phase 2, that the feasibility, the applicability in an operational setting and the potential impact of the product is convincing

According to what is established in this section, satisfactory completion, which entitles the contractor to receive the payment, does not mean automatically successful completion, which is one of the requisites for a partner to pass to the next phase.

5.6.4 Finalisation of phase 3: Possible follow-up PPI procurements

A call for tenders can be launched for any follow-up public procurement of innovative solutions (PPI) to deploy a commercial volume of innovative solutions.

5.7 Procedures for appeal

The Lead procurer will incorporate a voluntary **standstill period of five (5) calendar** days from the date following electronic notification to unsuccessful tenderers of an award decision. Any clarification or questions must be submitted in writing via the eTendering platform before the end of the standstill period.

Any legal claim, petition or application for judicial review, with regard to the eCare PCP procedure, whether before civil law courts or administrative courts, shall be made before the Italian jurisdiction. By submitting a Bid, the Bidder accepts the exclusive jurisdiction of Italian courts.

Decisions taken with regard to the selection of bidders, awarding them with Phases 1, 2 or 3 or excluding them from the eCare PCP procedure should be challenged by means of an administrative remedy before the Benevento administrative Court (Tribunal Administrative de Benevento, Via Raffaele de Caro, 7, 82100 Benevento BN, Italy).

Any dispute or claim arising out of or in connection with the execution of the Framework Agreement or of the Phases contracts entered into between the Buyers Group and the Contractor, shall be heard by Benevento administrative Court.

Any dispute between the Parties arising out of or in connection with the Framework Agreement shall in the first instance be referred to the Contractor's Representative and the Lead Procurer's Representative for resolution. The Parties agree to work together in good faith to reach an agreed settlement of any such dispute. If within fourteen (14) Days of being referred to both the above

Representatives, the dispute has not been resolved, the Parties agree to submit the dispute to a senior executive of the Contractor and the appropriate representative of the Lead Procurer as the Lead Procure sees fit and who shall have responsibility to settle such dispute on behalf of the Lead Procurer. The Parties shall meet within seven (7) Days of the referral to them of any dispute and shall work together in good faith to resolve the dispute. If within fourteen (14) Days, the dispute has not been resolved, the dispute may be referred, subject to mutual agreement, to mediation by a mediator to be agreed between the Parties. The fee for the appointed mediator shall be shared equally between the Parties. Noting in this section shall preclude either Party from commencing an action for a legal remedy where time is of the essence and the remedy sought is only available in a court of law. In all other circumstances the Parties shall attempt to resolve a dispute in accordance with clauses the procedure set in this section.

The Benevento administrative Court will have exclusive jurisdiction to deal with any dispute which has arisen or may arise out of or in connection with the Framework Agreement.

6 APPENDIX 1: Electronic submission of the eCare Tender

Tenders should be submitted electronically via the eTendering platform available on the eCare website https://ecare.app.jaggaer.com/web/login.html

More information and support manuals are available on the eCare Website: https://ecare-pcp.eu/tender.html

For any **IT questions, utilization doubts or problems** relating to the eTendering Platform, please contact the Helpdesk:

- Phone: +34 917870225
- Email: helpdesk_ES@jaggaer.com
- Helpdesk office hours are from **08:00** to **19:00 CET** (**Monday** to **Friday**)

Please note that the Helpdesk is **only for IT questions related to the use of the eTendering Platform. All other questions about eCare PCP TENDER** should be addressed by reading the PCP Tender documents. However, in case your question is not answered in the documents, you can contact the Lead Procurer **via message section on the eCare eTendering Platform.**

Using the eTendering platform allows the Lead Contracting Authority to electronically open the Tender, generate an electronic report of the opening and make it available to the Contracting Authorities. To participate, tenderers can electronically submit their Tender and digitally sign it.

Express interest and register are required to submit electronic tenders in e-Tendering.

A specific **Tenderers' eTendering Platform Manual** will be available for Tenderers with further instructions to register, prepare and submit their offers in the platform.

The eTendering applications can be used in different software environments. In general, you will need a computer equipped with:

1) A standard web browser:
    a. Microsoft Edge
    b. Google Chrome
    c. Mozilla Firefox (ESR) 68+
    d. Safari 13.0.5+ for MacOS

    Internet Explorer 10/11 is NOT recommended. Cookies support must be enabled.

2) Operating System: Microsoft Windows 7, Microsoft Windows 8, Microsoft Window 10. Other operating systems such as Linux, Mac OS X or other versions of Windows although not officially supported, may be compatible with supported browser.

3) Java 1.3 or higher

<u>Technical guidelines:</u>

- An electronic tender or request to participate consists of one or more documents.
- There is no limit on the number of characters allowed in the Technical Envelope response. However, the **eCare PCP recommends being clear in your response, synthetic in the information given and focused**.
- Each Response Envelope (Qualification, Technical and Financial) has a specific section for **attaching additional information** if the Tenderer consider it necessary.
- You can send any kind of file type (.doc, .xls, .avi, .ppt, pdf...). Sending multiple documents is possible by using a ZIP file.

- **However, except for ADDITIONAL ATTACHMENTS section in which any kind of file is allowed, the rest of ATTACHMENTS must be submitted in PDF format.**
- The size of a single file cannot exceed 50 megabytes. The total file size of the tender cannot exceed 1GB.
- When in doubt, contact the helpdesk, but **be sure to do this reasonably in advance.**

Registering and logging in

- You should first register as a supplier and express your interest in the tender at https://ecare.app.jaggaer.com/web/login.html
- The **Tenderers' eTendering Platform Manual** contains a section explaining all necessary steps.
- After saving your profile, you will receive an email containing an activation link.

Submitting of the Tender

- Once you have your response to all Envelopes, you can electronically sign (authorized representative) the qualification, technical, and financial envelopes (with an external tool, as indicated in section 4.1 of this document) and submit your tender electronically via e-Tendering Platform.
- Further instructions on the procedure to sign and submit the offers electronically will be given in the eTendering Platform Manual.