CRANE

TD1 Request for Tender

Tender Procedure

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Glossary

Acronym	Meaning
API	Application Programming Interface
CET	Central European Time
Care Plan	Personalised plan for the medical care of the person
EU	European Union
EHR	Electronic Health Record
GDPR	General Data protection Regulation
GPA	Government Procurement Agreement
HIS	Hospital Information System
IRP	Intellectual Property Rights
OMC	Open market Consultation
PCP	Pre-commercial procurement
PHR	Personal Health Record
PIN	Prior Information Notice
PPI	Public procurement of innovative solutions
Q&A	Questions and answers
R&D	Research and Development
SCG	Security Classification Guide
SME	Small and Medium Enterprise
TDx	Tender Document x
TED	Tenders Electronic Daily (European Public Procurement Portal)
URL	Uniform Resource Locator (online address of a webpage)
VAT	Value Added Tax
WTO	World Trade Organisation

Foreword

Acceptance of all the information stated in this document is a prerequisite for placing a tender to this call. All tenderers that tender for the tender are deemed to have accepted the rules stated in this document and the provisions of the Swedish law.

Executive summary

This CRANE Request for Tenders invites all interested parties to present their offers for R&D services to develop and test a technological infrastructure that allows easy compliance with GDPR, affords end-to-end state-of-the-art data protection, mitigates data breaches, and empowers data holders to retain control and transparency; an infrastructure that is based on user-driven design, stimulating uptake and awareness of privacy principles and data use, and affording organizational interoperability.

CRANE is a R&D (Research & Development) project which takes the form of a Pre-Commercial Procurement (PCP).

According to the guidance for PCP procurement documents, this request for tender has the following structure:

In this document, **Chapter 1** gives the general context and background explaining the PCP approach and how it differs from traditional procurement. It also includes the information generated through an Open Market Consultation (OMC) with potential tenderers in the preparation stage for the PCP.

Chapter 2 includes relevant information about the tender and the contract: introduces a description of CRANE services to be procured by the PCP and the expected outcomes distributed by each of the 3 phases of which it is composed. A description of the procurers involved is also provided. Finally, the key contracting elements are described: overall timing of the phases, budget distribution, time schedule and IPR (Intellectual Property Rights) considerations are addressed.

Chapter 3 addresses the evaluation of tenders: Eligible tenderers, joint tenders and subcontracting requirements and conditions are described. This section also explains which exclusion and selection criteria will be checked when presenting the proposal. Then, the award criteria, that will be considered to select tenderers, are defined in detail. Finally, the evaluation procedure is explained including the award criteria used.

Chapter 4 describes the content and format of the tenders including the submission system, the format of tenders, the three envelopes in which the proposal must be split (administrative, technical and financial) and the closing time.

Chapter 5 contains other tender conditions like the communication language, confidentiality, contract implementation including monitoring, payments, eligibility for passing to the next phase and cancellation of the tender procedure. Also, information on data protection, 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):

Table 1 List of Tender Documents

TENDER DOCUMENTS (TD)
TD1 – Request for tenders
TD2 – Challenge brief
TD3a – Declaration of Honour - Exclusion Criteria
TD3b – Declaration of Honour - On-Off-Award Criteria
TD4 – Power of Attorney
TD5 – Tender Application – Administrative Information Template
TD6 – Tender Application - Technical Information Template

TENDER DOCUMENTS (TD)
TD7 – Tender Application Template – Financial
TD8 – PCP Framework Agreement
TD9 – Specific contract for Phase 1, 2, 3

All these documents can be downloaded directly from the CRANE PCP website (https://crane-pcp.eu/).

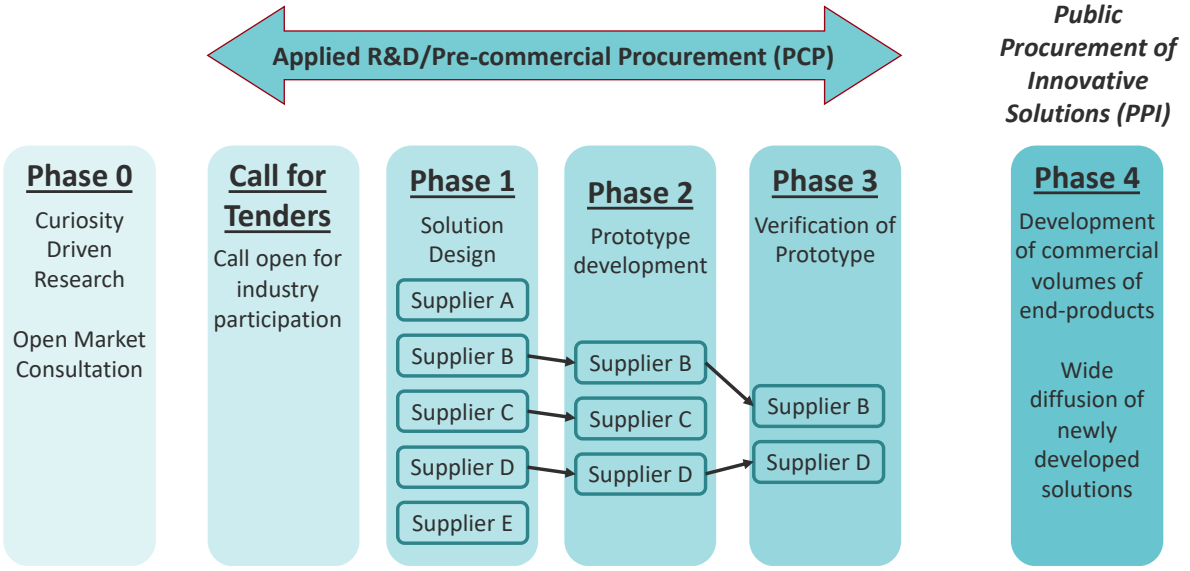
1 General context and background

This procurement is a pre-commercial procurement (PCP) carried out within the CRANE project financed with funds from the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No. 965277 – CRANE European Union and it is conducted by Region Västerbotten (Sweden). RVB are the lead procurer for this PCP process. There are all together three healthcare providers engaged in the PCP process, i.e. Region Västerbotten (RVB) from Sweden, Region Agder from Norway and Region Extremadura from Spain.

Public procurers of CRANE PCP aim to challenge innovative players on the market via an open, transparent, and competitive process, to develop a technological infrastructure that allows easy compliance with GDPR, affords end-to-end state-of-the-art data protection, mitigates data breaches, and empowers data holders to retain control and transparency; an infrastructure that is based on user-driven design, stimulating uptake and awareness of privacy principles and data use, and affording organizational interoperability. CRANE understand that data will continue to be stored where data are generated, but CRANE will demonstrate how to unlock this data and make it available to individuals. This infrastructure will be validated with data driven services for self-management of three chronic conditions (diabetes, CVD, and COPD) based on monitoring and broad use of personal data, communication and data sharing with healthcare, social care services, and other relevant entities, feedback and recommendations about the health status, and motivation for behavioural change.

This document describes the Value Based Evaluation Process from evaluation of tenders, to selection of tenderers through 3 development phases (figure 1).

Figure 1 The PCP Phases in CRANE



PCP is characterised by the following features:

- Competitive development in phases to identify solutions offering the best value for money
- Public procurement of R&D services
- Open, transparent, non-discriminatory approach – no large-scale deployments
- Sharing of IPR-related risks and benefits under market conditions
- Exemption from EU public procurement directives, the World Trade Organisation (WTO) Government Procurement Agreement (GPA) and EU state aid rules
- Open Market Consultation (OMC)

- EU funding

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

PCP targets situations that require radical innovative R&D initiatives 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 several competing contractors at the same time, to compare different approaches to solve the problem. 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 **three phases** (Design, Prototyping, and Verification of Prototype, of a limited set of 'first' services). Evaluations after each phase progressively identify the solutions that meet the customers' needs and offer the best value for money. 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. In using a phased approach with gradually increasing contract sizes per phase, it 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 CRANE PCP, pocurers may or may not decide to follow-up the PCP with a public procurement to deploy the innovative solutions at large scale (PPI).

1.2 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 require 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. In addition, PCP is described in the Procurement Innovation Guideline (Brussels, 18.6.2021, C(2021) 4320 final) and in Regulation (EU) 2021/695 (Article 26).

The R&D services 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 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.

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

1.3 Open, transparent, non-discriminatory approach – No large-scale deployments

PCP is open to all operators on equal terms, regardless of size, geographical location, or governance structure. There is, however, a place-of-performance requirement that they must perform at least 50% 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 past this project. 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.

***Note**: At least 50% of the contracted R&D services are required to be performed in EU Member States or Horizon 2020 associated countries.*

1.4 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-exclusive development price'; see Section 2.6). Moreover, the procurers must receive rights to use the R&D results for internal use and licensing rights subject to certain conditions.

For the regulation and implementation of IPRs in Pre-commercial procurement see the Guidance on Innovation Procurement (Brussels 18.6.2021, C(2021) 4320 final) (Annex I) and the Regulation (EU) 2021/695 (article 26.3).

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

PCP procurements are 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]

They are 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).

PCP procurements do not constitute state aid under the **EU state aid rules**[4] if they are implemented as defined in the PCP communication[5], namely by following 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

[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

[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)

[5] Commission Communication: Pre-Commercial Procurement: driving innovation to ensure sustainable, high quality public services (COM(2007) 799) and PCP staff working document (SEC(2007)1668).

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.)

1.6 Open Market Consultation

In preparation for the CRANE PCP call for tenders, an Open Market Consultation (OMC) was conducted to actively approach the market and get in-depth, targeted marked feedback.

The start of the CRANE OMC was advertised online through the publication of a Prior Information Notice (PIN document number 2022/S 033-084774).

The OMC was aimed at:

- informing potential suppliers (industry) about the CRANE pre-commercial procurement opportunities,
- explaining in detail the pre-commercial procurement process,
- receiving feedback about the requirements and common challenges from potential suppliers about the scope of the procurement envisaged in CRANE (including technical specifications),
- facilitating matchmaking among potential suppliers in need of support in the building of consortia capable of addressing the needs of the procurers in full,
- assessing the state-of-the-art technologies and relevant R&D&I projects in the field.

The CRANE OMCs was conducted through a series of events that, due to the ongoing COVID-19 pandemic, were held as online webinars on the following dates:

- Swedish OMC – 27 April 2022
- Norwegian OMC – 3 May 2022
- Spanish OMC – 5 May 2022
- International OMC – 11 May 2022
- Brokerage session – 8 June 2022

To complement the analysis, all potential applicants for CRANE PCP were encouraged to fill in an online OMC questionnaire[6], with the purpose to gain insights into existing technologies, and a matchmaking service[7] was offered by the project to support potential tenderers in identifying partnerships.

Over 200 economic actors and stakeholders participated in the OMC events. Using the OMC questionnaire they were able to provide further information on their state of-the-art-technologies. These would include evidenced gaps, shortcomings, trends and implications as well as feeding the development of the CRANE Challenge Brief. Participation in the OMC events is not a prerequisite for submitting a tender for this call.

As a summary of the most relevant OMC activities carried out within 18th of April and 20th of June 2022 we can list:

1) CRANE Website full coverage new section and related tools (Events registration, Matchmaking, 1-ON-1, etc).

2) CRANE Questionnaire in order to collect feedback from Industry (available at D3.3). A total of 23 answers have been received. The related results can be found in D3.3 and have been incorporated to CRANE related documents (D2.2, D2.5 and tender documents).

[6] https://crane-pcp.eu/questionnaire/

[7] https://crane-pcp.eu/matchmaking/

3) Scope and Use Cases specifically elaborated documents in order to support industry stakeholders to gain knowledge about CRANE (available at CRANE website and at D3.3).

4) Three regional focussed and one European approach webinars (online) explaining CRANE concept and the particularities for each buyer region. The related agendas and recordings are available at CRANE website.

5) One brokerage event (online) with 15 presenters and over 35 attending companies. To present in the event all companies where required to answer in advance CRANE OMC Questionnaire. The recording and agenda are available at CRANE website.

6) FAQs section with over 50 questions being raised by stakeholders and clarified by CRANE consortium.

7) CRANE Matchmaking tool developed and integrated in the project website to promote contact and cooperation among companies interested in creating a consortium to participate in the PCP process. It will remain open until the tender deadline.

8) 1-ON-1 Meetings from interested industry stakeholders in order to discuss with CRANE Consortium the concept and provide additional inputs to it.

9) Specific dissemination events and actions carried out by all CRANE consortium members at local, national and European level. Similar coverage from social networks as well as customized contacts (a database for relevant stakeholders has been elaborated by CRANE consortium members and used for direct communication).

10) CRANE Model updated based on the inputs from OMC activities and feedback received in the 1-ON-1, Questionnaire and related events.

All the proceedings of the OMC, results and related documentation have been included in the D3.3 OMC Report. In addition, the OMC events and Q&As have been published on the project website ensuring its availability to all OMC participants and other interested stakeholders.

1.7 EU funding

This PCP is part of a project that is funded by the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No 965277 – CRANE (see https://crane-pcp.eu /).

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

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

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

2 Tender profile

2.1 Description of services to be procured

This procurement is for R&D services to develop original and innovative solutions to tackle the challenge shared by the Buyers Group of "providing citizens of an intelligent technologies' infrastructure, to enable for citizens to get control over their public and personal health data, to easily self-manage and consent access to their data to different entities, such as healthcare services, analysts and researchers, which are able to get them back useful insights for their own health management".

CRANE infrastructure will be validated with a **proof of concept** where **citizens in rural areas use their health data to improve the self-management of their chronic conditions**.

The PCP includes the purchase of a limited set of prototypes and first test and validation of products and services resulting from the R&D. The cost of prototypes must be lower than the cost of R&D services."

2.1.1 PCP challenge

Provision and management of care and support for patients with chronic diseases requires a multifaceted effort across healthcare and care settings for which multiple challenges remain, partly caused by existing fractures in systems and delivery that currently lead to individuals "falling through the cracks". Many of the challenges connects to data management, data that are currently locked into different silos of different service providers.

CRANE must enable secure and efficient dataflow between the various Health and social care providers and their many different data systems, and provide easy and understandable ways of managing necessary consent forms for the inhabitants/patients. Aggregated use of health data requires new, true and honest thinking of what patient centred care are about. In addition, healthcare from home through self-monitoring and self-care generates high quantities of data which require effective and efficient data management so insights and knowledge from collected health data can be harvested. We need to add to this picture that many citizens are equipped with different kind of sensors, and they gather a lot of private health data outside healthcare and social care services. This sensor data can, in combination with other siloed health data, help to predict the development of different chronic conditions and can in combination with citizens complete health data sets help avoiding future health care referrals and admissions and in general help delaying the negative progression of the citizens chronic conditions. A new service solution is needed, that unlocks health data for preventive use to improve health and well-being for citizen with chronic conditions and at the end citizens at large.

The three Buyers represented in the CRANE consortium share the sense of urgency to radically improve and develop the integrated care model for patients with chronic diseases. They are willing and ready to adopt an innovative integrated care solution that unlock the silos, to overcome fragmented health and care service provision. CRANE will jointly procure R&D services to shape an ICT-enabled integrated care service solution, supporting the implementation of a comprehensive multidisciplinary and cross-organisational care model. A fully integrated patient pathway, for people living with chronic diseases.

The CRANE solution will enable procurers to provide better health and care for patients with chronic diseases with a special focus on:

- Radical improvement of the hospital discharge processes and other care transitions.
- Profound increase of collaboration efficiency and improvement of patient experiences of the care system.
- Tailored provision of secondary prevention measures.
- Digitally enabled real patient-empowerment and self-management support.
- Innovative performance monitoring, including for example new ways of PREMs and PROMs collection.

As most services can also contribute to integrated care service delivery to people living with other chronic conditions, CRANE welcomes, in line with procurer interests and market demand, suppliers with an integrated care solution easily adaptable to conditions also prioritised by the procurers such as respiratory, metabolic, other cardiovascular conditions, or cancer. Furthermore, it is of value to CRANE procurers that the new platform will be reusable for a more integrated management of other prevalent resource-consuming long-term conditions, such as dementia or frailty. The CRANE solution can work as supporting system, not necessarily needed to be seamlessly integrated into existing ICT systems, but can contribute to support processes and working practices and must enable better dataflow within the Health and Social care systems.

Developed in competition under the PCP instrument, the CRANE solution has the potential to serve 1,320,000 patients with chronic conditions in the procurer countries when fully rolled out.

A dedicated document (TD2 – CRANE Challenge Brief) provides a detailed description of the expected scope and functionality of the CRANE solutions. This is a common challenge shared by all procurers in the Buyers Group.

2.1.2 Expected outcomes per phase

This procurement is organised in stages in accordance with the PCP instrument (see section 1).

Summary

The content of the proposal **lays the ground for the overall R&D effort** and prepares work to be conducted for the following competitive phases.

In their proposal, tenderers are requested to describe a solution supporting **CRANE** to make the citizens' public & personal health data automatically accessible to provide, through intelligent technologies, new smart and tailored insights. During the project, tenderers are expected to apply their approach in full to the pilot sites.

In Phase 1, five contractors apply their solution design approach for the CRANE Challenge. The design level is schematic; planning and calculations are preliminary. During this phase, contractors and procurers will interact in a co-design and co-creation process where doubts and decisions will be agreed-upon. This phase aims to verify the conceptual, technological, organisational, regulatory, safety and budgetary feasibility of the solutions.

In Phase 2, three contractors refine and increase the level of detail of their designs and develop a prototype. The design level is as detailed as possible and calculations should be final. The use of the Co-Design procedure should be intensified. This phase aims to turn the schematic design to a prototype preparing all parties involved for rapid validation and implementation; and to give future users the opportunity to test the solution.

In Phase 3, two contractors implement their solution to be verified by Buyer Regions in the selected Pilot Sites in each country of the 3 Buyers. The solutions are installed, integrated, made operational, maintained and performance data collected.

After the end of the project there is the possibility of a follow-up project (PPI) that will facilitate the widespread implementation of the solutions depending on project success and whether service prices are, at this point, commercially competitive or require further support (see section 5.5).

(The following Phases description and timing are indicative. At the beginning of each Phase, the Lead Procurer will specify the exact Phase description, dates of accomplishment of the milestones and of submission of deliverables and will communicate them to all the Phase awardees).

The following tables contain a description of the objectives, the associated outputs and results, and the tasks to be carried out (milestones and deliverables) for each of the three phases. All the deliverables are required to be met in the preceding phase for progression into subsequent phases.

Expected outcomes for Phase 1: Solution Design

Table 2 Expected outcomes for Phase 1: Solution Design

Phase 1 – Solution Design	
Objectives	During Phase 1, the selected Contractors are asked to provide a solution design and determine the approach to be taken to develop CRANE solutions and services needed and demonstrate the technical, financial, and commercial feasibility of the proposed concepts and approach to meet the procurement needs made by the Buyers Group in their assessment of the tenders. During this phase, contractors and procurers will interact in a Co-Design and Co-Creation process where doubts and decisions will be agreed-upon.
Output & results	The solution design, End of Phase 1 report, should include: • Evidence of having answered to the functional requirements requested in CRANE PCP TD2: Challenge brief and the mandatory recommendations made by the Monitoring Team during the assessment of the Interim Outcome Update. • Description of the data sources that are to be provided and integrated in the solution for Phase 2, both from the Buyers (public sources) and from external sources. These could include: EHR, HIS, PHR, or Care Plan Management Tools for patients which use “machine readable ”code systems and/or structured, standards compliant data, etc presenting Open APIs/Interfaces. • A governance model for CRANE Open Platform considering the different requirements described in TD2. It should also describe the approach and tools to the agile methodology to be used in developing the CRANE infrastructure and the underlying services. • An architecture and components, including the different services and devices that are expected to be brought to the solution, which must be compliant with the requirements described in TD2. The conceptual architecture described in TD2 should be considered just as an example for inspiration. • An illustration of the implementation of the use case presented in TD2. • The draft business model for the whole operation of the infrastructure • The proposed approach to the provision of patient self-management, education, and support to different layers and groups of users. • A mock-up of the user interface. • A presentation to the trust building, privacy methods and technologies, including encryption. • The content of the basic patient summary per region. • The planned approach for scalability and sustainability of the energy intensive algorithms/protocols/processing (eg. blockchain, transactions per seconds, smart contracts, processing power, validation methods). Finally, the report has to include the research protocol, informed consent and data management procedures for Phase 2, proof of concept, and a Data Management Plan, including data sharing agreements, to be defined put in place in the three Buyers Regions after approval by their ethics committees and other authorising entities / agencies (if applicable).

Milestones	By when? (See section 2.7 Time schedule)	How?	Output & results
M1.1) Kick-off meeting	Start of Phase 1	Physical or online meeting. To be decided (tbd)	Presentation of Monitoring Team. Presentation of Phase 1 procedures, methodologies, timelines, and plans to deliver Phase 1 by contractors. Q&A.
M1.2) Interim progress review	Mid phase 1	D1.2 submitted + presentation + evaluation (physical and/or online tbd)	Report and presentation, describing the progress achieved. Overview of risks and contingency plans. Evaluation of the solution design progress presented by contractors.
M1.3) Solution design - End of phase 1 completed	End of phase 1	D1.3 submitted + presentation + evaluation (physical and/or online tbd)	Report and presentation, describing Phase 1 results and outcomes. Evaluation of the contractors' solution design.
Deliverables	**By when? (See section 2.7 Time schedule)**	**How?**	**Output & results**
D1.1) Phase 1 project abstract	One month after starting Phase 1	D1.1 submitted	Report with the project 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 tbd)	Report describing the progress achieved in the solution design during the period in question and plans for the next period. Overview of risks and contingency plans.
D1.3) Solution Design -End of Phase 1 Report	End of phase 1 (Half a month before ending of Phase 1)	Report + presentation (physical and/or online tbd)	Report including technical, financial, and commercial feasibility of the solution design. It should also include: All the issues described in the section "Output and results" of this table for phase 1. A description of any results generated (incl. technical results and any videos submitted). A list of names and location of personnel that carried out the R&D activities. A declaration of used resources, broken down as in the offer. Due evidence of the resources deployed shall be appended to the report including the company financial report that proofs financial feasibility. A declaration that at least 50% of

			The work was carried out within the EU27 or a country associated with Horizon 2020. A draft of the Ethics protocol to be approved in Phase 3. If applicable, the planned measures to protect IPR generated from the execution of the tender. A draft of the 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

Expected outcomes for Phase 2: Prototyping

Table 3 Expected outcomes for Phase 2: Prototyping

Phase 2 – Prototyping	
Objectives	1. Develop, demonstrate, and validate CRANE solution prototypes V1 under lab conditions. Prototypes at this stage is conceived of as non- or partly functional prototypes of key system components. 2. Development of CRANE solution prototypes V.2. Prototypes at this stage are conceived of as functional prototypes, demonstrating component behaviour and system-wide interaction. Also operating in the conditions that address pilot site needs. 3. Present the research protocol for the pre-market clinical proof of concept and the Data Management Plan ("DMP") to be carried out in Phase 3. Including: citizens informed consent, application for ethical approval and any additional certificate or authorisation (if required).
Output & results	The prototype v1 and v2 are subject to lab testing. A suitable number of data-sets (n>2) will be involved in each pilot location. V2 prototypes will be presented by suppliers at each procurer site. By the end of Phase 2, each successful contractor will have a prototype mock-up • Prototypes pass al the defined tests with end users for one pathology at least. • Testing take place according to common protocols. • Progress of the work monitored in status calls. • The business model for the whole operation of the infrastructure. • The detailed approach to the provision of patient self-management, education, and support to different layers and groups of users. • The approach for scalability and sustainability of the energy intensive algorithms/protocols/processing (eg. Blockchain, transactions per seconds, smart contracts, processing power, validation methods). • Description of the data sources that are to be provided and integrated in the solution for Phase 3, both from the bidder consortium and from external sources.

	• Research protocol to be carried out in Phase 3 and Data Management Plan including: informed consent, data sharing agreements, application for ethical approval and any additional certificate or authorisation (if required). • Written report and on-site presentations.		
Milestones	By when? (See section 2.7 Time schedule)	How?	Output & results
M2.1) Kick-off Phase 2 meeting	Start of Phase 2	Physical or online meeting tbd	Phase 2 Action Plan agreed by the monitoring team and each contractor. Q&A resolution
M2.2) Prototype v1 iteration	3 Months after the starting of Phase 2	Report + presentation + evaluation (physical and/or online tbd)	Report and presentation, describing the progress achieved or physical demonstration (in procurer's facilities) or online demonstration tbd. Overview of risks and contingency plans. Evaluation of the solution design progress presented by contractors.
M2.3) Prototype v2 iteration	8 Months after the starting of Phase 2	Report + presentation + evaluation (physical and/or online tbd)	Report and presentation, describing the progress achieved or physical demonstration (in procurer's facilities) or online demonstration tbd. Overview of risks and contingency plans. Evaluation of the solution design progress presented by contractors.
M2.4) Prototype validations in lab conditions	Month 10 of Phase 2	Demonstration	Physical demonstration (in procurer's facilities) or online demonstration tbd
M2.5) Demonstration for Stakeholders including EU representatives	Month 10 of Phase 2	Demonstration to EU representatives	Physical demonstration or online demonstration tbd
M2.6) End of Phase 2 review	End of Phase 2	Report	Report and presentation, describing Phase 2 outcomes. Evaluation of the contractors' solution prototypes.
Deliverables	**By when? (See section 2.7 Time schedule)**	**How?**	**Output & results**
D2.1) Phase 2 project abstract	One month after starting Phase 2	Report	Abstract (in the format required by the EU for publication) template.
D2.2) Prototype v1 iteration	3 Months after the starting of Phase 2	Demonstration of the status of the Prototypes v1. (Virtual / physical meeting tbd). 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.

D2.3) Prototype v2 interaction	8 Months after the starting of Phase 2	Demonstration of the status of the Prototypes v1. (Virtual / physical meeting tbd). 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.
D2.4) Prototype validations in lab conditions	Month 10 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 for Stakeholders including EU representatives	Month 10 of Phase 2	Physical or Online demonstration of prototypes to EU representatives	Evaluation of the whole Prototype phase in a presentation and report, including Prototype lab test results
D2.6) End of prototype phase report	End of Phase 2 (half a month before ending of Phase 2)	Report + presentation (physical and/or online tbd)	Report including technical, financial, and commercial feasibility of the solution design. It should also include: • presentation of the prototypes including development details, operational procedures and a report explaining the output and feedback from the monitoring briefings by the Buyers Group. • A description of any results generated (incl. technical results and any videos submitted). • A section that explains the IPR approach taken by the contractor. • A list of names and location of personnel that carried out the R&D activities. • A declaration of used resources, 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 with Horizon 2020. • The Ethics protocol to be approved by the 3 Buyers Ethics Committees before pilot testing, in Phase 3, starts • Report on the effect of KPI's.

			• Updated DMP • Updated business model and commercialisation plan. Financial statement
D2.7) Abstract of the main results achieved	End of Phase 2	Report	Abstract (in the format required by the EU for publication) template

Expected outcomes for Phase 3: Verification

Table 4 Expected outcomes for Phase 3: Verification

Phase 3 - Verification			
Objectives	Perform research to: • Implementation and deployment the CRANE service solutions for an extended test under real-life conditions at all procurer sites (in each country of the 3 Buyers) for all proposed pathologies in each pilot site. • Testing of pilot service solutions at each pilot site, including: ○ Operational maintenance during piloting and definition of performance standards for commercial deployment. ○ Establishment and operation of a service support center for CRANE end-users in each pilot testing site adapted to each pilot site characteristics. ○ Evaluation of pilot service solutions against commonly agreed protocols and metrics.		
Output & results	Well-functioning CRANE service solutions in the field-testing sites environments of the Buyers Regions. Implementation (in each test-site): • Suppliers install the pilot systems at each site in close collaboration with the respective site partner. • Implementation covers installation and on-sit testing of central components, users' trainings, and preparation of user devices, if any, for roll-out. • Deploy all required integrations with data sources in each test-site. • Support procurers in the design of CRANE programmes to be implemented during the field testing. • Support and train end-user in the use of CRANE service solutions. • Run intensive testing of the whole CRANE service solutions in each test-site. Roll-on (validation in each test site with CRANE local stakeholders): • Support end-user in the set-up and use of CRANE service solutions. • Provide support and maintenance to all CRANE stakeholders in the operation of solutions. • Provide follow-up and support to preserve motivation and engagement of all CRANE stakeholders. • Keep an updated scoreboard with the proposed KPIs for follow-up. • Plans for scaling-up including interoperability requirements for full integration. • Detailed documentation of the various integrations across participating service providers. • Progress of the work is monitored in status calls.		
Milestones	**By when? (See section 2.7 Time schedule)**	**How?**	**Output & results**
M3.1) Kick-off meeting Phase 3	Start Phase 3	Physical meeting	Phase 3 Action Plan agreed by the monitoring team and each contractor. Q&A resolution

M3.2) Ethical Approval and participant recruitment confirmation	3 months after the starting of Phase 3	Recruitment completion	Document containing signed informed consents from field-testing participants. Formal approval of the 3 Buyers Ethics Committees of ethics protocol for the Field Testing
M3.3) Field Testing starting at the different sites	1 week after M3.2	Start of the Field Testing	Contractors start the Field Testing
M.3.4) Interim progress review	6 months after the field testing starting	Report + presentation+ evaluation (physical and/or online tbd)	Report and presentation, describing the progress achieved or physical demonstration (in procurers' facilities) and/or online demonstration tbd. Overview of risks and contingency plans. Evaluation of the solution design progress presented by contractors.
M3.5) Completion of the Field Testing	Month 14 of Phase 3	End of the Field Testing	Contractors finalise the Field Testing
M3.6) Final demonstration for Stakeholders including EU representatives	Month 15 of Phase 3	Physical demonstration	Physical demonstration to EU representatives
M3.7) End of Phase 3 review	End of CRANE project (one month after the end of Phase 3	Report	Report and presentation, describing Phase 3 outcomes. Evaluation of the contractors' field testing
M3.8) Text for the summary of overall lessons learnt from the PCP	End of CRANE project (one month after the end of Phase 3)	Report	Lessons learnt and results achieved from PCP
Deliverables	**By when? (See section 2.7 Time schedule)**	**How?**	**Output & results**
D3.1) Phase 3 project abstract	One months after start of phase 3	Report	Abstract (in the format required by the EU for publication) template.
D3.2) Interim Progress review report	6 months after the field testing starting	Report + presentation (physical and/or online tbd)	Report describing main progress in achieving the field-testing during the period in question and plans for the next period
D3.3) Demonstration for Stakeholders including EU representatives	Month 15 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.
D3.4) End of Phase Report	End of Phase 3 (30 days before	Report	Evaluation of the solution performance, including field testing

	ending of Phase 3)		outcomes and impact report. It should also include: • A complete description of validations performed. • A description of any results generated (incl. technical results and any videos submitted). • A section that explains the IPR approach adopted by the contractor. • A list of names and location of personnel that carried out the R&D activities. • A declaration of used resources, 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 with Horizon 2020. • Report on the effect of KPI's. • Updated DMP. • Updated business model and commercialisation plan.
D3.5) Abstract of the main Results achieved	End of phase 3	Report	Abstract (in the format required by the EU for publication) template
D3.6) Text of the summary of overall lessons learnt from the PCP	End of CRANE project (one month after the end of Phase 3)	Report	Abstract (in the format required by the EU publication) template

The offer in Phase 1 for Phase 2 and in Phase 2 for Phase 3 shall be an update of the original tender. All revisions and additions possible through work in the completed phase shall be made. The offer shall therefore include inter alia:

- updated assessment of patient benefits and procurer benefits,
- updated exploitation business plan,
- updated list of Background,
- updated approach for scalability and sustainability of the energy intensive algorithms/protocols/processing (e.g. Blockchain, transactions per seconds, smart contracts, processing power, validation methods),
- any new evidence of the feasibility of achievement of technical objectives and benefits to patients and procurer health systems.

In addition, by the end of phase 2 the contractors should be prepared to demonstrate the developed v2 prototypes to the European Commission's part of regular technical reviews in EU projects.

Furthermore, as detailed previously, contractors have to develop an Ethics protocol through Phase 1 and Phase 2 that must be approved by the three Buyers Ethics Committees before piloting in Phase 3 starts.

The final report shall include an updated assessment of patient benefits, procurer benefits and updated information on the evidence on which this assessment is made, including evidence generated by the contractor in phase 3 of PCP.

In Phase 3 each contractor is to provide for the duration of the pilot full specification access to the innovative system (including all necessary hardware for its proper functioning) for testing to at least the number patients and clinician users listed in the table below.

Moreover, testing of the solution with the users below is planned to be carried out in parallel in all testing sites listed in the table below and should be reflected in the tenderer's resource planning.

Procurer	Pilot site	
Region Västerbotten	Storuman Municipality	Vilhelmina Municpality
Extremadura	Jarandilla de la Vera	Villanueva de la Vera
Agder Region (*)	Arendal	Kristiansand

Table 5 Pilot Sites per procurer

(*) Agder municipalities for piloting could be changed.

In Phase 1, end users will not be directly involved in the R&D process, as their inputs have already been collected by the local Procurer's research team. Users will be involved in phases 2 and 3, being the recruitment an overall responsibility of the procurers, nevertheless the process shall be supported by the contractors (e.g. by providing patient leaflets with more information about the solution, informed consent templates, etc.). On the other hand, training of the participants, and others involved in the pilot, will be responsibility of the contractor, this has to be considered in the tender.

Final users will include: **independent patients** that are interested in their self-care; **dependent patients** with caregivers/relatives interested in using the CRANE solution as a form of support for patient care

All in all, CRANE buyers will appoint a clinical team to support and follow-up contractors during the CRANE PCP Challenge. Furthermore, CRANE buyers will facilitate access to EHR Data by a simple procedure (like pdf). But, contractors will be accountable for Data collection and treatment.

The procuring regions represented by the Buyers Group are responsible for medical treatment and evaluation. Contractors support the evaluation, e.g., by integrating questionnaires into the system, analysing raw data about the use of the interfaces, etc.

2.2 Tender closing time

Tender closing time is 23:59 CET, on 6th of November, 2022.

2.3 Procurers and other parties involved in the PCP

This procurement relates to a joint PCP that will be carried out by the Lead Procurer Region Västerbotten [RVB][8].

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:

- Region Agder, Norway
- Region Extremandura, Spain

The Lead Procurer is part of the Buyers Group. All legal names and registration numbers of the members of the Buyers Group can be found in the CRANE Prior Information Notice.

In addition to the Buyers Group, the following entities are participating in the PCP, but are not Members of the Buyers Group:

- **Centre for connected care**, centre for research-based innovation to accelerate the adoption of integrated patient centric services to create health value.
- **EUROB Creative**, highly specialized technology provider SME (Digital Health, Big Data and Blockchain) that acts both as a technology provider and developer of products and services for healthcare and security.
- **PPCN**, Digital health Technology & Consultancy group specialized in ICT development, Procurement, Project management, Market expansion, regulatory advisory & Strategy & Innovation projects
- **VALDE INNOVA,** consulting company integrated by a network of senior collaborators with specialized profiles in innovation procurement at European level, experience in European Projects management, and methodologies for co-creation.

These entities are granted access to information shared during the PCP, if they need this information to implement the CRANE Grant Agreement. They are bound by an obligation of confidentiality. They have no rights to results or IPRs from the PCP. The Linked Third Party has clear obligations and rights under the CRANE Grant Agreement.

The project will continuously inform other procurers having expressed interest in the project. Suppliers will be given opportunity to present their solutions as events with interested procurers. Interested procurers are not granted any rights.

2.4 Contracting approach

The PCP will be implemented by concluding a Framework Agreement with each successful tenderer and Specific Contracts for each of the three R&D phases.

A Framework Agreement and a Specific Contract for Phase 1 are planned to be awarded to a minimum of five contractors.

A call-off will be organised for Phase 2, with the aim of awarding three Phase 2 contracts. Only offers from contractors that successfully completed Phase 1 will be eligible for Phase 2. The procurers will

[8] Official name: Region Västerbotten, National registration number 232100-0222 Address: Regionens hus, Köksvägen 11, Umeå Post address: Region Västerbotten, 901 89 Umeå, Sweden

validate the Phase 2 prototypes via, if possible, face-to-face demonstration meetings with the suppliers on the premises of each procurer's pilot site.

A second call-off will be organised for Phase 3, with the aim of awarding a minimum of two 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 the pilot sites of the procurers – in Region Västerbotten (Sweden), Region Agder (Norway) and Region Extremandura (Spain)

The Framework Agreement sets the framework conditions for the entire duration of the PCP (covering all the phases). There will be no renegotiation. The Framework Agreement will be signed before the start of Phase 1 and 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.

The call-offs between Phases 1 – 2 and 2 – 3 require binding offers for the next respective phase, which are requested with the end-of phase deliverables for the previous phase. As the evaluation takes place at the very end of a phase, both the completion of the phase (successful or not successful) and the offer for the next phase are part of that evaluation.

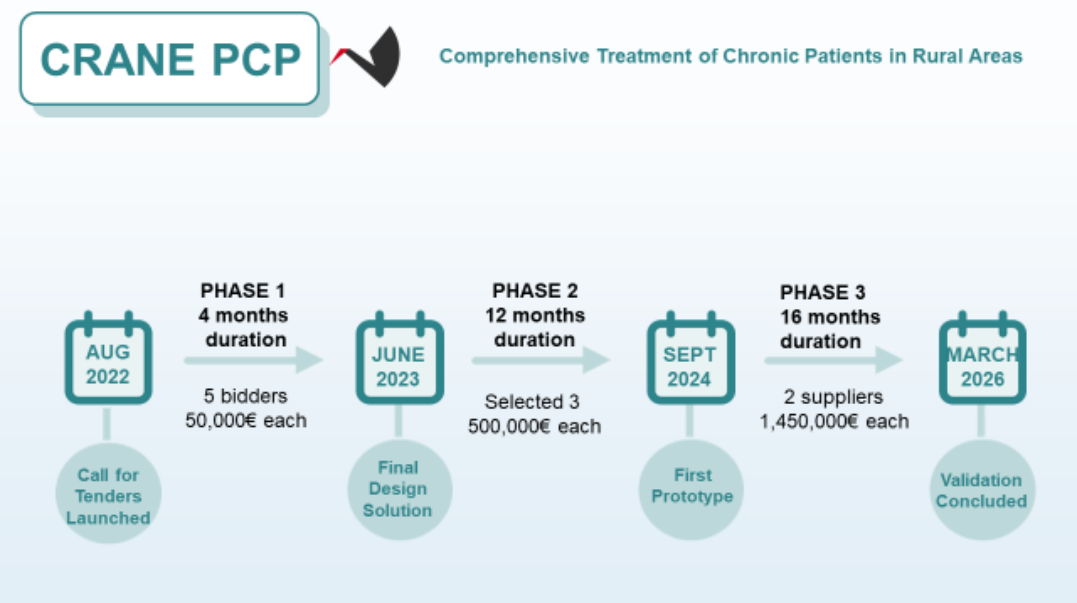
In the following table a summary of the overall timing of the PCP including its individual phases (excluding evaluation periods) is detailed.

Table 6 CRANE PCP overall timing

Phase	Start date	End date	Duration
Call for tenders	September 2022	November 2022	2 months
Phase 1	February 2023	June 2023	4 months
Phase 2	September 2023	September 2024	12 months and a half
Phase 3	December 2024	March 2026	16 months and 3 weeks

The illustration below demonstrates funds available for each phase, expected no of months of each phase, and between which periods each phase shall be conducted:

Figure 2. The PCP phases in CRANE: Schedule and budget



2.4.1 Total budget and budget distribution per phase

The aim of this section is to explain how much funds are available to award winning tenderers for each phase of CRANE PCP, and totally:

The total budget for the PCP is 4,650,000 € including non-deductible VAT

The maximum budget available for Phase 1 is 250.000 € excluding VAT

The maximum budget available for Phase 2 is 1.500.000 € excluding VAT

The maximum budget available for Phase 3 is 2.900.000 € excluding VAT

The expected number of specific contracts to be awarded under the CRANE PCP is five specific contracts for Phase 1, three specific contracts for Phase 2, and two specific contracts for Phase 3.

For Phase 1, offers will be accepted 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 passing 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 slightly different than stated here. 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.

Note: Each proposed contract is stated to a maximum amount excluding VAT. If VAT cannot be recovered from one winning tender that non-deductible VAT will be reduced from available funds available for next phase. Third phase contracts will be adjusted so a total allocation for contracts will not exceed total budget for CRANE PCP: 4 650 000€ including non-deductible VAT.

Based on procurer assessments for appropriate resourcing of each phase, including reductions due to IPR arrangements. The expected maximum allowed ceiling price, specified in TD7, for each tender and and phase is:

Table 7 CRANE PCP budged distribution across Phases

Type	Phase 1	Phase 2	Phase 3
Maximum total budget per phases (excluding VAT)	250.000 €	1.500.000 €	2.900.000 €

Expected number of contractors to be funded	5	3	2
Maximum budget per contractor (excluding VAT)	50.000 €	500.000 €	1.450.000 €
Duration of the phase	4 months	12 months and a half	16 months and 3 weeks

The offer is subject to value for money (see section 3.5).

Since all suppliers will be paid by the Lead Procurer (centralised payments), and RVB is the Lead Procurer in the CRANE PCP, the valid Swedish and EU VAT legislation will be applied in the project. These provisions also apply to suppliers from other countries outside of EU VAT legislation.

2.5 Time schedule

The following table gives and overview of the planning timing of the CRANE PCP phases:

	Tender periods
	Execution of PCP phases periods

Table 8 Timing schedule

First tender procedure (framework agreement and Phase 1 contracts)	
Date	**Activity**
05th September 2022	Publication of the Contract Notice in TED
05th September 2022	Publication of CRANE PCP call for tender
12th October 2022	Deadline for submitting questions about tender documents
19th October 2022	Deadline for lead procurer to publish final replies to questions (Q&A document)
06th November 2022	Deadline for submission of tenders for the framework agreement and Phase 1
07st November 2022	Opening tenders
20th January 2023	Award decision & Tenderers notified of classification
21th January 2023 – 04th February 2023	Standstill period (15 days TD1)
10th February 2023	Deadline for signing framework agreements and phase 1 specific contracts
13th February 2023	Publication of contract award notice in TED
Implementation of phase 1	
Date	**Activity**
14th February 2023	Start of phase 1 – Kick-off
18th April 2023	Deadline to deliver and present D1.2, Interim Progress Report for phase 1
6th June 2023	Deadline to deliver and present D1.3 Solution Design - End of phase 1 Report review
20th June 2023	End of phase 1
Second tender procedure (Phase 2 contract)	
Date	**Activity**
22nd Mai 2023	Publication of Call-off for phase 2 offers *Submission of offers (tenders) for phase 2 starts*
21st June 2023	Deadline to submit call-off for Phase 2 *Only offers from contractors that successfully completed phase 1 will be evaluated*
22nd June 2023	Opening of offers (tenders) for phase 2
7th July 2023	Award decision and notification
08.07.2023-23.07.2023	Standstill period (15 days)

31st August 2023	Deadline for signing of Phase 2 specific contracts
Implementation of phase 2	
Date	**Activity**
4th September 2023	Start of phase 2 & Kick-off
4th December 2023	Deadline to deliver and present D2.2 Prototype v1 iteration
3nd Mai 2024	Deadline to deliver and present D2.3 Prototype v2 iteration
23nd June 2024	Deadline to deliver and present D2.4 Prototype validation in lab conditions and D2.5 Demonstration for Stakeholders including EU representatives
4h September 2024	Deadline to deliver and present D2.6 End of prototype phase report
18th September 2024	End of phase 2
Second tender procedure (Phase 3 contract)	
Date	**Activity**
3rd September 2024	Publication of call-off for phase 3 *Submission of offers (tenders) for phase 3 starts*
2nd October 2024	Deadline to submit call-off for Phase 3 *Only offers from contractors that successfully completed Phase 2 will be evaluated*
3rd October 2024	Opening of offers (tenders) for phase 3
11th November 2024	Award decision and notification
12.11.2024- 27.11.2024	Standstill period
28th November 2024	Signed contracts sent to tenderers
Implementation of phase 3	
Date	**Activity**
2nd December 2024	Start of Phase 3 & Kick-of
3rd February 2025	Ethical Approval and participant recruitment confirmation
10th February 2025	Field Testing starting at the different sites
8th September 2025	Interim progress review
14th February 2026	Completion of the Field Testing
24th February 2026	Demonstration for Stakeholders including EU representatives
31st March 2026	End of Phase 3
21st April 2026	End of Phase 3 review
21st April 2026	Summary of overall lessons learnt from the PCP

Note: The time schedule is indicative. The Buyers Group reserves the right to adjust it.

Note: The standstill period for each phase begins from the award decision and notification and lasts until date of signature by the Lead Procurer.

Note: All work shall be completed at the latest two months before end of the CRANE Grant Agreement.

2.6 IPR issues

2.6.1 Ownership of results (foreground)

Each contractor will keep ownership of the IPRs attached to the results they generate during the PCP implementation. The tendered price is expected to take this into account.

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

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),

2.6.2 Commercial exploitation of results

Combined, the CRANE procurers represent attractive national markets, as well as an overall market. They represent three countries and are responsible for the care of over 63 million people. Over 50 million people in Europe have more than one chronic condition.

The contractors are expected to start commercial exploitation of the results at the latest four years after the end of Phase 3.

The contractors are obliged to prepare in good time for exploitation as follows:

- If certification as a medical device is necessary, the contractor must apply for certification at the earliest possible opportunity
- If extension or modification of existing standards, or new standards, are required for or would promote exploitation, contractors must take any opportunity to offer their contributions to the relevant standards bodies.

Procurers will promote the R&D results among other procurers and assist in widely disseminating the results of the contract.

The feasibility of the business plan to commercially exploit the R&D results will be assessed as part of the award criteria (see section 3.4).

2.6.3 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), a complete list of all Background and planned Sideground must be provided with the Tender as part of TD6, Technical Application Template, including its ownership and the commercial conditions for its use for any Member of the Buyers Group:

a) to use the Results and the proposed solution for their own purposes,
b) to exploit the Results as provided for in the Framework Agreement.

The estimated price for any use of third-party Background and the fully annualised charge for the tenderers' own Background and Sideground must be fully included in the calculation of total cost in case of possible ownership of the system solution for procurers.

Ownership and obligations regarding Background and Sideground is further specified in the Framework Agreement.

3 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.

Tenders may be submitted by a single entity or in collaboration with others. The latter can involve either submitting a joint tender (see 3.1.1) or subcontracting (see 3.1.2), or a combination of the two approaches.

Note: *There are requirements relating to the place of performance of the R&D services as well as to the share of personnel costs in R&D services: At least 50 % of the total value of R&D 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.*

Single tenderers or members of the group may not participate in more than one tender. The Buyers Group reserves the right to exclude any tender in breach of this provision.

Participation in the OMC is not a condition for submitting a tender.

For Phases 2 and 3, participation is limited to tenderers that successfully completed the preceding phase.

3.1.1 Joint tenders

It is required for joint tenders that:

- each member of the group of tenderers assumes joint and several liability for the performance of the contract,
- the group of tenderers must mandate one of them with the power to sign the Framework Agreement and specific contracts provided in their name and on their behalf (“Lead Contractor”).

To meet these requirements, each of the members of a group of tenderers except the Lead Contractor must provide with the TD5, Tender Application Template, an originally signed power of attorney conforming to the template provided in TD4 Power of Attorney.

There may be no change in the composition of a group of tenderers that tendered at the beginning of the PCP procedure.

The Buyers Group may exceptionally authorise changes in the composition of a group that tendered at the beginning of the PCP procedure (during the proposal selection) and/or the formation of a new group different from the one that tendered at the beginning of the tendering process. Nevertheless, any such authorisation, to be provided in writing at the discretion of the Buyers Group, shall not apply if:

- It implies the entry of new participants different from those tendering individually or jointly at the beginning of the PCP procedure, or of participants previously withdrawn or excluded from said procedure or in default under the Framework Agreement or under a Specific (phase) Contract
- It leads to a reduction of the number of Specific Contracts in a phase below the minimum numbers set in Section 2.4.
- It leads, according to an independent legal report, to IPR/confidentiality issues (i.e. if associated participants selected for Phase 1 decide to continue as individual entities or to join other consortia).

- The new tender resulting from the change no longer meets the selection criteria required under section 3.3.
- It occurs during the execution of a specific (phase) contract, except in the event of the insolvency of one of the members of the consortium, corporate restructuring operations affecting one or several of the members of the tendering group or the merger, take-over, transformation or assignment of a company or business unit.

3.1.2 Subcontracting

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.

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 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.

The tenderer remains fully liable to the Buyers Group for the performance of the framework agreement and each Specific Contract.

Before subcontracted work begins in any Specific Contract, the tenderer must provide the Buyers Group with an originally signed agreement with the subcontractor including a clear description of the work to be subcontracted and a declaration that the subcontractor:

- 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 CRANE 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.

Addition or replacement of subcontractors

If, subsequently, the tenderer needs to change or add new subcontractors (Phases 1 through 3), these new subcontractors must observe the requirements described in the above section and following the same form. Nevertheless, no change in subcontractor shall be possible if:

- It leads to a reduction of the number of Specific Contracts in a phase below the minimum numbers set out in Section 2.4.
- It leads, according to an independent legal report, to IPR/confidentiality issues (i.e., if associated participants selected for Phase 1 decide to continue as subcontractor for another tender).
- It prevents the tenderer from meeting the selection criteria required under section 3.3.

Changes and additions to subcontractors named in prior offers require authorisation by the Buyers Group following the same criteria described above for joined tenders.

The approach to subcontracting (selection of subcontractors and management) is to be described in the tender.

3.2 Exclusion criteria

The exclusion criteria related to the Declarations of Honour are as follows:

Table 9 Exclusion criteria

Exclusion criteria	Evidence
A) Conflict of Interest	Declaration of Honour (TD3a)
B) Exclusion grounds as defined in Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014	Declaration of Honour (TD3a)

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

Tenderers shall explicitly assure that they are not subject to any of the exclusion criteria listed above by presenting a duly signed declaration of honour, using for this purpose the template provided in Declaration of Honour on Exclusion Criteria (TD3a).

In case of subcontracting, all subcontractors whose share of the contract is above 10 % must provide a Declaration of Honour on Exclusion Criteria (TD3a) signed by an authorised representative.

Should there be any reasonable doubt as to any of these criteria, tenderers may be requested to provide additional information and/or evidence.

Tenders that do not meet the administrative procedures will be excluded.

A) Conflict of interest

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.

Note: *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.*

B) Exclusion grounds as defined in Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014

Grounds relating to criminal convictions

The lead procurer shall exclude a tenderer if it has been the subject of a conviction by final judgement for one of the following reasons:

- Participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA
- Corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union and Article 2 of Council Framework Decision 2003/568/JHA (34), as well as corruption as defined in the national law of the lead procurer or the economic operator
- Fraud within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests

- Terrorist offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting or aiding or abetting or attempting to commit an offence, as referred to in Article 4 of the aforesaid Framework Decision
- Money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;
- 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.

The obligation to exclude a tenderer shall also apply where the person convicted by final judgement is a member of the administrative, management or supervisory body of that tender or has powers of representation, decision, or control therein.

Grounds relating to the payment of taxes or social security contributions

A tenderer shall be excluded from participation in this procurement procedure where the lead procurer is aware that the tender is in breach of its obligations relating to the payment of taxes or social security contributions, and where this has been established by a judicial or administrative decision having final and binding effect in accordance with the legal provisions of the country in which it is established or with those of the country of the lead procurer.

Furthermore, the Lead Procurer may exclude from participation in this procurement procedure a tenderer where the Lead Procurer can demonstrate by any appropriate means that the tenderer is in breach of its obligations relating to the payment of taxes or social security contributions.

This paragraph shall no longer apply when the tenderer has fulfilled its obligations by paying or entering into a binding arrangement with a view to paying the taxes or social security contributions due, including, where applicable, any interest accrued or fines.

Grounds of insolvency or professional misconduct

The lead procurer may exclude a tenderer in any of the following situations:

- Where the tenderer is bankrupt or is the subject of insolvency or winding-up proceedings, where its assets are being administered by a liquidator or by the court, where it is in an arrangement with creditors, where its business activities are suspended, or it is in any analogous situation arising from a similar procedure under national laws and regulations.
- Where the lead procurer can demonstrate by appropriate means that the tenderer is guilty of grave professional misconduct, which renders its integrity questionable; Where the lead procurer has sufficiently plausible indications to conclude that the tenderer has entered into agreements with other economic operators with the intention of distorting competition.
- Where a conflict of interest cannot be effectively remedied by other less intrusive measures.
- Where a distortion of competition from the prior involvement of the tenderers in the preparation of this procurement procedure cannot be remedied by other, less intrusive measures.
- Where the tenderer has shown significant or persistent deficiencies in the performance of a substantive requirement under a prior public contract, a prior contract with a contracting entity or a prior concession contract which led to early termination of that prior contract, damages, or other comparable sanctions.
- Where the tenderer has been guilty of serious misrepresentation in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment of the selection criteria.
- Where the tenderer has undertaken to unduly influence the decision-making process of the lead procurer, to obtain confidential information that may confer upon it undue advantages in

the procurement procedure, or to negligently provide misleading information that may have a material influence on decisions concerning exclusion, selection or award.

3.3 Selection criteria

The purpose of the selection criteria is to determine whether a tenderer has the financial, economic, 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.

The selection criteria are as follows:

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

To measure these criteria, suppliers are asked to provide the following evidence:

- Provide a description of maximum five most relevant reference and/or previous projects (executed during the last 5 years).
- Demonstrate the expertise and working experience required to undertake an innovative R&D project by providing detailed information of key expertise in house which they consider necessary to complete the project.
- Present a Business Continuity / Disaster Recovery / Risk Management plan that ensure the described services are delivered in the event of a disruption.
- Confirm that the Tenderer will take the appropriate level of insurance cover if it’s to be successful in winning the contract.
- Latest Financial statement for supporting financial structure.

Table 10: Selection criteria

Selection Criteria	Evidence
A) Ability to perform R&D up to original development of the first products or services	Description of the capacity, materials and equipment that is available to the tenderer for research, lab prototyping, limited production and supply of the first set of products or services and demonstration of feasible scale up.
B) Capacity to secure trust for CRANE service solution	Demonstrating how to secure trust for CRANE service solution, i.e. ability to design: 1. an open and transparent development process 2. a co-creation-oriented development process 3. a solution that handles user privacy accordance to GDPR 4. a development process including trusted third party which also follows the points above
C) Ability to demonstrate how to commercially exploit the results of the PCP, including intangible results in particular IPRs and connect to trusted third party, or similar structures available.	Description of the financial and organisational structures, including trusted third party that are available to the tenderer for management, exploitation and transfer of IPRs and for generating revenue by marketing commercial applications of the results

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

3.4 Award criteria

There are two types of award criteria (on/off criteria and weighted criteria).

3.4.1 On/off criteria

Tenders must comply with the following on/off award criteria:

Table 11 On/Off criteria

On/Off Criteria	Evidence
A) Compliance with the definition of R&D services	Evidence required as detailed below and Declaration of Honour on on/off Award Criteria (TD3b)
B) Compatibility with other public financing	
C) Compliance with the requirements regarding the place of performance of the contract	
D) Compliance with ethics requirements	
E) Compliance with security requirements	
F) Compliance with GDPR and the European Data Governance Act.	

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

The offers for each phase will be evaluated against these criteria.

A) Compliance with the definition of R&D services

R&D covers fundamental research, industrial research, and experimental development, as per the definition given in the EU R&D&I state aid framework[9]. 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 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.[10] 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 the total amount of 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, clearly distinguishing the units and unit prices for items that concern products,

[9] See Point 15 of the Commission Communication on a framework for state aid for research and development and innovation (C(2014) 3282).

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

- 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.

B) Compatibility with other public financing

Tenders that receive public funding 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. Compliance needs to be confirmed in a dedicated section of the Declaration of Honour on on/off Award Criteria (TD3b).

C) Compliance with requirements relating to the place of performance of the contract

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

- 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
- 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[11].

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), clearly indicating 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 honour that, where certain activities forming part of the contract are subcontracted, subcontractors will be required to comply with the place of performance obligation to ensure that the minimum percentage of the total amount of activities that must be performed in the EU Member States or in countries participating in Horizon 2020 is respected.

[11] List of H2020 associated countries

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[12] , and, in particular, avoiding fabrication, falsification, plagiarism and other research misconduct),
  - applicable international, EU and national law,
- include plans to carry out activities that are prohibited in all Member States or in a country outside the EU (where those activities are allowed),
- include activities whose aim is to:
  - include activities that do not focus exclusively on civil applications
  - do not comply with the ethics requirements specified in the Framework Agreement.

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[13])
  - 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 How to complete your ethics self-assessment[14].

Note: *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.

E) 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,

[12] The European Code of Conduct for Research Integrity of ALLEA (All European Academies).

[13] See Article 2(1) EU export control Regulation No 428/2009.

[14] European Commission. (2019). Horizon 2020 Programme: Guidance How to complete your ethics self-assessment. https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

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 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.

Note: *If necessary for the tender procedure or for performing the contract itself, contractors will be requested to ensure appropriate security clearance for third parties (e.g., for external experts needed to evaluate the proposal).*

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 licences required under EU, national or international law.

E) Compliance with GDPR and European Data Governance act.

Tenders will be excluded if they do not comply with GDPR https://ec.europa.eu/info/law/law-topic/data-protection_en and the European Data Governance act https://ec.europa.eu/eurostat/cros/system/files/03._data_governance_act.pdf.

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

3.4.2 Weighted 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 on/off award criteria, and the administrative instructions are met.

The award criteria scorecard and the overall tender evaluation approach developed in CRANE 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[15], and by the national and regional experiences of the buyer's organisations.

Award criteria scorecard

The award criteria are grouped into the following domains:

- **Excellence:** focusing on the understanding of the tender of the CRANE challenge, alignment with the CRANE vision, maturity, and evidence of effectiveness of the proposed approach, and compliance with the CRANE specifications (requirements, use cases and process models).
- **Value Based Impact:** with a focus on the extent to which the expected outputs of the tender contribute to the CRANE objectives and the procurers' needs for health management among their populations. Value is expected to be created in the whole environment of the procurers, with a specific focus on benefits for patients, the procurers, and the wider healthcare systems they are a part of.
- **Implementation:** focusing on the quality and efficiency of the proposed implementation approach, as well as the necessity to involve a variety of stakeholders in the design process (e.g., patients and healthcare professionals), i.e., complaint with the principles of design thinking and co-creation.

[15] https://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/from-evaluation-to-grant-signature/evaluation- of-proposals/elig_eval_criteria_en.htm

- **Technical compliance of the proposed solution:** focusing on the evidence, maturity, capability of the solution in the realm of CRANE, GDPR & legal rules and ethical requirements.

Table 12 Weighted award criteria for Phase 1

Award criteria for Phase 1[1]		Maximum points	Threshold
C1	**EXCELLENCE**		
C1.1	To which extent the solution shows that self-management, healthcare and care are improved by insights from a broader collection of data	10	6
C1.2	To which extent the solution caters for data sharing and alignment between diverse entities (also beyond healthcare and care organisations)	10	6
C1.3	Demonstrate cost efficiency of CRANE solution	10	6
C1.4	To which extent the solution fulfils the CRANE requirements.	10	6
	Total for Excellence	**40**	**24**
C2	**VALUE BASED IMPACT**		
C2.1	Solution shall demonstrate increased perceived value for the patients	5	4
C2.2	Solution shall demonstrate improved value for Buyers employees	2,5	1
C2.3	Solution shall demonstrate value including economic impact for healthcare and care organisations	2,5	1
C2.4	Total costs of the solution	5	3
C2.5	Quality of the suppliers business model, including demonstrating scalability and commercialisation	5	3
C2.6	Follow the development of the emerging European health data market including actors (e.g. concepts trusted third party and EU Health Data Space etc.)	5	3
C2.7	An appropriate and functional consent model	5	3
C2.8	Quality of the risk assessment of the proposed model (e.g. certifications, standards, norms, practices etc)	5	3
	Total for Value Based impact	**35**	**21**
C3	**IMPLEMENTATION**		
C3.1	Quality and completeness of the work-plan as well as detail of tasks, methodology, milestones, and deliverables.	5	3
C3.2	Feasibility of plan and resources to meet the objectives specified	5	3
C3.3	Relevance of the proposed way to involve CRANE users (co-creation) in all phases of development	2,5	1,5
C3.4	Quality of the tenders/suppliers KPIs to follow up the work plan.	2,5	1,5

	Total for implementation	**15**	**9**
C4	**TECHNICAL COMPLIANCE**		
C4.1	Ability to use technologies supporting CRANE requirements. *(Automated health data access, secure, anonymized, encrypted and automated analysis with insight generation etc.)*	2,5	1,5
C4.2	Agile Software Development Methods	2,5	1,5
C4.3	Legal & regulatory	2,5	1,5
C4.4	Ethics compliance	2,5	1,5
	Total for Technical Compliance	**10**	**6**
	Overall total score for tender	**100**	**60**

Table 13 Weighted award criteria for Phase 2

Award criteria for Phase 2		**Maximum points**	**Threshold**
C1	**EXCELLENCE**		
C1.1	To which extent the solution shows that self-management, healthcare and care are improved by insights from a broader collection of data	10	6
C1.2	To which extent the solution caters for data sharing and alignment between diverse entities (beyond healthcare and care organisations)	10	6
C1.3	Demonstrate cost efficiency of CRANE solution	10	6
C1.4	To which extent the solution fulfils the CRANE requirements.	5	3
	Total for Excellence	**35**	**21**
C2	**VALUE BASED IMPACT**		
C2.1	Solution shall demonstrate increased perceived value for the patients	5	3
C2.2	Solution shall demonstrate improved value for Buyers employees	5	1
C2.3	Solution shall demonstrate value including economic impact for healthcare and care organisations	5	3
C2.4	Total costs of the solution	5	3
C2.5	Quality of the suppliers business model, including demonstrating scalability and commercialisation	5	3
C2.6	Follow the development of the emerging European health data market including actors (e.g. concepts trusted third party and EU Health Data Space)	5	3
C2.7	An appropriate and functional consent model	5	3
C2.8	Quality of the risk assessment of the proposed model (e.g. certifications, standards, norms, practices etc)	5	3
	Total for Value Based impact	**40**	**24**

C3	**IMPLEMENTATION**		
C3.1	Quality and completeness of the work-plan as well as detail of tasks, methodology, milestones, and deliverables.	5	3
C3.2	Feasibility of plan and resources to meet the objectives specified	5	3
C3.3	Relevance of the proposed way to involve CRANE users (co-creation) in all phases of development	2,5	1,5
C3.4	Quality of the tenders/suppliers KPIs to follow up the work plan.	2,5	1,5
	Total for implementation	**15**	**9**
C4	**TECHNICAL COMPLIANCE**		
C4.1	Ability to use technologies supporting CRANE requirements. *(Automated health data access, secure, anonymized, encrypted and automated analysis with insight generation etc.)*	2,5	1,5
C4.2	Agile Software Development Methods	2,5	1,5
C4.3	Legal & regulatory	2,5	1,5
C4.4	Ethics compliance	2,5	1,5
	Total for Technical Compliance	**10**	**6**
	Overall total score for tender	**100**	**60**

Table 14 Weighted award criteria for Phase 3

Award criteria for Phase 3		**Maximum points**	**Threshold**
C1	**EXCELLENCE**		
C1.1	To which extent the solution shows that self-management, healthcare and care are improved by insights from a broader collection of data	5	3
C1.2	To which extent the solution caters for data sharing and alignment between diverse entities (beyond healthcare and care organisations)	5	3
C1.3	Demonstrate cost efficiency of CRANE solution	5	3
C1.4	To which extent the solution fulfils the CRANE requirements.	5	3,5
	Total for Excellence	**20**	**12,5**
C2	**VALUE BASED IMPACT**		
C2.1	Solution shall demonstrate increased perceived value for the patients	10	6
C2.2	Solution shall demonstrate improved value for Buyers employees	5	3,5
C2.3	Solution shall demonstrate value including economic impact for healthcare and care organisations	10	6
C2.4	Total costs of the solution	5	1,5
C2.5	Quality of the suppliers business model, including demonstrating scalability and commercialisation	5	3,5

C2.6	Follow the development of the emerging European health data market including actors (e.g. concepts trusted third party and EU Health Data Space)	5	1,5
C2.7	An appropriate and functional consent model	5	3,5
C2.8	Quality of the risk assessment of the proposed model (e.g. certifications, standards, norms, practices etc)	5	3,5
	Total for Value Based impact	**50**	**29**
C3	**IMPLEMENTTATION**		
C3.1	Quality and completeness of the work-plan as well as detail of tasks, methodology, milestones, and deliverables.	5	3,5
C3.2	Feasibility of plan and resources to meet the objectives specified	5	3
C3.3	Relevance of the proposed way to involve CRANE users (co-creation) in all phases of development	5	3
C3.4	Quality of the tenders/suppliers KPIs to follow up the work plan.	5	3
	Total for implementation	**20**	**12,5**
C4	**TECHNICAL COMPLIANCE**		
C4.1	Ability to use technologies supporting CRANE requirements *(Automated health data access, secure, anonymized, encrypted and automated analysis with insight generation etc.)*	2,5	1,5
C4.2	Agile Software Development Methods	2,5	1,5
C4.3	Legal & regulatory	2,5	1,5
C4.4	Ethics compliance	2,5	1,5
	Total for Technical Compliance	**10**	**6**
	Overall total score for tender	**100**	**60**

Description of the Weighted Award Criteria

C1 - EXCELLENCE of the proposed solution

C1.1 - To which extent the solution shows that self-management, healthcare, and care are improved by insights from a broader collection of data

Proposed solutions should be innovative, based on an assessment of the market offers, on-going and upcoming technological developments and research which has bearing on the CRANE challenge. The proposed solutions should demonstrate that CRANE will provide additional valueable insights and so improve healthcare and care compared to conventional monitoring of chronic patients.

C1.2 - To which extent the solution caters for data sharing and alignment between diverse entities (also beyond healthcare and care organisations)

Tenders need to show that CRANE will be able to facilitate alignment with diverse entities relevant for the healthcare of the population, not only health and social services, but e.g., also municipalities or NGO's by sharing data (always consent by citizens), for instance, activities accessible in the local community related to preventive health measures which can be integrated in the patient care plan through CRANE.

C1.3 - Demonstrate cost efficiency of CRANE solution

Novel concepts can be introduced as part of the solution, but there should be evidence available which helps show the cost efficiency of the proposed solution, achievable within the duration of the CRANE project. The long-term aim of the procurers is to be able to include the solutions as part of standard care, therefore the solutions sought in the PCP cannot be of experimental nature. The approaches proposed should reference literature about outcomes of studies and evaluation trials and discuss the results' reliability and the evaluation's rigour.

C1.4 - To which extent the solution fulfils the CRANE requirements

A clear explanation should be provided to understand how the proposed solution matches the requirements documented in the TD2 Challenge Brief. Specific reference can be made to certain requirements, functionalities and use cases.

C1.4.1. Added value services beyond the CRANE requirements and use cases

Detail any added value of the proposed solution and its use beyond the requirements of CRANE PCP TD2 Challenge Brief. Make specific reference to functionalities of the proposed solution, detailed in previous sections.

C1.4.2. Understanding of the emerging European health data market including actors

Tenderers need to demonstrate an understanding of the European health market, including actors and detail: how they will enable trust to the CRANE solution through the usage of trusted third party(ies) as well as compatibility with and EU Health Data Space.

C1.4.3. An appropriate and functional consent model, which e.g. enables coordinated individual patient plans

Tenderers need to demonstrate that the solution has a functional consent model.

C1.4.4. Risk assessment of proposed model

Tenders need to demonstrate a sustainable risk assessment for the proposed model, including but not limited to; certifications, standards, norms, practices etc.

C2 – VALUE BASED IMPACT of the proposed solution

C2.1 - Solution shall demonstrate increased perceived value for the patients

Tenderers should describe the benefits patients are expected to receive when the proposed solution is in operation. Positive or negative effects for patients may include (non-exhaustive):

- Degree of loneliness
- Number of physically consultations from health care workers to patients
- Level of well-being and quality of life
- Patient's control over own health
- Response time in acute situations
- Level of accessibility of healthcare workers
- Level of flexibility
- Level of stress
- Level of trust
- Quality of the health care service
- Number of setbacks
- Level of health risk and complications.
- Number and length of hospitalizations

To assess the business case for acquisition of the proposed solution by health services, quantification of positive and negative effects will be necessary. Realistic estimates of positive and negative effects should be provided where possible, expressed per 1,000 patients and year.

C2.2 - Solution shall demonstrate improved value for Buyers employees

Tenderers should describe the benefits employees are expected to receive when the proposed solution is in operation. Positive or negative effects for employees may include (non-exhaustive):

- Use of time per patient per month
- Number of patients per month per health care worker
- Overview of the patient's health condition
- Ability to make good decisions for the patients
- Level of flexibility
- The work conditions
- Level of cooperation between the health care workers and other actors
- Level of understanding of the patient's complete health condition

To assess the business case for acquisition of the proposed solution by health services, quantification of positive and negative effects will be necessary. Realistic estimates of positive and negative effects should be provided where possible.

C2.3 - Solution shall demonstrate value including economic impact for healthcare and care organisations

Tenderers should describe the benefits organisations are expected to receive when the proposed solution is in operation. Positive or negative effects for the healthcare and care organisations may include (non-exhaustive):

- Number of cancellations
- The length of treatment queues
- Number of alarms and emergencies
- Quality of the services
- Data management and GDPR compliance
- Cooperation between health care services and other actors
- Economic value-based impact
    - Cost of damages and repair
    - Training and education costs; Time used training and interpretation of results from the patients
    - Less hospitalization
    - Less use of medicine
    - Less physically consultations
    - Less travel costs for patients and health care workers
    - Investments in the CRANE solution and support

To assess the business case for acquisition of the proposed solution by health services, quantification of positive and negative effects will be necessary. Realistic estimates of positive and negative effects should be provided where possible.

C2.4 - Total cost of the solution

The total cost of deploying the proposed solution includes both payments to system providers, summarised as total cost of system, and additional time required by procurer staff, especially clinicians, summarised as procurer annual operation costs. Tenderers need to ensure that all additional costs incurred in deploying the proposed solution are considered.

Different figures should be given for different scales of deployment (e.g. for at least 1,000 patients and 1,000,000 patients). One-off costs should be depreciated over a maximum of five years. All costs incurred by a procurer from third parties to reap the benefits from the proposed solution must be listed (licensing, maintenance, replacement, insurance, etc.). Costs may include:

- Implementation costs, set-up costs, including hardware, shipping, installation and configuration
- Operation and maintenance including hosting, security updates and upgrades
- Replacement of sensors and other components with short lifetimes
- Adaptation to existing IT systems, e.g. new EHR
- Additional costs incurred for diabetes medication, external services, etc.

C2.5 - Quality of the supplier's business model, including demonstrating scalability and commercialisation

Tenderers need to explain the proposed approach to commercially exploit the results of the PCP and to bring a viable product or service onto the market. This includes a business strategy for commercialising the solution (including market expansion plans, business models, capital plan etc.).

C2.6 - Understanding of the emerging European health data market including actors

Detail your understanding of the European health market, including actors. Including, how they will enable trust to the CRANE solution through the usage of trusted third party(ies) as well as compatibility with and EU Health Data Space.

C2.7 - An appropriate and functional consent model, which e.g. enables coordinated individual patient plans

Tenderers need to demonstrate that the solution has a functional consent model.

C2.8 - Quality of the risk assessment of the proposed model

To ensure Value-Base Impact of the solution, tenders need to define a sustainable risk assessment procedure also including certifications, standards, norms, practices etc.

C3 - Implementation of the proposed solution

C3.1 - Quality and completeness of the work-plan as well as detail of task and result descriptions

Detail a comprehensive work plan, to include work packages, tasks and responsibilities, need to be drawn out for all PCP phases detailing the specific timelines for all deliverables (always in accordance with the timelines set out in the TD1 Timeline and the Milestones in TD1).

C3.2 - Feasibility of plan and resources to meet the objectives specified

Details on the resources needed to achieve the work-plan have to be provided for each organisation involved in the tender. Other resources such as travel and licenses need to also be quantified and provided.

The operational capacity of the suppliers aligned with the plan and resources need to be convincing and address all phases. The scope and intensity of work increases in Phases 2 and 3 of the PCP, where suppliers will need to build prototypes, interact frequently with users (patients and healthcare professionals) of the procurers, pilot the services for several months, provide support in training, change management, a dedicated helpdesk, etc. Past experiences of the procurers have shown the importance of working with local partners to cover the full scope of the procurement, including localisation of the solution to the local language, regular exchanges in meetings with the suppliers and their users (in many cases, communication with patients and healthcare professionals is done using their mother tongue). The tender plan should have a convincing operational capacity, e.g., reflected already in the consortium composition, or by having a plan and reserved budget for involving local subcontractors while complying with the limit on use of subcontracting.

C3.3 - Relevance of the proposed way to involve clinicians and patients in design and development

Co-creation is an important aspect. The CRANE procurers have consulted users when preparing the second and third phase. Users need to be involved in the work of the suppliers as well, including in the prototype and testing phases.

C3.4 - Quality of the tenders/suppliers KPIs to follow up the work plan.

Tenders should indicate key relevant measuring units that will support the correct implementation of their solutions in relation to the CRANE challenges value created for the patients, the employees, the procurers and the healthcare sector.

C4 - TECHNICAL COMPLIANCE of the proposed solution

C4.1 - Ability to use technologies supporting CRANE requirements.

The Tenders should demonstrate the technologies which they intend to use to support the CRANE solution e.g., automated health data access, secure, anonymized, encrypted and automated analysis with insight generation etc.

C4.2 - Agile Software Development Methods

Description of previous experiences to demonstrate the level of competency on agile Software development practises.

C4.3 - Legal & regulatory

Describe how your proposal will warrant compliance of their solution with the legal and regulatory requirements (including GDPR) at European level and in the procurers' regions where solutions will be tested.

C4.4 - Ethics compliance

Describe your plan to develop the field- testing in phase 3 in the procurers' regions where solutions will be tested, including the research protocol with ethical implications to submit to ethical committees' approvals.

3.4.3 Points system

The awarding criteria, which are dependent on a value judgement, are assessed using the following model.

The awarding criteria will be assessed using a 10-point weighted system, the evaluation framework is kept simple-use for evaluators while explaining the scores is easy to potential tenderers / bidders / applicants.

Each award criteria have a scale of values, ranging from zero to 2.5, zero to 5 or zero to ten. The values are, associated with descriptors such as “excellent”, “very good”, "good", “fair, "poor" or “fail” and a threshold value. Tenders with an award criterion score below the threshold will be excluded. Each award criterion is assigned to a domain. A domain score is the sum of the scores of the constituent award criteria, and each domain has an independently defined threshold value. The system forces the evaluation towards specific values and simplifies the calculation. If unanimity cannot be achieved, the Evaluation Committee will reach its decision by simple majority vote.

The Technical Offer sent by tenderers should include all relevant information to evaluate the weighted awarded criteria.

(the points in the same scoring range are given comparing the offers among themselves once they score in the same range)

Table 15 Points system

ASSESSMENT			DESCRIPTION
2,5 point criteria	5 point criteria	10 point criteria	
0	0	0	**Fail** Fails to address the criterion under examination or cannot be judged due to missing or incomplete information
0,5	1	2	**Poor** the criterion is addressed in an inadequate manner, or there are serious inherent weaknesses
1	2	4	**Fair** While the criterion is broadly addressed, there are some weaknesses
1,5	3	6	**Good** The criterion is addressed well, although improvements would have been necessary
2	4	8	**Very good** The criterion is addressed well, although certain improvements are still possible
2,5	5	10	**Excellent** All relevant aspects of the criterion are successfully addressed; any shortcomings are minor

3.5 Price-quality ratio

Tenders must score above the weighted award criteria thresholds given, for each threshold. Tenders that do not reach the minimum quality thresholds will be rejected.

The contracts will be awarded to the most economically advantageous tenders, i.e., the tenders scoring above all thresholds and offering the best price-quality ratio determined in accordance with the formula below

$$Total\ Score_{Tender\ i} = 80\% * Quality\ Score_{Tender\ i} + 20\% * \left(\frac{lowest\ price\ of\ all\ tenders}{Price_{Tender\ i}} * 100\right)$$

The price applied is to be the **total offered price** relating to the next specific contract (contract for each phase) in the PCP. For the first tender, the price for phase 1 will be applied.

The maximum score for a tender is 100 points, of which 80 % correspond to the technical quality and 20 % to the financial offer, as shown in the formula above.

Should there be any doubt as to the application of any of these criteria to a tender / offer, tenderers may be requested to provide additional information.

3.6 Evaluation procedure: Opening of tenders & evaluation

3.6.1 Opening of tenders

Tenders will be evaluated in a non-discriminatory manner in accordance with the EU Directives on public procurement.

The Lead Procurer will open the tenders which have been submitted by the given deadline.

The location will be the Region Västerbotten, Sweden on 1st of November, 2022 at 10:00 local time.

3.6.2 Organisation of the tender evaluation

The tender evaluation is carried out by an Evaluation Committee, which is appointed by the regional buyer organisations.

The experts in the Evaluation Committee should reflect relevant expertise areas – procurement, clinical, technical, business, ethical. 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.

The Lead Procurer draws up a list of the members of the Evaluation Committee, based on persons appointed by the other procurers.

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.*

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 Swedish regulations, specifically," Public Procurement Act (2016:1145), in Swedish: Lag (2016:1145) om offentlig upphandling", and work in accordance with all the provisions and content of the Contract Notice.

The nomination and appointment of the Evaluation Committee shall take place in good time for meeting deadlines set for the evaluation of tenders.

Note: *For Phases 2 and 3, no differences in the composition of the Evaluation Committee or in the procedure are expected.*

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.

3.6.3 The Evaluation process

The Evaluation Committee may request clarification or additional evidence if needed. The tenderer concerned will be notified by the Lead Procurer by email. The tenderer will have 5 calendar days (from the day they receive the notification) to send the clarifications and / or evidence requested. After this deadline, if no answer is received from the tenderer, the offer may be rejected and excluded from the tender evaluation. The tenderer will be informed by the Lead Procurer by email.

The process is illustrated in figure 3, and the actors involved in the evaluation process are:

- **Lead Procurer, i.e. RVB - Procurement Department at Västerbotten**. They have the overall responsibility for the Crane Project and are responsible for:
    - preparation of Tender material together with the Consortium
    - facilitate the selection of Tenders
    - evaluating the incoming tenders based on the Exclusion Criteria
    - collecting and consolidating final evaluation decisions from the Evaluation Committee throughout the PCP process
    - communicate the final selections throughout the PCP process.
- **Evaluation Committee** are responsible for final selection of tenders and offers throughout the evaluation process. They will use inputs from the Regional Evaluation Committees, the Technical Compliance team and the Value Based Evaluation Team in their evaluation process. The team will consist of 6-9 members appointed by the regional byer organisations.

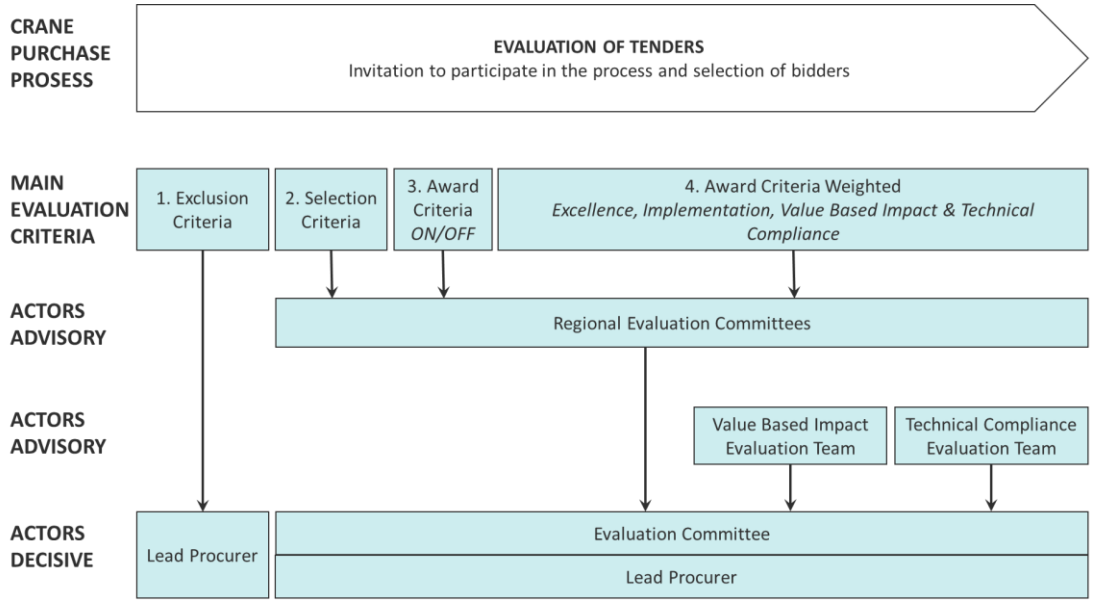
- **Regional Evaluation Committee** is responsible for:
    - evaluating the tenders and offers throughout the evaluation process based on selection criteria and the Award Criteria, including on/off criteria
    - reporting results and reflections to the Evaluation Committee.

  Each region will have their own Regional Evaluation Committees containing 4-6 professionals and strategists, including both healthcare services at regional level and municipal healthcare and/or social care sector if necessary. The members are appointed by the regional buyer organisations.
- **Value Based Impact Evaluation Team** are responsible for:
    - evaluating the tenders and offers throughout the evaluation process based on the Value Based Impact Award criteria
    - Reporting their results and reflections to the Evaluation Committee.

  Each region will select a team of 4-6 professionals and patients. Members shall ensure that the patient perspective, organisational perspective and professional perspective are taken care of. The members are appointed by the Evaluation Committee.
- **Technical Compliance Evaluation Team** are responsible for:
    - evaluating the tenders and offers throughout the evaluation process based on the Technical Compliance Award criteria
    - reporting their results and reflections to the Evaluation Committee.

  The Evaluation Committee will appoint 4-6 professionals within Health Information and Communication Technology and Data Management for the Technical Compliance Evaluation Team.

Figure 3 The PCP Evaluation Process in CRANE



Only tenders that satisfy the provided requirements including administrative requirements, that are not excluded based on the exclusion criteria and that meet the selection criteria, are admissible for evaluation under the weighted award criteria.

The Evaluation Committee plans to, within three weeks of the start of the evaluation, issue its reports on selection and award, respectively include justification of the evaluation outcome, the tender scoring, the tender rank, and a summary report with evaluation comments that should be addressed by the selected tenders in the next PCP phase.

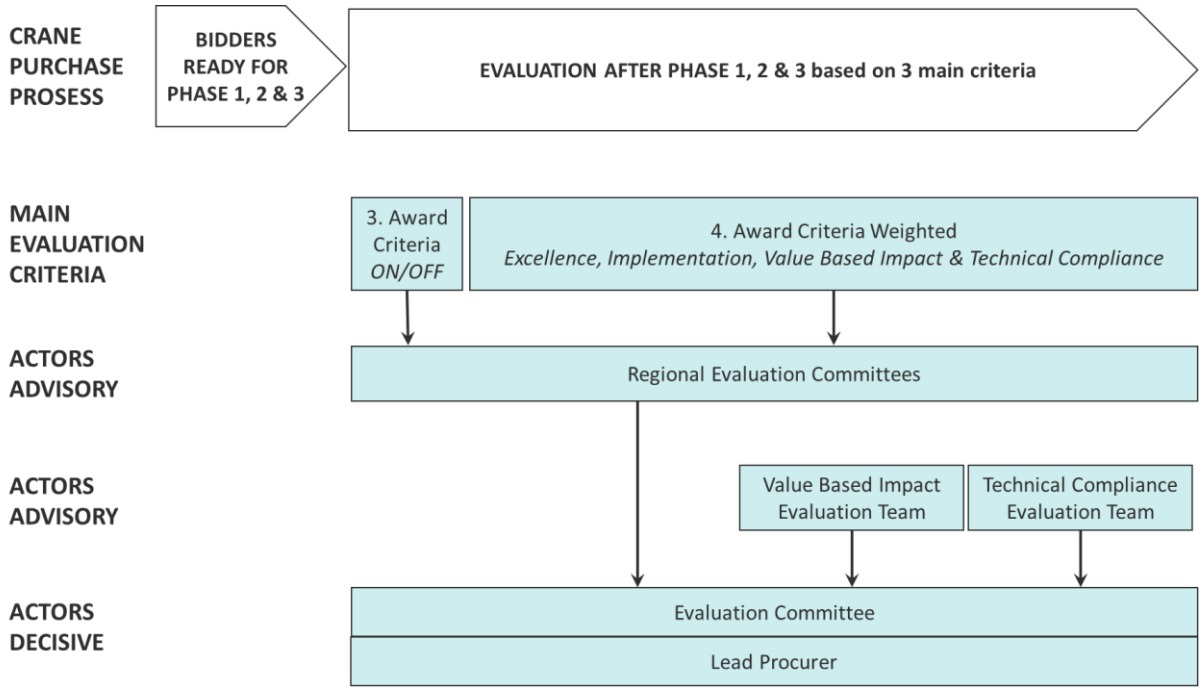
The Evaluation Committee will reach its decision by a Simple Majority vote. Should the vote result in a tie, the vote of the Lead Procurer breaks the tie. It is, however, expected that the Evaluation Committee members make their best endeavours to reach unanimous decisions as to the content and conclusions of the reports. The Evaluation Committee will incorporate evaluation comments from all Evaluation Committee members.

Each member of the Evaluation Committee shall carry out their tasks in an independent manner, applying their professional judgement.

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.*

For Phases 1, 2 and 3, no differences in the composition of the Evaluation Committee or in the procedure are to be expected apart from not including the Exclusion and Selection criteria as shown in figure 4.

Figure 4 The PCP Evaluation Process in CRANE after phase 1, 2 and 3



The Buyers Group, through Evaluation Committee, headed by the Lead Procurer will evaluate the tenders and offers for the call-offs for phase 1, 2 and 3 jointly and make a joint award decision.

For each phase and each tender received, the Lead Procurer will send an evaluation form to the European Commission or its agency as part of the deliverables to be submitted at the end of the tender evaluation. It will include: The final scores awarded, a qualitative appraisal per evaluation criterion, minutes of the evaluation meeting and the final ranking list by suppliers and replies to a challenge, if any.

4 Content and format of tenders

4.1 Format

Tenderers shall submit tenders electronically not later than the deadline specified in section 2.2. Tenders where the electronically submitted and the signed paper copy diverge will be excluded.

Tenderers should take full account of all the tender documents which can be downloaded from the project website: https://crane-pcp.eu/ after completion of the online tenderer identification form.

Table 1 contains a list of CRANE PCP tender documents.

Note: The following documents must be submitted as part of the tender: TD3a, TD3b, TD4 (not required for a single organisation as tenderer), TD5, TD6, TD7.

Electronic submission of tender shall be through the RVB – Procurement Portal, currently eAvrop. It will be also accessible through the CRANE project website: https://crane-pcp.eu/

All offers must indicate for how long are binding in TD5, Administrative Tender Application Template: the minimum validity period of offers should be at least six months from the deadline for submission of CRANE tenders.

Any questions on the request for tender, tender documents or tendering process must be sent to

crane-pcp@crane-pcp.eu before the deadline set in the timeline in this document.

Tenders that do not comply with the formal and delivery requirements described in this section will be rejected.

4.2 Administrative section

Note: Only those tenders that fully comply with the administrative provisions will proceed to the next round of evaluation.

To provide the Administrative information tenderer shall fill out the framework for all administrative information of TD5, Tender Application – Administrative Information Template.

The Administrative Section shall contain information and evidence on the legal capacity, non-disqualification from exclusion criteria, economic and financial standing of the tender and technical and professional solvency from the selection criteria, and fulfilment of the on/off award criteria, to be provided by means of the documents and forms described below:

1. The legal capacity and the representation of the tenders shall be proved by a signed Legal Entity Form with its supporting evidence. All tenderers (including all members of the group in case of joint tender) must provide this form. The form is available on: http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm
2. In the case of a joint tender, the documentation referred to in section 3.1.1 of this Call for tender shall be provided
3. In the case of subcontracting, the documentation referred to in section 3.1.2 of this Call for tender shall be provided
4. The non-subjection of the tender to any of the exclusion grounds contained in section 3.2 of this Call for tender shall be proved by means of the types of evidence referred to in that section
5. The fulfilment of the tender of the selection criteria contained in section 3.3 of this Call for tender shall be proved by means of the types of evidence referred to in that section
6. The fulfilment of the tender of the on/off award criteria contained in section 3.4.1 of this Call for tender shall be proved by means of the types of evidence referred to in that section

The tenderer (or the leader in case of joint tenders) must provide a Financial Identification Form with its supporting documents. Only one form per tender should be submitted. No form is needed for subcontractors and other members of the group in case of joint tender. The form is available on: https://ec.europa.eu/info/sites/default/files/about_the_european_commission/eu_budget/fich_sign_ba_gb_en_0.pdf

The documentation to be included in the administrative section may be submitted in English, or in a language other than the previous ones, provided that, in the latter case, the original documents are accompanied by their translation into English and a duly signed copy is annexed to the tender

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

4.3 Technical section

Tenders must include a technical offer, containing:

- a technical and commercial plan that outlines
  - the tenderer's idea for addressing all the requirements given in the PCP challenge description, relating both to functionality and non-functional, data, organisational and legal requirements; and
  - 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 clear explanation should be provided to understand how the proposed solution matches the weighted award criteria,
- 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[16] as background or results? (YES/NO)" and if YES information,
- on how these issues will be addressed (see section 4.2).

Technical section cannot be complemented and tenders failing to meet these requirements will be excluded.

The technical part must provide a detailed technical offer for phase 2 (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).

Tenderers are requested to use the tender template TD6 and follow the instructions therein.

The information provided in the technical section of the tender will be used to evaluate the tenders, based on the weighted award criteria and the on/off criteria.

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

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

The technical section is limited to 80 pages.

WARNING!

All what you offer for the CRANE PCP has to be original as we have required in section 1 due to PCP means that public procurers develop **new (*) solutions** for a technologically demanding mid- to long-term challenge that is in the public interest and requires **new (*) R&D services**. In this case, the offer must identify what parts of its proposed solution are original for CRANE. For this reason, see, moreover, the *"warning"* of the next section.

(*) It is not considered "new": the part that is an exactly reply offered and with the contract formalized in other EU-funded pre-commercial procurements. For this reason, the tenderers have to identify the different part offered for the CRANE PCP respect the other EU-funded pre-commercial procurements and has to explain his adjust to the needs to the CRANE PCP. See next section for how will be paid.

If the differences aren't accredited the tenderers will be evaluated with 0 points because it will be considered that a solution for CRANE isn't developed.

4.4 Financial section

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).

For that please use the breakdown of the financial tender template TD7.

Since the payments to contractors are centralised through the lead procurer, and RVB is the Lead Procurer in CRANE PCP, the valid Swedish and EU VAT legislation will be applied in the project. These provisions also apply to suppliers from other countries outside of EU VAT legislation.

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 on/off 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; hours of junior developers in country M at b euro/hour) (to demonstrate compliance with the requirement relating to place of performance in on/off 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.

Note: 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 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 based on the price award criteria and the on/off award criteria.

More detailed information for 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 phases 2 and 3.

WARNING!

In relation to the previous section, the financial offer must identify (as expressed in TD7 - financial section) what parts of the proposed solution are not original for CRANE. Apart from that, they must identify the price, although these parts are not going to be financed.

The parts identified in the financial section must be the same identified in the technical section,

The purpose of this regulation is that all the tenderers has the same and equal conditions for the CRANE PCP.

In relation to the previous section, if the differences aren’t accredited, the cost will be 0 and won’t be paid.

5 Miscellaneous

5.1 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.

For prototype testing in phase 2 and field testing in phase 3, the local languages (Swedish, Norwegian and Spanish) shall be used. This relates to tasks such as demonstration of prototypes in front of local end users (healthcare professionals and patients), continuous communication with key procurer personnel and support staff on the ground (e.g., a hospital's data protection officer), maintaining a helpdesk throughout the pilot phase, etc.

With the submission of their proposals, tenderers accept these requirements.

5.2 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 authorised 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).

5.3 Unauthorised communication – Questions

The Q&A from the Open Market Consultation can be found on https://crane-pcp.eu/faqs/. It contains all questions and their answers submitted via the OMC events or via email crane-pcp@crane-pcp.eu.

The Buyers Group might also receive questions from potential tenders during the tender period. The answers to these questions will be published on the project website. It is the responsibility of all prospective Tenders to check the Project Website for additional information posted during the Tender Period.

For the call-offs for Phases 2 and 3, the answers will not be published, but distributed to all contractors that successfully completed the previous phase.

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

5.4 Confidentiality

Tenderers must keep confidential any information obtained in the context of the tender procedure (including EU-classified information[17]).

Although no secrecy can be guaranteed, provisions of the Public Access to Information and Secrecy Act (2009: 400) will apply. 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.

5.5 Contract implementation

Successful tenderers will be requested to sign both a Framework Agreement and specific contracts for phases 1, 2 and 3 (see the models given in TD8 and TD9).

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

5.5.1 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 monthly monitoring online meetings between each contractor and the supervisor/monitoring team. The Buyers Group can request a higher frequency of monitoring meetings, where necessary.

The contractor will be asked to discuss the results achieved in the preceding period and present an updated work plan. The monitoring team and supervisor are allowed to visit the contractor's premises to monitor progress. The contractor can also visit the procurer's premises, at its own expense.

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 written feedback to contractors after meetings or visits. Detailed information on the role of the supervisor will be provided after award of a specific contract. The role is intended to allow contractors to improve the way in which their solutions address the problem set out in the PCP description.

Monitoring in phase 2 includes testing of prototypes v1 and v2 with end-users of the procurers. The testing is done as demonstration meetings and feedback is given to the suppliers by the procurers. The demonstration meetings are not subject to evaluation and should be seen as milestones in the PCP process.

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 the Evaluation Committee composed of representatives of the Buyers Group.

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 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. (A PCP could, for instance, be satisfactorily completed even if it concludes that the innovation is not feasible.)

The assessment will consider the efforts made by contractors to take into account the feedback from the supervisor or the monitoring team. The buyers group aims to approve as 'satisfactory' or reject submitted deliverables within 15 calendar days.

Where the Evaluation Committee judges the completion of deliverables or milestones to be unsatisfactory, the Buyers Group may decide to reduce or withdraw payments for that deliverable and/or may terminate the contract according to Article 17 of the Framework Agreement.

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 must notify the Lead Procurer in good time of the bank account to which payments are to be made in a document bearing the signature of the authorised signatory of the contractor following procedures reasonably required by the Lead Procurer.

Contractors' invoices must provide a price breakdown showing the number of units and resulting price for each of the unit prices defined in the offer in a format agreed with the Lead Procurer (in order to verify compliance with the definition of R&D, on/off award criteria).

5.5.2 Payments based on satisfactory completion of milestones and deliverables of each 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 the CRANE Evaluation Committee.

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 resources have been allocated to the planned objectives
- if the resources 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 is made using the end of the phase report form, or (if applicable) the milestone report form and the requirements of this form have been met.

"Reasonable minimum quality" of a demonstration (for phase 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 means 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 satisfactorily completed, and the efforts made by the contractors evaluated.

The assessment will consider the efforts made by contractors to consider 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 the 2.5 Time Schedule section.

Where the CRANE Evaluation 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 17 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:

- Approved: the contractor can consider the element is satisfactory
- 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.
- Non-satisfactory: the CRANE Evaluation 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:

- Number of units
- 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 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).

Payment Schedule

- Payment for Phase 1: 100 % of the total price offered by the contractor will be accepted for invoicing from the date the lead procurer declares satisfactory completion of Phase 1.
- Payment for Phase 2: 50 % of the total price offered by the contractor will be accepted for invoicing from the date the Lead Procurer declares the satisfactory completion of the Phase 2 D2.2 Prototype v1 iteration deliverable. 50 % of the total price offered by the contractor will be accepted for invoicing from the date on which the lead procurer declares the satisfactory completion of Phase 2.
- Payment for Phase 3: 50 % of the total price offered by the contractor will be accepted for invoicing from the date on which the lead procurer declares the satisfactory completion of D3.2 Interim progress review deliverable and onsite testing results. 50 % of the total price offered by the contractor will be accepted for invoicing from the date on which the lead procurer declares the satisfactory completion of Phase 3.

Payments will be made to the bank account provided by the contractor within 30 days from the date of receipt, by the Lead Procurer, of a correct and approved invoice. The final payment of Phase 3 will be settled only after the CRANE project consortium receives a full grant from the European Commission at or after the end of the project.

5.5.3 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 forth 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.

Note: Note the difference between satisfactory completion (requirement for payment) and successful completion (prerequisite for passing from one phase to the next).

5.5.4 Finalization of Phase 3: Possible follow-up PPI procurements

A new call for tenders, out of the scope of CRANE, may be launched for a follow-up public procurement of innovative solutions (PPI) to deploy a commercial volume of innovative solutions.

5.6 Cancellation of the tender procedure

A Framework Agreement may be terminated at any time, including during performance of a Specific Contract, under the conditions set out in Article 17 of the CRANE PCP Framework Agreement (TD8).

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.

5.7 Procedures for appeal

The Lead Procurer has incorporated a voluntary standstill period as described in Section 2.5. The standstill period for each phase begins from the award decision and notification and lasts until date of signature by the Lead Procurer.

Any clarification, questions or appeals must be submitted in writing to crane-pcp@crane-pcp.eu before the end of the standstill period.

Any legal claim, petition, or application for judicial review with regard to the CRANE PCP Procedure shall be heard by the competent court, administrative or civil, (please see Article 20 of the Framework Agreement). By submitting a Tender, the Tenderer accepts the exclusive jurisdiction of Swedish courts.

Decisions made during the procurement may be reviewed in administrative procedure at the Administrative Court in Förvaltningsrätten i Umeå in accordance with Swedish law.

Decisions taken regarding the selection of tenders may be challenged only by means of an administrative remedy before the court.

Tenderers are referred to the Framework Agreement on the subject of dispute resolution in the performance of a Framework Agreement.

CRANE

Comprehensive treatment of chronic patients in rural areas

region västerbotten

Centre for Connected Care

EUROBcreative
Intelligence on the move

JUNTA DE EXTREMADURA
Vicepresidencia Segunda y Consejería de Sanidad y Servicios Sociales

PPCN
Making impact & change

REGIONAL COORDINATION GROUP
E-HEALTH AND WELFARE TECHNOLOGY
AGDER

VALDE INNOVA

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